# OPPORTUNITIES AND ADVANCEMENTS IN STEM CELL RESEARCH

## HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

JULY 17, 2001

**Serial No. 107–38**

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# OPPORTUNITIES AND ADVANCEMENTS IN STEM CELL RESEARCH

**TUESDAY, JULY 17, 2001**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
*Washington, DC.*

The subcommittee met, pursuant to notice, at 2:05 p.m., in room 2154, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Gilman, Mica, Ose, Jo Ann Davis of Virginia, Weldon, Cummings, Blagojevich, Allen, and Schakowsky.

Also present: Senator Hatch, and Representatives Burton, Lewis of Kentucky, Smith of New Jersey, Waxman, and Maloney.

Staff present: Chris Donesa, staff director; Roland Foster, professional staff member; Conn Carroll, clerk; Conor Donahue, intern; Sarah Despres and Tony Haywood, minority counsels; Ellen Rayner, minority chief clerk; Earley Green, minority assistant clerk; Lorran Garrison, minority staff assistant; Joshua Sharfstein, minority professional staff member; and Piper Nieters, intern.

Mr. SOUDER. The subcommittee will come to order.

Good afternoon, and thank you all for being here today.

Today's hearing will examine the opportunities presented with stem cell research, the ethical questions involved, as well as some of the issues that thus far have been largely overlooked.

Before we begin, I would like to thank three people in this room who are here on behalf of thousands of other children in this country. Hannah, Luke, and Mark are too young to understand their impact on the debate currently before this body, but their presence is truly a reminder that every child, every life is precious.

This is a principle understood by the Founders of our great Nation, who found that, "all men are created equal, that they are endowed by their Creator with certain unalienable rights, that among these are life, liberty, and the pursuit of happiness." It is a principle I hope will guide this hearing, guide this body, and guide our President as we examine the issues of human life and science that are before us today.

Stem cells, only relatively recently discovered, are the fundamental building blocks for all the tissues in the body. Stem cells are believed to offer science perhaps the greatest potential for uncovering treatments and cures for some of the most devastating diseases that afflict millions of Americans. In fact, in the short time since

these cells have been discovered, stem cells have already been used to successfully treat patients for a number of conditions, including stroke, cancer, arthritis, and leukemia.

Some would have us believe that these and other potential cures can only occur if the Federal Government approves and provides funding for research on stem cells derived from destroying living human embryos. This is a false assumption.

In September 1999, the National Bioethics Advisory Commission issued a statement entitled, "Ethical Issues in Human Stem Cell Research," which concluded:

"In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research . . . The claim that there are alternatives to using stem cells derived from embryos is not, at the present time [9/99], supported scientifically. We recognize, however, that this is a matter that must be revisited continually as the demonstration of science advances."

Scientists now know that embryos are not the only source of stem cells. Every one of us, it turns out, holds an unknown amount of stem cells that can be derived without harm or injury. "Adult" stem cells capable of transforming into countless cell and tissue types have been located throughout the human body, including in the brain, muscles, blood, placentas, and even in fat. Researchers have only begun to unlock the potential of these adult stem cells.

Stem cells from fat have been transformed into cartilage, muscle, and bone. Adult bone marrow stem cells have been transformed into muscle, cardiac tissues, neural cells, liver, bone, cartilage, and fat. And just this May, researchers announced that they had identified an adult cell that appears capable of becoming virtually any cell in the body.

Contrary to the impressions created by advocates for embryonic stem cell research, the potential of such cells remains entirely speculative, because embryonic stem cells have never been successfully used in clinical applications with human patients. Lost in the debate is the fact that all of the clinically successful human applications of stem cells to date have been conducted with adult stem cells. Today we will hear from one patient, Nathan Salley, who has successfully been treated for leukemia with stem cells from cord blood.

One of the few successes scientists have achieved using embryonic stem cells has been the apparent conversion of such cells into insulin-producing pancreatic islet cells in mice. Yet the mouse embryonic stem cell work merely replicates an advance made with adult stem cells over a year earlier. However, the mouse embryonic stem cells secreted only one-fiftieth the normal amount of insulin, and diabetic mice implanted with the cells still died. In contrast, scientists using adult stem cells achieved full insulin expression from their differentiated adult stem cells, including full ability to protect from diabetes once transplanted back into the mice. There is no reason, therefore, to believe that adult stem cells do not have the same—if not greater—potential than stem cells derived from embryos.

In a review of the available science on stem cells compiled for HHS Secretary Tommy Thompson, the National Institutes of Health admits, "an urgent question in stem cell research today is whether stem cells in adult tissues have the same capacity to proliferate and differentiate as do embryonic stem or germ cells."

Before the U.S. Government condones with Federal funding research that results in the destruction of living human embryos, we have a moral obligation to explore and exhaust every available ethical alternative. We are fortunate that such alternatives are plentiful and have already yielded great successes.

This is not to say that the so-called "spare" embryos at fertility clinics across the country cannot serve a useful purpose. Today we will hear how these "leftover" embryos have brought hope and joy to a number of childless families. Who can argue young Hannah, Mark, and Luke, who we see before us today—adopted as embryos—would have been better left to research than to be allowed to fulfill their gift of life?

There is no question that stem cell research is a complex issue, and understanding and the oversight of such research is limited. Even without government sponsorship, research on stem cells derived from killing human embryos has occurred and continues. In fact, just last week a group of scientists in Virginia announced that they have created living human embryos solely for the purpose of destroying them for their stem cells. Days later, a Massachusetts company announced that it is attempting to clone human embryos for stem cell research.

We all desperately want to find cures for the diseases that affect our friends, our families, and our neighbors. Yet, in our quest to find these cures, we must not ignore or rationalize the tremendous moral questions posed by destroying living human embryos. Neither should we overlook all the ethical alternatives that exist that do not require the taking of one's life in order to improve the life of another.

Thank you all for being here today, and I look forward to your testimony.

[The prepared statement of Hon. Mark E. Souder follows:]

Opening Statement of Chairman Mark Souder

# "Opportunities and Advancements in Stem Cell Research"

## Subcommittee on Criminal Justice, Drug Policy and Human Resources

July 17, 2001

Good afternoon and thank you all for being here today.

Today's hearing will examine the opportunities presented with stem cell research, the ethical questions involved, as well as some of the issues that thus far have been largely overlooked.

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Lost in the debate, is the fact that all of the clinically successful human applications of stem cells to date have been conducted with adult stem cells. Today we will hear from one patient, Nathan Salley, who was successfully treated for leukemia with stem cells from cord blood.

One of the very few successes scientists have achieved using embryonic stem cells has been the apparent conversion of such cells into insulin producing pancreatic islet cells in mice. Yet the mouse embryonic stem cell work merely replicates an advance made with adult stem cells over a year earlier. However, the mouse embryonic stem cells secreted only 1/50$^{th}$ the normal amount of insulin, and diabetic mice implanted with the cells still died. In contrast, scientists using adult stem cells achieved full insulin expression from their differentiated adult stem cells, including full ability to protect from diabetes once transplanted back into the mice.

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Thank you all for being here today. We look forward to your testimony.

Mr. SOUDER. Now I yield to the ranking member, Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

With technological advances come new possibilities, new hopes, and new challenges. The issue of Federal funding for embryonic stem cell research raises ethical questions of first impression. Obviously, there are strongly held, good-faith arguments on both sides of this issue. Opponents of embryonic stem cell research argue that many questions remain about whether this research will benefit patients anytime soon. This is true. But it is equally important to remember that there are some things we do know.

We know that top scientists believe that embryonic stem cells may lead to breakthrough treatments for devastating disorders affecting countless American families. These cells offer hope to thousands of children who suffer paralyzing spinal cord injuries each year. They may someday alleviate the suffering of 1 in every 100 Americans over the age of 65 afflicted with Parkinson's disease. Embryonic stem cells have also shown enormous promise in animal models for the treatment and potential cure of diabetes, a disease that threatens the health of millions of children and adults in our country each year.

The National Institutes of Health reported in June to President Bush, "The discovery of methods to isolate and grow human embryonic stem cells in 1998 renewed the hopes of doctors, researchers, and diabetes patients and their families that a cure for Type I diabetes, and perhaps Type II diabetes as well, may be within striking distance."

We also know that alternatives to embryonic stem cells have significant limitations. Adult stem cells, for example, are difficult for scientists to find and do not thrive in culture as well as an embryonic stem cell. Umbilical cord stem cells also show promise, but, according to the National Institutes of Health report to President Bush, top scientists do not consider their use a satisfactory substitute for embryonic cells.

Whether or not the Federal Government funds research using embryonic stem cells, that research is certain to proceed in the private sector. As William Safire put it in a recent New York Times op-ed, "The stem cell genie is out of the research bottle. Whether driven by private funds here or by the investment of money by foreign governments," Safire writes, "embryonic cells will be used to achieve breakthroughs to cures."

A recent reminder of this came in the form of news reports about the controversial research of the Jones Clinic in which embryos, perhaps for the first time, were cultivated for the specific purpose of conducting stem cell research. This highlights another important consideration; namely, that the Federal research would be subject to rules that do not exist in the private sector. Indeed, the advent of Federal funding for embryonic stem cell research would attract many of the best and most responsible scientific voices and minds to this important area of inquiry.

If, on the other hand, the Bush administration upholds a ban on Federal funding, many scientists who receive Federal funding for other research would face substantial obstacles to participation in this critical research. Indeed, allowing Federal funding may have the welcome effect of concentrating research in the hands of re-

searchers who will be subject to Federal guidelines that are designed to promote scientific ethics and public accountability. Such research would be conducted in the light of day, subject to public scrutiny, and by the best scientific minds.

Excluding federally funded scientists, by contrast, excludes many of the best minds in the field from working on some of the most challenging scientific questions that may very well yield cures or effective treatments to some of the diseases I've indicated. Moreover, destruction is the ultimate fate of thousands upon thousands of in vitro embryos, regardless of whether they are used for research. Under NIH guidelines, only embryos already slated for destruction and obtained with a doctor's consent, only after they have decided not to implant them, would be eligible for use in federally funded research. It is ironic that the fate of these embryos has become a focus of intense public attention because of efforts to ensure that some benefit comes from their creation.

Embryonic stem cell research conducted according to Federal guidelines would in no practical sense result in the deprivation of life. It holds a very real promise, however, of saving, extending, and improving the quality of tens of millions of lives affected by some of the most debilitating and dangerous human diseases and disabilities.

Now that the genie is out of the bottle, Mr. Chairman, the question before us is quite simply whether the U.S. Government will take the lead in guiding this research along a well-designed, scientific and ethical path. I hope that my House and Senate colleagues and President Bush will bear these considerations in mind as the debate on this important subject proceeds.

I look forward to hearing the testimony of our witnesses today.

[The prepared statement of Hon. Elijah E. Cummings follows:]

STATEMENT OF CONGRESSMAN ELIJAH E. CUMMINGS, RANKING MEMBER

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY & HUMAN RESOURCES

COMMITTEE ON GOVERNMENT REFORM

HEARING ON STEM CELL RESEARCH

July 17, 2001

Mr. Chairman,

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Mr. SOUDER. Next I would like to yield to one of the most distinguished Members of the U.S. Senate, and certainly one of the leaders in the health area. Though we don't agree on this particular issue, when I was first married, I sent financial support, while we were scraping for every little dollar, to three candidates in the United States, and he was one of them, even though I lived in Indiana, and I have a tremendous respect for him, whether we agree or disagree on the nuances of this issue. He has been a leader in health care, and it's a great honor to introduce Senator Orrin Hatch.

Senator HATCH. Well, thank you, Mr. Chairman. That's so nice of you, and I appreciate it very much. Thank you for holding this important hearing today. It will yield a much-needed and very valuable perspective to the debate around stem cells. I also appreciate your accommodating my schedule, and I am very grateful to be with all of you distinguished Members of the House here today.

With your permission, I will summarize my remarks and submit my longer statement for the record.

First, let me recognize the important work this committee and this subcommittee are doing. Mr. Chairman—or should I say, "Mr. Chairmen"—you have developed this panel into a real power center in the House.

I would also be remiss if I did not recognize my old friend and ally—well, sometimes ally—Representative Waxman. Henry and I have collaborated on some of the most important public health legislation enacted. We have also been on opposing sides more than once, and I have to say I prefer working with you rather than against you, Henry.

Let me make clear at the outset that I consider myself to be strongly pro-life. I am vigorously opposed to abortion, and I always have been and always will be. The theme of your hearing today is that there are alternatives to embryonic stem cell research such as adult stem cell research or adoption of embryos. The lovely children and their families who have traveled here today prove that there can be good alternatives. By all means, let these good alternatives proceed.

But I also think we would be making a critical mistake if we were to shut off the avenue of research that scientists have found to be the most promising at this point, embryonic stem cell research. Over the past months I have devoted countless hours of study to this important issue, reflecting on my spiritual teachings, the law, the science, and the ethical issues presented by embryonic stem cell research. My conclusion was that the support of embryonic stem cell research is consistent with pro-life and pro-family values. This research holds out promise for improving and extending life for more than 100 million Americans suffering from a variety of diseases, including heart disease, Parkinson's, Alzheimer's, ALS, multiple sclerosis, cancer, and diabetes.

I recognize that there are some whose very heart-felt feelings cannot allow them to agree with this conclusion. It is my fervent hope that we can find an acceptable middle ground which will help all of us feel more comfortable about pursuing promising stem cell research.

Mr. Chairman, to me the most compelling fact is that with the in vitro fertilization process it is inevitable that extra embryos are created, embryos that simply will not be implanted in a mother's womb. As these embryos sit frozen in a test tube outside the womb under today's technology, there is no chance for them to develop into a person. While I think we definitely should consider ways to foster adoption of embryos, there are a host of issues associated with this—legal, religious, privacy, and public health—which must be developed fully. While those issues are being considered, the reality today is that each year thousands of embryos are routinely destroyed. Why shouldn't these embryos slated for destruction be used for the good of mankind?

While I understand that others in the pro-life community will disagree with me, I believe that a human's life begins in the womb, not a petri dish or a refrigerator. It is inevitable that in the IVF process extra embryos are created that simply will not be implanted in a mother's womb. To me the morality of this situation dictates that these embryos, which are routinely discarded, be used to improve and extend life. The tragedy would be in not using these embryos to save lives when the alternative is that they will be slated for destruction. Yes, by all means, pursue adoption of the embryos where this is feasible, but allow strictly regulated research to be pursued for those embryos which cannot be adopted, embryos which most certainly will be discarded.

Before I close, I would like to comment on the work of the Jones Institute for Reproductive Medicine in Norfolk, Virginia, which is creating embryos in order to conduct stem cell research. I find the work of this clinic extremely disturbing. To me, this type of research is indicative of the problems we will continue to encounter if we do not allow Federal funding with strict research guidelines for embryonic stem cell research. As this case illustrates, without stringent NIH ethical requirements, we are opening the door to an array of different research standards which I believe could create some serious consequences.

Mr. Chairman, today we stand on the threshold of a great opportunity. Embryonic stem cell research may be the single most important scientific discovery in our lifetimes. The most renown scientists in the country have told us that this research holds forth the promise of treatments and perhaps cures for some of the most debilitating diseases affecting our Nation and the whole world. I think it would be a mistake to cutoff Federal support for this research.

Just a few hours ago, the NIH issued its report on stem cells. It's a very, very interesting report. Let me just read a couple of paragraphs and then I will finish. I think these are very important paragraphs, and so I have singled them out, but I think the whole report is deserving of great study.

"Stem cells in adult tissues do not appear to have the same capacity to differentiate as do embryonic stem cells or embryonic germ cells. Embryonic stem and germ cells are clearly pluripotent; they can differentiate into any tissues derived from all three germ layers of the embryo (ectoderm, mesoderm, and endoderm)."

And then this: "Human embryonic stem cells can be generated in abundant quantities in the laboratory and can be grown"—that is,

allowed to proliferate—"in their undifferentiated (or unspecialized) state for many, many generations. From a practical perspective in basic research or eventual clinical application, it is significant that millions of cells can be generated from one embryonic stem cell in the laboratory. In many cases, however, researchers have had difficulty finding laboratory conditions under which some adult stem cells can proliferate without becoming specialized."

Well, those are just a couple of paragraphs in what I consider to be a pretty important study commissioned by the Secretary of HHS, a pro-life Secretary, Tommy Thompson.

I look forward to working with you, Mr. Chairman, and others on this issue, and I appreciate your allowing me to participate in this valuable hearing today. I just want to say it is a real privilege to be over here in the House and to be with all of you. Thank you so much.

[The prepared statement of Senator Hatch follows:]

**Testimony of the Honorable Orrin G. Hatch**
**before the House Subcommittee on Criminal Justice**
**July 17, 2001**

Mr. Chairman,

Thank you and Representative Waxman for inviting me to testify today. Henry and I have a long history of working together on many issues. We also have opposed each other on many issues. And I have to say I always prefer working with you, Henry!

Mr. Chairman, you and I both share strong pro-life, pro-family values and we both strongly oppose abortion. You and I have consistently voted in favor of pro-life legislation in the United States Congress. I commend you for holding this important hearing and would like to take this opportunity to share with you how I came to the decision to support federal funding for embryonic stem cell research.

Over many months, I devoted hours of study to this important issue, reflecting on my spiritual teachings, the law, the science, and the ethical issues presented by embryonic stem cell research.

My conclusion was that the support of embryonic stem cell research is consistent with pro-life and pro-family values. Let me emphasize four points for you this morning.

First, I think that support of this vital research is a pro-life, pro-family position. This research holds out promise for more than 100 million Americans suffering from a variety of diseases including heart disease, multiple sclerosis, Parkinson's, Alzheimer's, ALS, cancer, and diabetes.

Second, in the *in vitro* fertilization process, it is inevitable that extra embryos are created, embryos that simply will not be implanted in a mother's womb. As these embryos sit frozen in a test tube, outside the womb, under today's technology, there is no chance for them to develop into a person.

While I have no objection to considering ways to foster adoption of embryos, there are a host of issues associated with this which must be worked out. And while those issues are being considered, the reality today is that each year thousands of embryos are routinely destroyed. Why shouldn't these embryos slated for destruction be used for the good of mankind?

Third, while I understand that many in the pro-life community will disagree with me, I believe that human life begins

in the womb, not a petri dish or refrigerator. It is inevitable that in the IVF process, extra embryos are created that will simply not be implanted in a mother's womb. To me, the morality of the situation dictates that these embryos, which are routinely discarded, be used to improve and extend life. The tragedy would be in not using these embryos to save lives when the alternative is that they will be slated for destruction.

Fourth, there is no guarantee that any stem cell research will reap the benefits we hope, but it is clear that embryonic stem cell research holds tremendous promise. Some hold out adult stem cell research as a good alternative. By all means, we should continue adult stem cell research. But, I do not believe it would be wise to cut off support for embryonic stem cell research, since many eminent scientists believe it is the more promising avenue of research.

I also would like to take this opportunity to share my thinking on the legislation our colleague, Rep. Chris Smith, has introduced to direct the National Institutes of Health to establish a stem cell donor bank.

I strongly support efforts to help couples who cannot have children begin to realize the abundant joy and fulfillment that only a family can bring. That obviously is the case with these two wonderful children who appear before you today. But, that being said, the embryo adoption issue could raise a whole host of new legal issues. There are also religious issues - for example, in my own Church, surrogate motherhood is strongly discouraged, so adoption of the embryo might not be seen as an option. There are privacy issues. And, we would need to make sure we weren't transmitting communicable diseases, or that women weren't giving birth unknowingly to relatives.

While our colleague has raised issues we all should consider, the bottom line is that he advocates cutting off federal support for a very promising area of scientific research.

Before I close, I'd like to comment on the work of the Jones Institute for Reproductive Medicine in Norfolk, Virginia, which is creating embryos in order to conduct stem cell research. I find the work of the clinic extremely troubling.

To me, this type of research is indicative of the problems we will continue to encounter if we don't allow federal funding with strict research guidelines for embryonic stem cell research. As this case illustrates, without stringent, NIH ethical requirements, we are opening the door to an array of different research standards, which I believe could create some serious consequences.

Mr. Chairman, today we stand on the threshold of a great opportunity. Embryonic stem cell research may be the single-most important scientific discovery in our lifetimes. The most renowned scientists in the country have told us that this research holds forth the promise of treatments and perhaps cures for some of the most debilitating diseases affecting our nation, and the world. I think it would be a mistake to cut off federal support for this research.

I appreciate the opportunity to testify before your Subcommittee and would be happy to answer any questions from members of the Subcommittee.

Mr. SOUDER. Thank you. I would now like to recognize our distinguished chairman, Mr. Burton, for an opening statement.

Mr. BURTON. Thank you, Mr. Chairman. I deliberately did not prepare an opening statement because, while I am a very strong supporter of the pro-life position, I think we are facing a moral dilemma here in this country, and I think we ought to listen to all the facts and see if there isn't some kind of middle ground that can be achieved so that we can move on with scientific research that will benefit mankind. But if it imperils the right to life of children to be born, then, of course, we have to come down the moral side, in my opinion, and that would be to protect the life of a fetus that is about to become a human being.

But, at the same time, I think we need to hear all the facts and see if there is a middle ground, and I hope that all the parties on both sides of this issue, or all sides of this issue, take the time to listen to one another to see if something can't be worked out that will benefit all of us.

Thank you, Mr. Chairman.

Mr. SOUDER. Thank you. I would now like to recognize Mr. Waxman, the ranking member of the full committee, for an opening statement. It is a privilege to have you here.

Mr. WAXMAN. Thank you very much, Mr. Chairman, for calling this hearing. I am pleased that Senator Hatch was with us to deliver his statement. I thought it was an excellent statement.

It will come as no surprise to learn that I support this promising approach, this research, as a way to cure some of our most serious illnesses, but I think the best contribution I can make today is to try to focus about what this debate is about.

First of all, it is not a debate about abortion and a woman's right to choose to terminate a pregnancy. There are anti-abortion advocates on both sides of this issue, including my friend Orrin Hatch. It is not a debate about science. No one doubts that embryonic stem cell research holds potentially important breakthroughs in understanding, and the scientific consensus, as documented in that NIH report which the Senator referred to and which I would ask be included in the record, is clear that embryonic stem cells hold promise that other sources do not.

It is not a debate about the need. Advocates for people with Parkinson's, diabetes, Alzheimer's, and myriad other illnesses have come forward to support this research. It is not a debate about budgets. There is substantial funding available at the National Institutes of Health.

The stem cell debate is fundamentally about in vitro fertilization and what follows from it. In vitro fertilization is widely practiced and it is widely supported in the United States. Many of us have friends who have used it. I am sure that many of the people in the audience and on the dias know people who have used it. Simply put, in vitro fertilization is the combination of an egg cell and a sperm cell in a lab dish to create a fertilized egg or an embryo. The embryo is then transferred to the mother's womb, and if the IVF is successful, it will become implanted and develop into a full pregnancy.

In vitro fertilization often produces more fertilized eggs than are needed to allow a woman to become pregnant. In some cases, IVF

parents may donate these additional fertilized eggs to other people who want a child, and they are to be commended for doing so. If there is informed consent and agreement by donors and adoptive families, everything is appropriate.

But there are currently more fertilized eggs than used or needed, and thus, comes the question: Should scientists be required to discard these additional fertilized eggs or should they be allowed to study them? I think we should study them. To destroy them or bury them or even keep them frozen forever is simply wrong. It is as unreasonable as throwing out organs rather than transplanting them to people who need new organs.

Embryonic stem cell research is needed to help with disease and disabilities. I believe it is not only ethically permissible to do stem cell research; it is unethical not to do it.

In closing, I want to acknowledge that some people do differ in this area. Some believe that a fertilized egg, whether it is inside a womb or inside a test tube, is the same as a human being. They also oppose in vitro fertilization as it is generally practiced as well as some or all methods of family planning. I do not question their sincerity, but I simply do not agree. I do not believe that the government should abandon potentially life-saving research in order to give a cell, a special cell but only a cell, the same rights and protections as a person. If scientific and ethical standards can be met, the research must be allowed to go forward.

So long as in vitro fertilization is practiced, it will always present the question of discard or study. If we are to behave ethically toward the sick, we must answer by studying.

I look forward to hearing from our witnesses, and I hope that Congress will join together, wherever people are on the abortion debate, as we once did on the question of fetal tissue transplantation, to allow that transplantation research to go forward. We should allow this research to go forward as well. To stop it in its tracks seems to me to only discard these embryos and tell people who are anxious for life that their troubles are not important and their life is not as valuable. Thank you very much, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]

Statement of Congressman Henry A. Waxman
At a Hearing on Stem Cell Research
July 17, 2001

Over the past year, there has been a lot said about stem cell research. It will surprise no one to learn that I support this promising approach to treat and perhaps cure some of the most serious illnesses. I think the best contribution I can make today is to try to focus what this debate is about.

- It is **not** a debate about abortion and a woman's right to choose to terminate a pregnancy. There are anti-abortion advocates on both sides of this issue–including my friend Orrin Hatch who will be speaking to us today.

- It is **not** a debate about the science. No one doubts that embryonic stem cell research holds potentially important breakthroughs in understanding. And the scientific consensus (as documented in the NIH report, which I would ask be included in the record) is clear that embryonic stem cells hold promise that other sources do not.

- It is **not** a debate about the need. Advocates for people with Parkinson's, diabetes, Alzheimer's, and myriad other illnesses have come forward to support the research.

- It is **not** a debate about budgets. There is substantial funding available at the NIH.

The stem cell debate is fundamentally about *in vitro* fertilization and what follows from it. IVF is widely practiced and widely supported in the U.S. I have friends who have used it; I'm sure most people here today do, too.

Simply put, IVF is the combination of an egg cell and a sperm cell in a lab dish to create a fertilized egg–or an embryo. The embryo is then transferred to the mother's womb and, if the IVF is successful, it will become implanted and develop into a full pregnancy.

IVF often produces more fertilized eggs than are needed to allow a woman to become pregnant. In some cases, IVF parents may donate these additional fertilized eggs to other people who want a child. If there's informed consent and agreement by donors and adoptive families, that is appropriate.

But there are currently more fertilized eggs than are used or needed. And thus comes the question: Should scientists be required to discard these additional fertilized eggs or should they be allowed to study them?

I think we should study them. To discard them or bury them or even keep them frozen forever is simply wrong. It is as unreasonable as throwing out organs rather than transplanting them to people who need new organs. Embryonic stem cell research is needed to help with diseases and disabilities. I believe that it is not only ethically permissible to do stem cell research; it is unethical not to do it.

In closing, I want to acknowledge that some people do differ in this area. Some believe that a fertilized egg (whether it is inside a womb or inside a test tube) is the same as a human being. They also oppose IVF as it is generally practiced, as well as some or all methods of family planning. I do not question their sincerity.

But I sincerely do not agree.

And I do not believe that the government should abandon potentially life-saving research in order to give a cell–a special cell, but only a cell–the same rights and protections as a person. If scientific and ethical standards can be met, the research must be allowed to go forward.

So long as IVF is practiced, it will always present the question of "Discard or study?" If we are to behave ethically towards the sick, we must answer by studying.

I look forward to the hearing from the witnesses.

Thank you.

Mr. SOUDER. Thank you. Mr. Mica, do you have an opening statement?

Mr. MICA. Thank you, Mr. Chairman, and thank you for convening this hearing. I think it really will center around one of the most important ethical and moral debates that we have conducted not only in this committee, but also in Congress.

I think everyone jointly would like to assist those that suffer from Alzheimer's disease, who have had spinal damage, cancer, and other infirmities or fatal diseases that we could gain assistance to cure them or assist them in their suffering. The question, however, before us today is a question of the use of Federal funds, and the question I don't think is whether or not embryonic stem cells are taken from a refrigerator or a petri dish, but I think it goes beyond that. For one of the first times I can ever remember, it is the question of government really becoming involved in the question of creation of life, and then taking that life that is created and using part of it in experimental research. If this was proposed in the forties, people would be shocked. If this was proposed in the sixties and seventies, people would be astounded. But we do live in a different era. But, again, it raises incredibly significant moral and ethical questions that I think we are going to have to answer, particularly the use of Federal funds.

As emotional as this debate is between Members of Congress, I think it is just as emotional with the public at large. Many of those taxpayers are contributing to the Federal funds which may be used in a manner which they find objectionable. I can only say that this debate gives new meaning to the question that has been asked for centuries. Maybe Shakespeare framed it best when he said, "To be or not to be, that is the question." Hopefully, we will be able to sort out the answer.

Thank you, Mr. Chairman.

Mr. SOUDER. Mr. Allen, do you have an opening statement?

Mr. ALLEN. I do. Thank you, Mr. Chairman, for the opportunity to speak on embryonic stem cell research. I appreciate all of the work that you and Ranking Member Cummings have done to bring this important issue before the subcommittee.

I support stem cell research. Through their work with fetal tissue, researchers have been able to harness embryonic stem cells which have the ability to become any type of human cell. These discoveries are vital—indeed, the most promising part—of our effort to find cures and treatments for diseases such as Parkinson's, juvenile diabetes, Alzheimer's, and AIDS.

I recognize the ethical issues raised by this research, but I believe that Stanford University biologist/Nobelist Paul Berg, who signed a letter to President Bush in January supporting stem cell research, put it well. He said, "The cells exist and they're being destroyed, and you have to decide whether you are going to just let that happen without getting any of the potential benefits."

Limiting crucial research to adult stem cells, a position suggested by the President, is, I believe, shortsighted. Most scientists at the National Academy of Science Workshop on Stem Cells agreed that the evidence for the broad potential of adult stem cells is scant. This administration should implement the guidelines that were published by the National Institutes of Health last August. The

guidelines would allow funding for research only on frozen embryos which would not be used for other purposes by fertility clinics.

Continuing Federal support is critical because the resources devoted to this life-saving research needs to be increased. Banning Federal funding for stem cell research, as the Bush administration and some Members of Congress are considering, would not eliminate such research. The private sector will continue without the benefit of ethical regulation explicit in the stringent NIH guidelines. This Congress and this administration should promote funding for the medical community for pursuing this promising avenue of research that may improve the lives of millions of Americans.

HHS Secretary Tommy Thompson, in addition to many pro-life Members of the House and Senate like Senator Hatch, he has indicated his support, and they have theirs. They agree that stem cell research is not about being pro-choice or anti-choice. This is about medical discovery. Political considerations should not obstruct biomedical discoveries of this magnitude.

Again, I want to thank you, Mr. Chairman, for holding this hearing.

Mr. SOUDER. Thank you. The order that I am going in for opening statements are first in order of seniority on the subcommittee, then members of the full committee, then those who aren't on the committee who are guests today. Mr. Gilman, you're now recognized for an opening statement.

Mr. GILMAN. Thank you, Mr. Chairman. I want to thank you for conducting this hearing and for your leadership throughout our committee work.

I would also like to welcome today's witnesses, and I think we have some good panelists. We look forward to hearing from each and every one of them as we seek to learn more about stem cells and their place in medical research.

Stem cell research has recently become a highly debated issue that has divided our Nation. Recent studies have shown that the use of embryonic stem cells may hold the key to developing cures for a variety of diseases, including Parkinson's, Alzheimer's, juvenile diabetes, and spinal cord injuries, to mention a few.

I look forward to hearing from our medical experts who have come before our committee about the possible benefits of using embryonic cells against stem cells from other sources. The potential human health and scientific benefits of using embryonic stem cells should lead to an immediate reversal of the ban that prevents the NIH from pursuing invaluable embryonic stem cell research. Hopefully, the administration will make the right decision and, in turn, will help millions of Americans afflicted with so many of these serious illnesses.

Mr. Chairman, this is an important hearing, and I thank you and I thank our panelists for taking the time to be with us today. Thank you, Mr. Chairman.

Mr. SOUDER. Thank you. Congresswoman Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I ask unanimous consent to put my full statement in the record. I have some comments to make. Thank you.

I appreciate your calling this hearing today, Mr. Chairman. Stem cell research is a medical issue, one that I hope shall transcend po-

litical lines and instead focus on human lives. One such life is my mother-in-law at Lake Cremer who suffers from Parkinson's disease, as does our colleague and my dear friend, Lane Evans. Another life is my friend Bonnie Wilson, who is listening right now in the anteroom, whose daughter Jennifer has suffered for 25 years from juvenile diabetes, and another is Nadi Nalshami, my Deputy Staff Director, who is a long-time diabetes sufferer and worries about his daughter because diabetes runs in the family, who may needlessly suffer from diabetes.

And another is Carolyn Laughlin, the mother of two diabetic sons from my home town of Evanston, IL, who wrote to me this past April to share her family's struggles and urged my support, which I give, for federally funded stem cell research. She wrote, "Diabetes haunts my family every waking hour. Injections, blood testing, calculating food portions, are constant companions of my sons. Overnight I fear insulin reactions that will leave them unconscious. Long term, we face concerns of kidney failure, blindness, and amputations."

Adult stem cells, suggested as an alternative, have been instrumental in saving lives, and we can see, as we will be able to see, I think, from some of our panelists. However, there are recognized limitations on the usefulness of adult stem cells when compared to embryonic stem cells. While it is important to continue the research with adult stem cells, it is vital to include embryonic stem cells in this field of research.

Additionally, I urge my colleagues to keep in mind the other implications of not funding this research. Without public funding, scientists will increasingly turn to private companies. Private companies restrict the free flow of information, keeping their discoveries to themselves sometimes. Without the free flow of information, we risk slowing down major advancements in this field of research. We also risk losing our top scientists to other countries, as we have already seen happen. This has already been the result of the delayed decision in providing funding. Yesterday morning the newspapers reported the decision of Dr. Roger Peterson of the University of California, San Francisco, his decision to move to Britain to work on embryonic stem cell research.

Federal funding guidelines assure that the research will meet ethical standards and allow advancements to be made as quickly as possible. The Laughlins and millions of other families are counting on us.

I look forward to hearing from all of our witnesses today and engaging in a worthwhile discussion on this subject. Thank you, Mr. Chairman.

[The prepared statement of Hon. Janice D. Schakowsky follows:]

**STATEMENT OF CONGRESSWOMAN JAN SCHAKOWSKY ON STEM CELL RESEARCH**

Thank you Mr. Chairman for calling this important hearing today about Stem Cell Research. While the debate over whether or not federal funds should be used for research has demonstrated itself to be an extremely controversial subject here in Washington, it is clear that a majority of the American public strongly supports embryonic stem cell research.

Stem-cell research is a medical issue; one that I hope shall transcend political lines and instead focus on human *lives*. One such life is that of Carolyn Laughlin, the mother of two diabetic sons in my hometown of Evanston, IL, who wrote me this past April to share her families struggles and urge my support for federally funded stem-cell research.

She wrote, "Diabetes haunts my family every waking hour. Injections, blood testing, calculating food portions, are constant companions of my sons. Overnight, I fear insulin reactions that will leave them unconscious. Long term, we face concerns of kidney failure, blindness, and amputations."

Most scientists are in agreement that embryonic cell-research offers the greatest hope to families like the Laughlins. The unique characteristics of these cells could be critical to curing the 100 million Americans who suffer, not only from juvenile diabetes, but Parkinson's, Alzheimer's, cancer, heart disease, spinal cord injury, ALS, as well as many other diseases and conditions. We are on the thresh hold of not only saving lives but dramatically improving the quality of millions of lives. We must be cautious of closing doors that could realize that improvement.

Adult stem cells have been incredibly instrumental in saving lives, as we can see from some of our panelists. There are however, limitations on the usefulness of adult stem cells when compared to embryonic stem cells. Adult stem cells are difficult to obtain since they are often present only in minute quantities. They are also much more difficult to isolate and purify. Additionally, adult stem cells may have more DNA damage and they have a shorter life span than embryonic stem cells, rendering fewer cells. While it is important to continue working with adult stem cells, it is vital to include embryonic stem cells in this field of research. There is just not enough data currently to assume one stem cell source is better than another. We do a grave disservice to millions of sick Americans, as well as the millions who will develop these conditions in the future, by prohibiting promising research from continuing in both directions.

I additionally urge my colleagues to keep in mind the other implications of not funding this research. Without public funding, scientist will increasingly turn to private companies. Private companies restrict the free flow of information, keeping their discoveries to themselves. Without the free flow of information, we risk slowing down major advancements in this field of research. We also risk losing our top scientists to other countries. This has already been a result of the delayed decision in continued

funding. Yesterday morning, the newspapers reported the decision of Dr. Roger Pedersen's of the University of California, San Francisco to move to Britain to work on embryonic stem cell research. Last year, the British Parliament explicitly authorized research involving embryonic cells, as well as the creation of embryos for research purposes, for scientists who obtain permits. This action made Britain one of the most permissive nations on embryo work, though teams in Australia and Singapore have also aggressively pursued work on human embryonic stem cells. Without federal funding, we risk falling behind other countries such as Britain, Australia, and Singapore.

Finally, we must remain aware, that science is moving quicker than we are legislating. Last week we heard of both the development of embryos for research at the Jones Institute for Reproductive Medicine and embryo clones at the Massachusetts biotechnology firm, Advanced Cell Technology. Federal funding guidelines assure that research will meet ethical standards and allow advancements to be made as quickly as possible. The Laughlins and millions of other families are counting on us.

I do have some questions about stem cell research as they are derived from adults and embryos. I look forward to hearing from all of our witnesses today and engaging in a worthwhile discussion on this subject.

Mr. SOUDER. Congresswoman Davis.

Mrs. JO ANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman, and thank you, witnesses, for coming here today.

I would like to urge the administration to support ethical adult stem cell research and to reject Federal funding of stem cell research that results in the destruction of human embryos. We have been constantly told by supporters of embryonic research that the research will be performed on embryos that were destined to be otherwise discarded and that it is better that they be used for humane purposes and experimentation. Now we have learned that researchers are using human embryos created for the specific purpose of harvesting the stem cells for research, and donors are being paid for their participation. They are now creating human life to destroy it.

Human embryos are not commodities to be harvested and used for the benefit of others. The administration should not put its blessings on such research provided by Federal funding. Adult stem cell research is a promising and ethical alternative, and we should be focusing Federal dollars on pursuing the medical breakthroughs that it has produced.

Thank you, Mr. Chairman.

Mr. SOUDER. Dr. David Weldon.

Mr. WELDON. Thank you, Mr. Chairman. I just want to state that I practiced medicine for 15 years before I was elected to the U.S. Congress. I still see patients about once a month back in my congressional district. I have taken care of hundreds, perhaps thousands, of people with diabetes mellitus, an extremely common disease. I have seen the ravages of that disease, how it can cause blindness, neuropathies, vascular disease. I have taken care of many patients with Parkinson's disease, Alzheimer's disease, paralysis, a whole host of devastating diseases.

The issue that we are holding this hearing about is the ethical path that we are going to take in a whole new area called regenerative medicine, where these diseases will ultimately be overcome or conquered through the use of developing the tissues needed to replace the damaged or the injured tissues in the body. In the case of diabetes mellitus, particularly Type I diabetes, it is the islet cells, the beta islet cells that produce insulin that need to be replaced.

Now there are people who are trying to claim that embryonic cells are the most promising and that the adult stem cells are problematic, and I would challenge anybody who makes such an assertion to debate me on the merits of that issue, because I have reviewed the medical literature on this, and that is a preposterous assumption. Adult stem cells are currently today being used to treat leukemias. There are currently today research studies showing that adult stem cells have been used to treat lupus, to treat cartilage defects in kids.

The advocates for embryo stem cell research do not even have an animal model of the successful treatment of a disease. They do not even have an animal model for that. There are serious problems with this whole scenario in that the belief is you are sick; you get sick, you go to the doctor, and they will somehow either take an embryo and develop the cells to replace your need or take stem

cells from your body to develop the cells to replace your need. Well, embryonic stem cells, the advocates for embryonic stem cell research have not explained to me or any place in the scientific literature how they're going to overcome the issue of tissue rejection, whereas when you use adult stem cells, that's not operative. Indeed, all of the promising research appears to be in the arena of adult stem cells. Embryonic stem cell research, to me, is highly hypothetical.

I would like to add that what we are not debating today—and my colleague from Florida, Mr. Mica, pointed this out—whether this research is allowed in the United States. Embryonic stem cell research is currently legal in America. The issue is whether or not the Federal Government is going to fund this research. I would hold that, if this research was as promising as the advocates for this research claim, that the biotech community would be galloping into this arena to fund this area of research. Most of the promising research appears to be in adult stem cells.

There is a serious ethical problem, and the serious ethical problem is this: Are we going to hold as a culture or society a sanctity of human life ethic or a utilitarian approach to the value of human life? That is really what it boils down to. The utilitarian approach to human life says, well, we can use these things because somebody else might be helped. The opposite position is that human life is sacred and it needs to be defended and protected.

It has been claimed, and I have heard it said today, that it will be required to destroy these embryos. Nowhere are we debating that in this capital. We are debating whether or not it will be funded by the U.S. Government. I believe if you want to put your money in the most promising arena, it is in the arena of adult stem cell research, and that is based on my review of the medical literature. Again, I would challenge anybody to present to me the data that embryonic stem cells are the most promising, because they are not.

Mr. SOUDER. Thank you. We have been joined today by the distinguished gentlelady from New York, from our full committee, Congresswoman Maloney.

Mrs. MALONEY. Thank you very much, Chairman Souder. I thank you for holding this important hearing with Ranking Member Cummings.

I would like to ask unanimous consent to put my full statement in the record, but in the interest of time I would just merely like to state that I look forward to hearing from our panelists. One is a constituent of mine, Dr. Gerald Fischbach, a distinguished scientist from Columbia University, and one of my colleagues with whom I have worked many years, Joan Samuelson, from the Parkinson's Action Network. I am proud to be the founder and co-chair of the Parkinson's Task Force here in Congress in a bipartisan way.

Very briefly, earlier today, along with my colleague, Connie Morella, we stood with roughly 20 Members of Congress in the House and over 5 Senators in support of House Resolution 17, which I co-authored with Mrs. Morella, which calls upon government to support science, to support the guidelines from the National Institutes of Health, which have been vetted. It is a strong,

solid policy which is scientifically, legally, and ethically balanced and thoughtful.

Two of the Senators that joined us are against abortion; they are pro-life, and they made a very, very important statement that this debate has nothing to do with abortion; it has everything to do with life, saving people's lives, and they came out very, very strongly in support of the NIH guidelines.

We have been circulating a letter, and we have many people who have signed it in both the House and the Senate. One of my colleagues in the Senate told me that over 70 Senators have indicated to him their support for stem cell research.

There were seven individuals who joined us who are suffering from diseases, and there is no cure for these diseases. We call them the "seven faces of hope," hope that stem cell research can go forward and that there can be possibly a cure.

Many of us have been touched in a very personal way by the need for the President to approve the NIH guidelines. My father suffers from Parkinson's, and I have been able to see firsthand the terrible effect of this disease on him. I have met with many scientists who tell me there is no cure; at this point there is no cure.

But some have told me that, if we give them the tools, they believe they can solve this mystery; they can come up with a cure. Some have stated that they can do so within 5 years, if we give them the tools to go forward with stem cell research.

So my testimony that I am putting in the record basically says that we should support the scientists; we should support the professionals in our society who have researched this and who feel that they can come forward with cures. Let them do their job.

I would also like to place in the record a clipping from one of our national newspapers that talks about a scientist who is leaving America to go and work in another country that has Federal support for research. Granted, we could have private research, but isn't it better to have it out in the open with hearings, oversight, and with the very important support of Federal dollars?

So I thank the chairman. I look forward to all of the testimony and, again, request that I could place in the record the letter to the President, the resolution, the press clipping, and my statement in support of science. Thank you.

[The prepared statement of Hon. Carolyn B. Maloney follows:]

*14th District • New York*

**Congresswoman**

# *Carolyn* Maloney

**Reports**

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**Federal Funding of Pluripotent Stem Cell Research Should Continue**
**Congresswoman Carolyn B. Maloney of New York**

before the Criminal Justice, Drug Policy, and Human Resources Subcommittee
of the Government Reform and Oversight Committee
July 17, 2001

Mr. Chairman and Ranking Member, I appreciate the opportunity to participate in this hearing today.

The discussion of stem cell research is a very important and timely issue and I welcome the conversation and look forward to the testimony of today's distinguished witnesses. As many of you know, I am a strong proponent of pluripotent stem cell research. I am very hopeful that the President will allow the current NIH policy guidelines governing stem cell research to proceed. To this point, earlier this afternoon, I was joined by colleagues from both the House and Senate and both sides of the aisle to urge the President to keep the NIH guidelines in place.

It is critical that both public and private funding sources be marshaled for this research. Federal funding through the National Institutes of Health ensures that research will be conducted in the light of day and in accordance with the highest scientific and ethical standards.

Much of the debate has centered around the ethical questions raised when using embryos for research. The embryos in question are created in fertility clinics to help the many couples who are having difficulty conceiving a baby. Because of the advances of science, over the last twenty years, nearly 100,000 babies have been born in the United States with the help of assisted reproductive technologies, like in vitro fertilization (IVF). For those parents who have completed their families using procedures like IVF, they have a choice: they make keep their excess embryos in a frozen state for a time or they may donate them to other infertile couples. But there are also embryos that are in excess of clinical need. Instead of discarding them, couples may donate them for research.

The topic of stem cell research has generated more press and public debate than many issues I have seen in my career. In many ways it has been a conversation of hope -- hope for

cures of our most devastating diseases. I am reminded by the public debate of a fact that my colleagues already know: our citizens are generous, loving, and wonderfully altruistic people.

Each and every day, thousands of Americans give blood, tissue and bone marrow. In fact, according to the Red Cross, four million Americans gave blood in 2000 alone. Americans fill out organ donor cards and in many instances donate fertilized eggs or embryos to infertile couples who would like to have a child. In this same spirit of humanity, I urge the President to allow pluripotent stem cell research to continue. Under the guidelines, these stem cells are derived from donated embryos which were in excess of clinical need, and were obtained after the donating couple granted consent. This gift could truly make a difference to so many members of our American family.

When it comes to cutting edge science such as stem cell research, we policymakers are often called upon to make the tough choices. But in this instance, the vetting has already been done. The NIH guidelines issued last year are sound policy -- sound scientifically, legally and ethically. I urge the President to lift the Federal funding moratorium on this ground-breaking work.

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Mr. SOUDER. Thank you. We have also been joined by Congressman Lewis from the full committee.

Mr. LEWIS OF KENTUCKY. Thank you, Mr. Chairman. Thank you for giving me the opportunity to participate in the hearing today. Like many here, I have a strong interest in this issue. My sister, who suffered from diabetes during her life, passed away from lung cancer, and several members of my extended family have suffered from Alzheimer's disease.

I want to make it very clear that all of us emphatically support stem cell research. It holds great potential for curing diseases that plague society today. No one here is opposed to stem cell research. The question before the administration is whether to engage in ethical stem cell research or not.

Former President Clinton's National Bioethics Advisory Commission wrote in its September 1999 report, "In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research."

Mr. Chairman, I am pleased to present an ethical alternative that is less morally problematic and it is producing fantastic results. Large Scale Biology Corp., a biotechnology company based in Owensboro, KY, partnered up with an NIH research team to discover the protein responsible for making embryonic stem cells reproduce so rapidly, and they identified it. When this protein is applied to adult stem cells, they behave like embryonic stem cells. They reproduce rapidly and with the same genetic transferability.

The slowness of adult stem cell reproduction has been at the core of this debate. That argument has now been refuted by this research. LSBC and the NIH research team have already used their new-found growth factor to produce personalized cancer vaccines specifically curing non-Hodgkins lymphoma and sickle cell anemia. Legal doses of radiation have already been cured in lab tests, giving new hope to cancer patients who suffer with the effects of radiation treatment.

I am presenting a proven alternative today that avoids all the ethical problems created by the use of embryonic stem cells in research. I urge the committee and the President to support this holistically life-preserving research as a morally justifiable alternative that all of us can agree on.

I thank the chairman for holding this hearing today, and I hope this committee can hold future hearings on this alternative and other positive ways to engage in stem cell research. Thank you.

Mr. SOUDER. Thank you. We have also been joined by Congressman Chris Smith of New Jersey. Do you have an opening statement?

Mr. SMITH OF NEW JERSEY. Thank you very much, Mr. Chairman. Mr. Chairman, yesterday I met three wonderful children, Hannah, Mark, and Luke, along with their courageous and loving parents. Hannah, Mark, and Luke are here today to witness to the Congress, the President, and to the world, that every human being, no matter how small, has innate value, dignity, and purpose. They are here today as survivors, having overcome the perils of cryogenic freezing at a very young age. All three have emerged from their

frozen orphanages to be loved and cared for by their adoptive parents. They are pioneers, the start of a new chapter in adoption.

And they are, indeed, the lucky ones, because if the President and the Congress decide to federally fund human embryonic stem cell research, which is always fatal to the newly created human being—Mr. Waxman earlier mentioned that we just want to study them. To study them, you have to kill them. If we follow that and we federally fund that, a generation of Hannahs, Marks, and Lukes will be lost forever.

These littlest of human beings aren't potential life, but life with vast potential. So I find it highly offensive, insensitive, and inhumane to label human embryos as excess or throwaways or spare or expendable. Hannah, Mark, and Luke weren't spare; they weren't expendable; they weren't junk. These little kids, like little kids everywhere, are not excess. The miracle of human life deserves more respect than that. Hannah, Mark, and Luke are living proof that tens of thousands of human beings existing today in frozen orphanages can and should be placed with caring adoptive parents, not abandoned as fodder to a person in a white coat demanding more material.

Thankfully, there is a viable, scientifically sound, exciting alternative to destructive human embryo cell research. Adult stem cells and other post-natal stem cells, as Dr. Weldon pointed out so well, have enormous potential to cure a myriad of diseases and conditions without turning human beings into guinea pigs.

In the past few months several dramatic breakthroughs have been reported by the New England Journal of Medicine. The press is getting it right, and they are reporting it, validating the promise of adult stem cell research and highlighting the new dangers from the use of embryonic stem cells.

Dr. Donald Orlich of the National Human Genome Research Institute recently said, "We are currently finding that these adult stem cells can function as well, perhaps even better, than embryonic stem cells."

The supply of life-saving stem cells procured from ethical sources is limitless, and adult stem cells don't carry the severe risk of immune rejection and tumor formation, two problems associated with embryonic stem cells. Moreover, contrary to hype and hyperbole, adult stem cells have been used in many clinical trials with great success, while human embryonic stem cells have never been used successfully in clinical trials.

As a matter of fact, a New York Times story on March 8th of this year entitled, "Parkinson's Stem Cell Implant Yields Side Effects," noted that stem cells from fetal tissue gave patients terrible side effects. In the words of Dr. Paul Green, "The uncontrollable movements some patients suffered were absolutely devastating. It was tragic, catastrophic. It's a real nightmare and we can't selectively turn it off."

And unlike embryonic stem cells, which, again, have never been used in any clinical applications, adult stem cells are today helping to treat numerous conditions, including brain tumors, ovarian cancer, leukemia, breast cancer, non-Hodgkin's lymphoma, autoimmune diseases, stroke, anemia, blood, and liver diseases.

Mr. Chairman, as you may know, I have introduced legislation to expand Federal funding for adult stem cell research, to establish a stem cell bank using these ethically procured tissues, because it holds the promise of saving lives without destroying lives.

Furthermore, recent studies have shown that adult stem cells have the exciting potential to treat diabetes, and I, too, have diabetes in my family, Type I, two of my family members. It also can treat spinal cord injuries. Mr. Chairman, as you know, I'm chairman of the House Veterans' Affairs Committee. This year we provided over $700 million for health care and more money for research dollars because so many of our veterans are afflicted by many anomalies, including spinal cord injuries. I want to see cures. I want to see restoration. All of us do. The question is: How do we proceed? Will we do it ethically or unethically?

Let me also say, finally, Mr. Chairman—and I would ask that my full statement be made a part of the record—I am co-chairman of the Alzheimer's Caucus, and we have been pushing for more money for NIH. This year we hope to see it go up by about $200 million more and the following year by $250 million more than that, to get to about $1 billion for Alzheimer's. There's 4 million people today with Alzheimer's. That will jump to 14 million. We can find a cure, but we must do it ethically. We must marry up the research dollars with ethical and humane ways of doing research, not by killing human embryos.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Chris Smith follows:]

## *Statement of Rep. Chris Smith*
## *July 17, 2001*

Yesterday, I met three wonderful children – Hannah, Mark and Luke – along with their courageous and loving parents. Hannah, Mark and Luke are here today to witness to the Congress, the President and the world that every human being, no matter how small, has innate value, dignity and purpose.

They are here today as survivors, having overcome the perils of cryogenic freezing at a very young age. And all three have emerged from their frozen orphanages to be loved and cared for by their adoptive parents. They are pioneers – the start of a new chapter in adoption.

And they are indeed the lucky ones. Because if the President and Congress decide to federally fund human embryonic stem cell research – which is always fatal to the newly created human being – a generation of Hannahs, Marks and Lukes will be lost forever.

These littlest of human beings aren't potential life -- but life with vast potential. So it is highly offensive, insensitive and inhumane to label human embryos as excess or throwaway or spare or expendable.

Hannah, Mark and Luke weren't spare, expendable, or junk. These little kids – like little kids everywhere – are not excess. The miracle of human life deserves more respect than that.

Hannah, Mark and Luke are living proof that tens of thousands of human beings, existing today in frozen orphanages can and should be placed with caring adoptive parents, not abandoned as fodder to a person in a white coat demanding "more material."

Thankfully, there is a viable, scientifically sound, exciting alternative to destructive embryo stem cell research. Adult stem cells – and other post natal stem cells – have enormous potential to cure a myriad of diseases and conditions without turning human beings into guinea pigs.

In just the past few months, several dramatic breakthroughs have been reported by the *New England Journal of Medicine* and others validating the promise of adult stem cell research and highlighting new dangers from the use of embryonic stem cells. Dr. Donald Orlic of the National Human Genome Research Institute recently said that, "we are currently finding that these adult stem cells can function as well, perhaps even better than, embryonic stem cells."

The supply of life-saving stem cells procured from ethical sources is limitless. And adult stem cells don't carry the severe risk of immune rejection and tumor formation, two problems associated with embryonic cells.

Moreover, contrary to hype and hyperbole, adult stem cells have been used in many clinical trials with great success while human embryonic stem cells have never been used successfully in clinical trials.

As a matter of fact, a *New York Times* story on March 8, 2001, "Parkinson Stem Cell Implant Yields Side Effects" noted that stem cells from fetal tissue gave patients terrible side effects. In the words of Dr. Paul Greene, "the uncontrollable movements some patients suffered were 'absolutely devastating.' It was tragic, catastrophic. It's a real nightmare, and we can't selectively turn it off."

And unlike embryonic stem cells, which have never been used in any clinical applications, adult stem cells are today helping to treat numerous conditions, including brain tumors, ovarian cancer, leukemia, breast cancer, non-Hodgkin's lymphoma, autoimmune diseases, stroke, anemia, blood and liver disease. I have introduced legislation to expand federal funding for adult stem cell research because it already holds the promise of saving lives without destroying lives.

Furthermore, recent studies have shown that adult stem cells have the exciting potential to treat diabetes, spinal cord injuries, muscular dystrophy, blindness, Parkinson's, Alzheimer's, and glaucoma, as well as provide organ replacement, nervous system repair, muscle repair, tooth repair, brain repair, liver repair, retina repair, cartilage repair, blood vessel replacement, and heart valve replacement.

In view of this growing body of evidence supporting adult stem cell research, the only way to justify federal funding for embryo-destructive stem cell research is to take the position that a human embryo has no value -- none, zero, less than the dot above the i on this piece of paper. Now that medical advances have clearly demonstrated that adult stem cells are a legitimate alternative to research that destroys human embryos, the only way to justify embryo-destructive work is to assert that Hannah, Luke and Mark have no value at all.

For all of our sakes, I hope that ethics do matter in this debate. I hope that we can all agree that human embryos -- like these children before us -- have innate value. For once we determine that any human life can be destroyed in the name of science all life is devalued. In the course of human history, there have been too many cultures and societies that believed it acceptable to sacrifice the few, the weak and the vulnerable for the benefit of the strong and the many. But experience and ethics dictate that it is unacceptable for a society to destroy one life for the potential benefit of others, particularly when there are legitimate alternatives.

Adult stem cell research is scientifically justified, ethically responsible and morally acceptable. Embryonic stem cell research is not. No child is spare or leftover, and the weak and the vulnerable will always need someone to speak for them. We must speak for them, and for Hannah, Luke and Mark.

Mr. SOUDER. I thank the gentleman.

Before proceeding further, I would like to take care of a couple of procedural matters. First, I would ask unanimous consent that all Members have 5 legislative days to submit their full written statements and questions for the hearing record, and any answers to written questions provided by the witnesses also be included in the record, including those who have asked heretofore. Without objection, it is so ordered.

Second, I ask unanimous consent that all exhibits, documents, and other materials referred to by the Members and the witnesses, including in their opening statements, be included in the hearing record, and that all Members be permitted to revise and extend their remarks. Without objection, it is so ordered.

And on the third point, I want to clarify that this, after talking with the chairman and the ranking member in general on this subject, this should not be a precedent for the other subcommittees or the full committee. We have been doing it in this subcommittee on the issue of charitable choice; we have done it on the issue of methamphetamines just last week—including Members who aren't part of the subcommittee and the full committee, but we are going to review that policy after this hearing because of potential precedence on the full committee.

So, third, I would like to ask unanimous consent that the gentlelady from Maryland—these are the people who have requested it for this committee—the gentlelady from Maryland, Mrs. Morella; the gentlelady from New York, Mrs. Maloney; the gentleman from Kentucky, Mr. Lewis; the gentleman from New Jersey, Mr. Smith, and the Senator from Utah, Senator Hatch, who are not members of the subcommittee, be permitted to participate in the hearing after all members of the subcommittee have completed their questioning in each round. Without objection, it is so ordered.

Now if the witnesses on the first panel would come forward to the dais: Marlene Strege and her daughter Hannah, the first-ever adopted embryo family; Lucinda Borden and the adopted embryo twins, Mark and Luke Borden, and JoAnn L. Davidson of the Christian Adoption and Family Services.

And if you will remain standing as you come forward, as an oversight committee it is our standard practice to have all witnesses testify under oath. So if you will raise your right hands, I will administer the oath.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that all the witnesses have answered in the affirmative.

You can go ahead and sit down.

As you may know, we typically ask our witnesses to summarize their testimony in 5 minutes and will include your statement and any further additional comments in the record.

Mrs. Strege, if you would begin?

**STATEMENTS OF MARLENE STREGE; LUCINDA BORDEN; JOHN BORDEN; AND JO ANN L. DAVIDSON, CHRISTIAN ADOPTION AND FAMILY SERVICES**

Ms. STREGE. I am Marlene Strege, a resident of Fallbrook, CA. Today I am accompanied by my husband John and our daughter Hannah. Thank you for this opportunity to testify.

Our story begins in 1996, when John and I realized we had a fertility problem. We tried expensive infertility treatments for nearly a year, which proved ineffective. Estimates of the number of Americans affected by infertility range from 6.5 to 10 million couples. Traditional and international adoption could not satisfy my deepest longing to experience pregnancy and childbirth. Despite its high cost, we decided to pursue in vitro fertilization, but on January 14, 1997 we were told I had premature ovarian failure and was not producing eggs any longer. Physicians told us our only option was to obtain donor eggs.

I asked whether we could adopt embryos. The physician appeared agreeable at first, but then would not help us. Other physicians suggested donor embryos, but John and I were uncomfortable with this. It felt more akin to purchasing a car based on options than adopting a child.

During this time we also contacted what is now Nightlight Christian Adoptions to inquire whether they offered embryo adoption. Although they did not, the Executive Director thought they should offer this service. The Snowflake Embryo Adoption Program was born.

Hannah's genetic parents chose us for the embryo adoption the same way a birth mother chooses a family. We completed all the requirements for the State of California for adoption, including a home study. Following our matching and relinquishment of their embryos, we agreed with Hannah's genetic parents to an open adoption agreement in March 1998, including a confidentiality provision.

After successfully securing a physician, Hannah and her 19 siblings were flown overnight to our IVF clinic in Pasadena, CA. My body was prepared to receive three embryos with a series of hormonal injections. During my first transfer, no children successfully implanted. Accordingly, physicians thawed the remaining eight embryos on April 19, 1998. Three survived, including Hannah. The embryologist snapped a picture of Hannah and her siblings for our baby book. No mere dot, she contained the entire blueprint for human life.

Hannah continued to develop overnight outside my body. The physician referred to this as compaction, a process where the cells start to move to one side and a fluid-filled sac began forming. We have a picture of Hannah when this occurred outside my body on April 11, 1998, the day she and her siblings were transferred into my uterus.

On April 20, 1998, I learned I was pregnant, and an ultrasound on May 4, 1998 confirmed I was pregnant with one baby. Hannah, now safely in my womb, was only receiving from me oxygen, nutrients, a warm place to grow, and love throughout my entire pregnancy. Subsequent ultrasounds showed Hannah was doing just fine.

Hannah Eileen Strege was born on December 31, 1998. She is the best gift parents could have and no different than all children, all of whom were once embryos either in the petri dish or the fallopian tubes.

John and I adopted Hannah long before we knew about public controversy involving embryo stem cell research. Mary Tyler Moore and Senator Tom Harkin sparked our desire to speak out on this issue. We've had to watch Ms. Moore compare our daughter to a goldfish, and Senator Harkin likened her to a dot on a piece of paper and referred to her as expendable. Obviously, she is none of these.

Notwithstanding the message conveyed by the media, John and I care deeply about identifying therapies and cures for serious diseases. As an occupational therapist, I care for many people who have severe disabilities. My mother died from pancreatic cancer. We paid to save our daughter's cord blood at birth to advance umbilical stem cell research designed to overcome serious disease.

Another myth propagated by the media is that embryos exist "in excess of need." More infertile couples exist than embryos likely to survive thawing. My OB/GYN told me any woman can carry any embryo. Tissue and blood matching is not necessary. As embryo adoption proliferates in the wake of this controversy, the excess supply of embryos will evaporate.

Hannah is an ambassador for the roughly 188,000 frozen human embryos like her in frozen orphanages who could be adopted rather than terminated with assistance from my Federal tax dollars. We plead with Congress not to force millions of Americans like me to violate our consciences and participate in another form of genocide, especially when the advances possible with the other stem cells are not nearly exhausted.

In closing, I am very proud to be part of this new generation of adopting mothers.

[The prepared statement of Ms. Strege follows:]

**Testimony of Marlene Strege**
**before the**
**United States House of Representatives Committee on Governmental Reform**
**Subcommittee on Criminal Justice, Drug Policy, and Human Resources**
**Hearing on Embryonic Cell Research**
July 17, 2001

I am Marlene Strege, a resident of Falbrook, California and registered occupational therapist, holding a B.S. Magna Cum Laude from the University of Southern California. I am accompanied today by my husband, John, who is behind me holding my daughter, Hannah Strege, the first adopted former frozen embryo. Thank you for this opportunity to testify.

Our story begins in 1996, when John and I realized we had a fertility problem. We tried infertility treatment for nearly a year. It was expensive, costing as much as $2,000 per cycle. For us the treatment was also ineffective. We were devastated when we finally came to terms with this. I suffered all of the standard side effects associated with infertility, including severe depression and grief. I cannot adequately express how debilitating infertility proved to us.

Infertility is a medical disorder that has an international classification of diagnosis code (ICD-9).[1] Estimates of the number of Americans affected by it range from 6.5 to 10 million couples (or 13 to 20 million individuals).[2] Infertility has grown rapidly since the 1980's.[3] Experts are not sure of the reason, but believe it may be related to delayed marriages and pregnancy, sexually-transmitted diseases, pollution, diet, and lack of exercise.[4]

We explored in-vitro fertilization and traditional adoption as a substitute for genetic birth. However, both had serious drawbacks. Traditional adoption could not satisfy my deepest longing to experience pregnancy and childbirth. It can take months to identify and adopt a baby, particularly if the adoption involves a child from a foreign country. Traditional adoption obviously also does not have the advantage of prenatal bonding. I was prepared to do almost whatever it took to become pregnant.

Like many couples feeling this way, John and I decided to pursue in-vitro fertilization, despite its high cost. In 1997, a single IVF procedure was $12,000 at our clinic plus costly medication. We heard of a couple at the clinic, which spent $60,000 trying to become pregnant. They dipped into their retirement funds without successfully conceiving.

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[1] JOE S. MCILHANEY, JR., M.D., 1001 HEALTH-CARE QUESTIONS WOMEN ASK 433 (1998).
[2] *Id.*; Dominick Vetri, *Reproductive Technologies and United States Law*, 37 INT'L & COMP. L. Q. 505 (1988).
[3] MCILHANEY *supra* note 1, at 432-433.
[4] *Id.*

John and I pursued IVF anyway, only to be told on January 14, 1997, that I had premature ovarian failure and was not able to produce eggs any longer. Physicians informed us that our only option to conceive was to obtain donor eggs. It occurred to me to ask whether we could adopt embryos. The doctor looked puzzled and said he had never done this, but would ask families in his practice whether they would consider a "donation." He returned to us later with a list of embryos differing in prospective hair color, ethnicity, and other features. Like a waiter soliciting an entré, he would have taken our order.

John and I were uncomfortable with this. It seemed to us this was more like buying a car than conceiving. In addition, we had heard about lawsuits filed against the University of California at Irvine ("UCI"), alleging misappropriation of patient eggs and embryos.[5] Plaintiffs claimed that doctors implanted their embryos without their knowledge or consent, purportedly leading to the birth of several dozen children.[6] UCI was forced to close its Center for Reproductive Health as a consequence.[7]

To avoid these types of problems, we contacted what is now Nightlight Adoption Agency to inquire whether it offered embryo adoption. It did not. However, the executive director agreed that the agency should consider offering this service in light of the rapid growth of the IVF industry and recent events in Britain that led to the wholesale slaughter of 3,300 embryos.[8] The Snowflake Program, as well as a new frontier for adoption, was born out of this meeting of minds.

Hannah's genetic parents chose us for embryo adoption the same way a birth mother chooses a family with whom she wants to place her child. Both genetic families and prospective adoptive families involved in the Snowflake Program express their financial, religious, educational, and other preferences. Families must also provide thorough medical, psychological, paternal, and background information. We also completed an adoption home study at an expense of about $2,000. The home study was valid for embryo, traditional, or international adoption.

The adoption approach is much safer and satisfying for all concerned than mere embryo donation. Without the background information available through the Snowflakes Program, we would not have known the donor family's full psychological, medical, or other characteristics or, indeed, whether the embryo was a relative. Our daughter also would not have access to information on her parentage when she began dating. Last, donation would not communicate to Hannah the same special selection adoption connotes.

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[5] *See* Judith F. Daar, *Regulating Reproductive Technologies: Panacea or PaperTiger?* 34 HOUS. L. REV. 609, 609-14 (1997).
[6] *Id.* at 611.
[7] *Id.* at 612.
[8] Traci Watson, *Excess Embryos*, U.S. NEWS & WORLD REP. 10 (August 12, 1996); James Walsh, *A Bitter Embryo Imbroglio: Amid Dramatic Protests and Universal Unease, Britain Begins Destroying 3,300 Human Embryos*, TIME (August 12, 1996).

Following matching, we agreed with Hannah's genetic parents upon an open adoption agreement in March 1998. *See* Ex. A, Timeline. The agreement includes a confidentiality provision that prevents us from providing information about Hannah's genetic parents, other than to say that they, like many other families, were uncomfortable with the choices that the IVF clinic provided them.

Hannah and her nineteen siblings were shipped via FedEx in straws of two or three embryos in a canister of liquid nitrogen to our IVF clinic in Pasadena, California. They arrived on March 6, 1998. *See* Ex. A, Timeline. My body was prepared to receive three embryos with a series of hormonal injections (estrogen and progesterone), starting with the first day of my cycle. Ultrasounds were conducted to assess how my uterine lining was thickening.

At the right moment on or about March 7, 1998, physicians began the thawing process. Sadly, only three of 12 embryos survived this process and were transferred into my womb the following day. Freezing embryos leads to the death of, on average, more than half of them.[9] Not all embryos adhere to a mother's uterine lining either.[10] Therefore, adoptive mothers should be prepared to receive more than one transfer. The cost to us was about $2,500 per cycle plus drugs (costing about $40 per cycle) and miscellaneous expenses.

During my first transfer, no children successfully implanted. Accordingly, physicians thawed the remaining embryos on April 10, 1998. *See* Ex. A, Timeline. Three survived including Hannah. The embryologist snapped a picture of Hannah and her siblings for our baby book. *Id.* No mere "dot," she contained within her the entire blueprint for human life, including all of her human organs and tissues. She required a place to grow, nutrients and love – her same basic needs today – but Hannah did the rest.

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[9] *See* IVF Phoenix Infertility Information Booklet ("Not all embryos survive the freeze-thaw process. A 50% survival rate is considered reasonable. After the thaw, embryos retaining 50 percent or more of the cells they had before freezing are cultured and placed back in the uterus via a tube inserted in the cervix. The number returned varies with the desires of the patient under the guidelines of age categories; under 35 years old, up to four embryos, 35 years and older, up to six embryos. National statistics for women 39 or less is 27% per embryo transfer, for women over 39, 14% per embryo transfer. Delivery rates will be lower due to miscarriage."); Michael J. Tucker, Ph.D., *The Freezing of Human Oocytes [Eggs]*, http://www.ivf.com/freezing.html ("Whether eggs are mature or not, standard cryopreservation technologies appear to have their ultimate limitations not only in terms of cryosurvival (% of eggs that are alive after thawing), but also more importantly in their lack of consistency. 50% cryosurvival may be an adequate overall outcome and is now commonly reported, but not if it is a statistic that is arrived at by 90-100% survival in one case, and 0-10% in the next. Consequently, radically different types of freezing protocol may provide the answer to increased consistent success. Different approaches have been applied, and include replacing the principal salts in the freezing solutions in an attempt to help reduce the stresses on the egg membranes during cryoprotectant exposure. This has provided significant improvements in mouse egg freezing, though it has yet to be applied clinically in the human."); Michelle F. Sublett, *Not Frozen Embryos: What Are They and How Should the Law Treat Them?* 38 CLEV. ST. L. REV. 585, 593 (1990) (overall, "there is less than a ten percent chance of creating a live birth from a frozen embryo.").

[10] CENTER FOR DISEASE CONTROL, 1998 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 47 (2000).

In fact, Hannah developed overnight outside of my body before the transfer. The physician referred to this as compaction, a process wherein all of her cells started to move to one side and a fluid-filled sac began forming. We have a picture of Hannah after this occurred outside of my womb on April 11, 1998, the day she and her siblings were transferred to my uterus. *Id.*

On April 20, 1998, I learned that my first reliable blood test revealed an HCg level of 57, meaning I was pregnant with at least one child. A second elevated test on April 23, 1998 and ultrasound on May 4, 1998, confirmed this. *Id.* We grieved for Hannah's siblings, but were ecstatic to hear Hannah's heartbeat on May 14, 1998. *Id.* Words cannot explain how thrilled I was. By far, this is the greatest thing I have experienced.

By the end of the first trimester, I was weaned off all hormone injections. Like most mothers, I experienced morning sickness and nausea. The only complication in my pregnancy was an allergic reaction that I developed to the sesame oil in progesterone injections. On May 14, 1998, May 22, 1998, and August 20, 1998, additional ultrasounds revealed my baby was doing fine. *Id.* I felt her kick for the first time on July 25, 1998.

Hannah Strege was born through a caesarian section on December 31, 1998, at 7:07 AM, weighing 6 pounds, 14 ounces. *See Id.*; Ex. B, Birth Certificate. She is the best gift parents could have and no different than most children, all of who were once embryos. *See* Ex. A, Timeline. I keep a journal in my kitchen drawer of all of the touching things Hannah does or says; it is becoming overloaded. Recently, she began coming up to me and saying out of the blue with a big smile, "Mommy, I happy!" You cannot place a value on moments like these.

Jon and I never intended to disclose Hannah's origin to people other than our immediate family and friends. We adopted her long before we knew about any public controversy involving embryo stem cell research. Mary Tyler Moore and Sen. Tom Harken changed our plans. The most difficult two days that my husband and I have endured involved watching Ms. Moore compare my daughter to a goldfish and Sen. Harken liken her to a dot on a piece of paper and refer to her as expendable. Obviously, she is none of these.

Notwithstanding the message conveyed by the media, John and I care as deeply as anyone else about identifying therapies and cures for serious diseases. In my occupation, I care for many people who have severe disabilities. My mother died from pancreatic cancer. We ourselves suffer from a medical disorder. We paid to save our daughter's cord blood at birth to advance umbilical stem cell research designed to overcome serious disease. *See* Ex. C, Official Certificate of Deposit. However, the moral implications of this research and research using adult and placenta stem cells is vastly different from using embryo stem cells. One kills the subject human donor; the other does not. Even atheists can appreciate this dichotomy.

Another myth propagated in the media is that embryos exist "in excess of need." Setting aside the thoughts of many that the personhood of the embryo renders this inquiry irrelevant, the claim is empirically inaccurate. More infertile couples exist than embryos

likely to survive thawing.[11] Any woman can carry any embryo; tissue or blood matching is not necessary. As embryo adoption proliferates in the wake of this controversy, the "excess supply" of embryos will evaporate.

Looking into Hannah's eyes, I weep for the roughly 188,000 frozen human embryos like her placed in frozen embryo orphanages,[12] who could be adopted, rather than terminated with assistance from *my* federal tax dollars. We plead with Congress not to force millions of Americans like me to violate our consciences and participate in another form of genocide, especially when the advances possible with other stem cells are not nearly exhausted.

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[11] Based upon a conservative estimate of 188,000 frozen human embryos currently stored in IVF clinics, *see* Lori B. Andrews, *Embryonic Confusion; When You Think Conception, You Don't Think Product Liability; Think Again*, WASHINGTON POST at B1, B4 (May 2, 1999); a conservative thaw survival rate of 50 percent, *see supra* note 9; and a national pregnancy rate for IVF clinics of between 13.4 percent (over 40) to 37.2 percent (under 35), *see supra* note 10, between 12,600 and 35,000 children could be placed for adoption and born in the families of the 6.5 to 10 million infertile married couples in America who seek to raise children.

[12] Andrews, *supra* note 11.

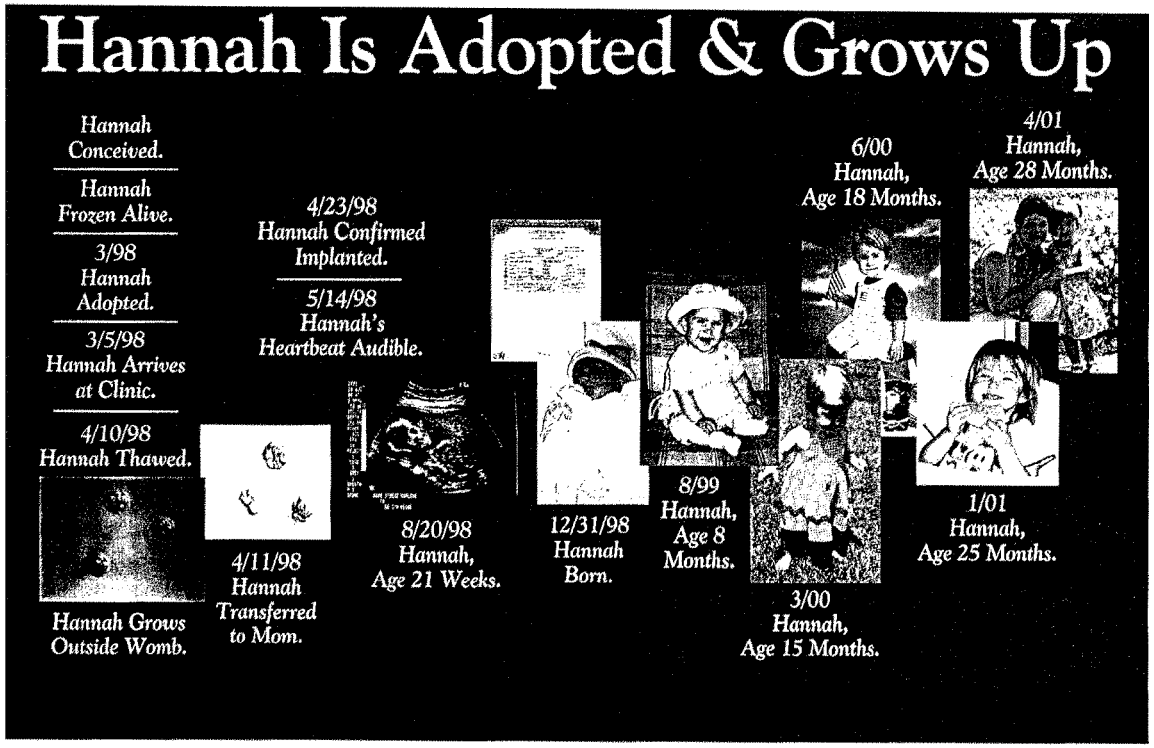
Hannah Is Adopted & Grows Up
Hannah Conceived.
Hannah Frozen Alive.
3/98 Hannah Adopted.
3/5/98 Hannah Arrives at Clinic.
4/10/98 Hannah Thawed.
Hannah Grows Outside Womb.
4/11/98 Hannah Transferred to Mom.
4/23/98 Hannah Confirmed Implanted.
5/14/98 Hannah's Heartbeat Audible.
8/20/98 Hannah, Age 21 Weeks.
12/31/98 Hannah Born.
8/99 Hannah, Age 8 Months.
3/00 Hannah, Age 15 Months.
6/00 Hannah, Age 18 Months.
1/01 Hannah, Age 25 Months.
4/01 Hannah, Age 28 Months.

Exhibit A

STATE OF CALIFORNIA

CERTIFICATION OF VITAL RECORD

# COUNTY OF SAN DIEGO

GREGORY J. SMITH
ASSESSOR/RECORDER/COUNTY CLERK

CERTIFICATE OF LIVE BIRTH
STATE OF CALIFORNIA
USE BLACK INK ONLY

STATE FILE NUMBER: 1 199837 043986

LOCAL REGISTRATION DISTRICT AND CERTIFICATE NUMBER

| | | | | |
|---|---|---|---|---|
| THIS CHILD 0358 | 1A. NAME OF CHILD — FIRST (GIVEN): HANNAH | 1B. MIDDLE: EILEEN | 1C. LAST (FAMILY): STREGE | |
| | 2. SEX: FEMALE | 3A. THIS BIRTH, SINGLE, TWIN, ETC.: SINGLE | 3B. IF MULTIPLE, THIS CHILD 1ST, 2ND, ETC.: - | 4A. DATE OF BIRTH — MM/DD/CCYY: 12/31/1998 |
| | 4B. HOUR — (24 HOUR CLOCK TIME): 0707 | | | |
| PLACE OF BIRTH | 5A. PLACE OF BIRTH — NAME OF HOSPITAL OR FACILITY: SHARP MARY BIRCH HOSPITAL | 5B. STREET ADDRESS — STREET, NUMBER, OR LOCATION: 3003 HEALTH CENTER DR. | | |
| | 5C. CITY: SAN DIEGO | 5D. COUNTY: SAN DIEGO | 5E. PLANNED PLACE OF BIRTH: HOSPITAL | |
| FATHER OF CHILD | 6A. NAME OF FATHER — FIRST (GIVEN): JOHN | 6B. MIDDLE: PALMER | 6C. LAST (FAMILY): STREGE | 7. STATE OF BIRTH: WA |
| | 8. DATE OF BIRTH: 03/28/1952 | | | |
| MOTHER OF CHILD | 9A. NAME OF MOTHER — FIRST (GIVEN): MARLENE | 9B. MIDDLE: TERESA | 9C. LAST (MAIDEN): ROELEEL | 10. STATE OF BIRTH: CA |
| | 11. DATE OF BIRTH: 07/09/1959 | | | |
| INFORMANT CERTIFICATION | I CERTIFY THAT I HAVE REVIEWED THE STATED INFORMATION AND THAT IT IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE. | 12A. PARENT OR OTHER INFORMANT — SIGNATURE: John Strege / Marlene T. Strege | 12B. RELATIONSHIP TO CHILD: PARENTS | 12C. DATE SIGNED: 1/1/99 |
| CERTIFICATION OF BIRTH | I CERTIFY THAT THE CHILD WAS BORN ALIVE AT THE DATE, HOUR AND PLACE STATED | 13A. ATTENDANT OR CERTIFIER — SIGNATURE — DEGREE OR TITLE: R Vance BRC | 13B. LICENSE NUMBER: 033554 | 13C. DATE SIGNED: 01/07/99 |
| | 13D. TYPED NAME, TITLE AND MAILING ADDRESS OF ATTENDANT: NATHAN HARRISON,MD,7920 FROST ST. #401 SAN DIEGO | | 14. TYPED NAME AND TITLE OF CERTIFIER IF OTHER THAN ATTENDANT: R THURMAN VANCE, BRC | |
| LOCAL REGISTRAR | 15A. DATE OF DEATH | 15B. STATE FILE NO. (STATE USE ONLY) | 16. LOCAL REGISTRAR — SIGNATURE | 17. DATE ACCEPTED FOR REGISTRATION: 01/14/1999 |

577941

This is a true and exact reproduction of the document officially registered and placed on file in the office of the San Diego County Recorder/Clerk

July 6, 2001

Gregory J. Smith
Assessor/Recorder/County Clerk

This copy is not valid unless prepared on an engraved border displaying

Exhibit B

07/06/21 05:30A P.003

ACCOUNT NUMBER [redacted]

cbr cord blood registry™

DEPOSIT NUMBER [redacted]

# OFFICIAL CERTIFICATE OF DEPOSIT

*This certificate is official record of deposit for the Cord Blood Stem Cells of*

***Hannah Eileen Strege***

*Cryopreserved at the Registry Vault this day the*

***1st of January 1999***

*This is a non-transferable legal claim to cord blood stem cells.*

*Dated:* 1/12/99

Thomas E. Moore
Chief Executive Officer

CORD BLOOD CRYOPRESERVATION SEAL REGISTRY

Paul Billings, M.D., Ph.D.
Medical Director

Exhibit C

Mr. SOUDER. Thank you very much. Mrs. Borden.

Ms. BORDEN. I am Lucinda Borden, and I am accompanied today by my husband John and my twin sons, Luke and Mark Borden.

I was told in 1997, after 5 years of trying unsuccessfully to conceive, that I could not ovulate. This was devastating for me and difficult for John, albeit John, as a widower, experienced the miracle of childbirth three times. Over the course of a year, I went through a severe grieving process involving denial, anger, and finally acceptance.

In the last stage of my grieving, John and I began considering traditional adoption as an alternative to conception. I had a few serious reservations. First, I could not experience pregnancy through child adoption. My deepest desire was to carry a baby and bond with it. I also hoped to control its nutritional and other input during the gestational period. Obviously, this would not be possible with traditional adoption.

Second, I was adopted through a closed adoption in 1965 and wrestled until 1997 with wanting to know about my biological parents. My adoptive parents strongly opposed this, fearing that I would abandon them. I began to share the same fear when we considered adoption. However, when I met my own genetic parents in 1997, I realized that the bond I shared with my adoptive family could never be severed. This assuaged my own fears about open adoption, designed to acquaint my children with their birth parents and allow them to ask the questions I wanted answered.

Accordingly, John and I decided to apply for an open adoption of a child in July 1999. We began a home study through Nightlight Christian Adoptions, the same agency through which I was adopted, and submitted a portfolio on our family. We also went through medical, psychological, paternal, and background evaluations.

Then the agency announced a new service: embryo adoption. Because it featured conception, we immediately changed course in favor of it. After reviewing our home study, Mark and Luke's genetic parents, Tim and Donna Zane, approved us as adoptive parents. We also selected them.

The Zanes conceived 10 embryos approximately July 1998. They froze six embryos for future use, in the event the initial transfer failed. Mark and Luke's genetic parents originally intended to terminate them if the embryos proved unnecessary to conceive. In February 1999, after they gave birth to triplets, they realized they could not destroy their six siblings. Surveying the Internet for a solution, the Zanes stumbled across the Snowflakes Program.

On December 10, 1999, the Zanes entered into contract with us for an open adoption. The Zanes authorized us to implant two straws containing three embryos each. We could not terminate any of the embryos and agreed to advise the adoption agency and the genetic family of the outcome of the implantation. Sadly, during thawing, three of the Zanes' embryos perished and could not be implanted.

I received 2 weeks of estrogen shots every 3 days to prepare my womb for implantation; 3 days before and 12 weeks after implantation, physicians also gave me daily shots of progesterone. I also had ultrasounds to ensure that my uterus was in good condition. The

actual procedure took minutes. Then I had to lay idle for a few hours in the office.

On January 31, three embryos were transferred into my womb. The embryologist took a picture of Mark and Luke and their sibling on this date. The following 2 weeks were the longest in our lives as we waited to find out if they would attach. On February 14, 2000, Valentine's Day, a blood test revealed I was pregnant. We were ecstatic. At this point we did not know how many children had attached. HCg levels over the next few weeks were high, but perhaps not high enough for triplets. On February 28, 2000, we had our first ultrasound and heard two heartbeats. We grieved for our third child, who we named Matthew, but rejoiced in Mark and, we were told, Hannah.

John and I began talking and singing to our kids right away. I felt both children kick for the first time during the week of June 2000. On September 27, I delivered twins at 36.5 weeks by C-section. Mark and, as it turned out, Luke were born. In keeping with our agreement with the Zanes, their birth certificates read "Mark and Luke Borden." The Zanes relinquished all parental rights over them.

Watching the twins mature has been fun and educational. They have interacted with each other since birth. Luke has a contagious laugh. Mark is serious and takes everything into perspective before giving a response. They have taught me so much about myself, as a woman, a wife, and a mother. It is hard to put into words their contribution to my life.

Like John and Marlene Strege, we have come forward today, despite our serious reservations about the effect of publicity on our family and kids, to plead with you not to approve funding for research that will kill frozen embryos such as Mark and Luke were roughly 1½ years ago.

We understand and share the passion many calling for embryo research have to find medical remedies for serious diseases. My own adoptive mother died from complications related to lupus, and my grandmother died from brain cancer. John's first wife perished from breast cancer. We have suffered terrible tragedy due to disease. However, we have also experienced unparalleled joy at the birth of Mark and Luke. We are confident that my mother and grandmother would never have sacrificed our children for their own therapy.

Nor do we think any such sacrifice is necessary for medical progress. It is clear that the advances possible with adult, placenta, and umbilical stem cells are in their infancy. On the other hand, recent articles suggest embryo stem cell research is deadly not just for the donor embryo, but for the recipient patient.

Mark and Luke are living rebuttal to the claim that embryos are not people. They are also testimony to the terrible loss this country will perpetuate if you approve Federal funding for embryo stem cell research. Thousands more children could be adopted by the millions of mothers desperately longing to conceive. Thousands more could lend their talents and skills to this country. Accordingly, we plead with you not to fund their slaughter.

And I ask that I be able to introduce my husband and my two sons.

Mr. SOUDER. Sure, go ahead.

Ms. BORDEN. This is John.

Mr. BORDEN. My name is John Borden, and I also testify to tell the truth. [Laughter.]

I have a very, very brief statement and I talk very loud. So, hopefully I won't require a microphone.

I just would like Lucinda to hold up that picture, and what you see is a picture of Mark and Luke and, unfortunately, the one child that we lost. I would like to ask every member of this committee, especially the members that aren't here, and that question is: Which one of my children would you kill? Which one would you choose to take? Would you want to take Luke, the giggler, who we call Turbo, or do you want to take the big guy, Tank? Which one would you take?

We thank the chairman and this committee for allowing us to make these statements. Thank you.

[The prepared statement of Ms. Borden follows:]

**Testimony of John and Lucinda Borden**
**before the**
**United States House of Representatives Committee on Government Reform**
**Subcommittee on Criminal Justice, Drug Policy, and Human Resources**
**Hearing on Embryonic Cell Research**
July 17, 2001

We are John and Lucinda Borden, residents of Fontana, California. John holds a MBA and is the Director of the Budget and Financial Analysis for the University of Redlands in Redlands, California. I hold a B.S. from Azusa Pacific University and am Director of Fiscal Services for East San Gabriel Valley Regional Occupational Program.

I was told in 1997 after five years of trying unsuccessfully to conceive that I could not ovulate. This was devastating for me and difficult for John, albeit John, as a widower, experienced the miracle of childbirth three times. Over the course of a year, I went through a severe grieving process involving denial, anger, and finally acceptance.

In the last stage of my grieving, John and I began considering traditional adoption as an alternative to conception. I had a few serious reservations. First, I could not experience pregnancy through child adoption. My deepest desire was to carry a baby and bond with it. I also hoped to control its nutritional and other input during the gestational period. Obviously, this would not be possible with traditional adoption.

Second, I was adopted through a closed adoption in 1965 and wrestled until 1997 with wanting to know about my biological parents. My adoptive parents strongly opposed this, fearing that I would abandon them. I began to share the same fear when we considered adoption. However, when I met my genetic parents in 1997, I realized that the bond I shared with my adoptive family could never be severed. This assuaged my own fears about an open adoption, designed to acquaint my children with their birth parents and allow them to ask the questions I wanted answered.

Accordingly, John and I decided to apply for an open adoption of a child in July 1999. We began a home study through Nightlight International Adoptions, the same agency through which I was adopted, and submitted a portfolio on our family, including pictures and an autobiography of ourselves, our family, and our marriage. We also went through thorough medical, psychological, paternal, and background evaluations.

Then, the agency announced a new service: embryo adoption. Because it featured conception, we immediately changed course in favor of it. After reviewing our home study, Mark and Luke's genetic parents, Tim and Donna Zane, approved us as adoptive parents. We also selected them.

The Zanes conceived 10 embryos on or about July 1998. They froze six embryos for future use, in the event the initial transfer failed. Mark and Luke's genetic parents originally intended to terminate them if the embryos proved unnecessary to conceive. In February 1999, after they gave birth to triplets, they realized they could not destroy their

six siblings. Surveying the internet for a solution, the Zanes stumbled across the Snowflakes Program.

On December 10, 1999, the Zanes entered into a contract with us for an open adoption, a copy of which is attached. *Id.*; Ex. A, Contract. The Zanes authorized us to implant two straws containing three embryos each. We could not terminate any of the embryos and agreed to advise the adoption agency and the genetic family of the outcome of implantation. Sadly, during thawing, three of the Zanes' embryos perished and could not be implanted.

I received two weeks of estrogen shots every three days to prepare my womb for implantation. Three days before and twelve weeks after implantation, physicians also gave me daily shots of projesterone. I also had ultrasounds to ensure that my uterus was in good condition. The actual procedure took minutes. Then I had to lay idle for a few hours in the office. The total cost of the procedure, $10,000, was roughly the same as for traditional domestic adoption and much cheaper than traditional international adoption.[1]

On January 31, 2000, three embryos were transferred into my womb. The embryologist took a picture of Mark, Luke, and their sibling on this date. Ex. B, Photograph. The following two weeks were the longest in our lives as we waited to find out if they would attach. On February 14, 2000, Valentine's Day, a blood test revealed I was pregnant. We were ecstatic! At this point we did not know how many children had attached. HCg tests over the next few weeks were high, but perhaps not high enough for triplets. On February 28, 2000, we had our first ultrasound and heard two heartbeats. We grieved for our third child, but rejoiced in Mark and, we were told, Hannah.

John and I began talking and singing to our kids right away. I felt both children kick for the first time during the first week of June 2000. I felt flutters before, but this time while laying on the couch Mark lit into me. I then lay on the other side and felt his sibling.

On September 27, 2000, I delivered twins at 36 ½ weeks by C-section. Ex. C, Photograph. Mark and, it turned out, Luke were born. In keeping with our agreement with the Zanes, their birth certificates read "Mark and Luke Borden." Ex. D, Birth Certificate. The Zanes relinquished all parental rights over them.

Watching the twins mature has been fun and educational. Ex. E, Photograph. They have interacted with each other since birth. Luke has a contagious laugh. Mark is serious and takes everything into perspective before giving a response. They have taught me so much about myself, as a woman, wife, and mother. It is hard to put into words their contribution to our lives.

Like John and Marlene Strege, we have come forward today, despite our serious reservations about the affect of publicity on our family and kids, to plead with you not to approve funding for research that will kill frozen embryos such as Mark and Luke were roughly one and one-half years ago.

---

[1] International adoptions cost between $16,000 and $20,000.

We understand and share the passion many calling for embryo research have to find rapid medical remedies for serious diseases. My adoptive mother died from complications related to lupus and my grandmother died from brain cancer. John's first wife perished from breast cancer. We have suffered terrible tragedy due to disease. However, we have also experienced unparalleled joy at the birth of Mark and Luke. We are confident that my mother and grandmother would never have sacrificed our children for their therapy.

Nor do we think any such sacrifice is necessary for medical progress. It is clear that the advances possible with adult, placenta, and umbilical stem cells are in their infancy. On the other hand, recent articles suggest embryo stem cell research is deadly not just for the donor embryo, but also the recipient patient.

Mark and Luke are living rebuttal to the claim that embryos are not people. They are also testimony to the terrible loss this country will perpetrate if you approve federal funding for embryo stem cell research. Thousands more children could be adopted by the roughly two million mothers desperately longing to conceive. Thousands more could lend their talents and skills to this country. Accordingly, we plead with you not to fund their slaughter.

Thank you.

# EMBRYO ADOPTION AGREEMENT

## I. PARTIES

The parties to this agreement are identified and defined as follows:

**A. Genetic Parents**
The genetic parents are [redacted] residing at [redacted] The genetic parents may hereinafter be referred to as embryo donors or donors.

**B. Adopting Parents**
The adopting parents are John and Lucinda Borden, husband and wife, residing at [redacted] California. The adopting parents may hereinafter be referred to as the designated recipients or birth parents of the embryos adopted hereunder. The term adopting parents shall include the terms adopting mother and adopting father.

**C. Subsequent Adopting Parents**
The term Subsequent Adopting Parents shall refer to any family selected by the genetic parents to be recipients of embryos identified herein which are not implanted in the adopting parents named herein in accordance with the terms of this agreement. It is the intention of the parties, including the subsequent adopting parents, that any subsequent adopting parents would become a signatory to this agreement and be bound by all the terms hereof.

**D. Christian Adoption & Family Services (CAFS)**
Christian Adoption & Family Services, located at 1698 Greenbriar Lane, Suite 219, Brea, California 92821, hereinafter referred to as CAFS or agency, is an agency licensed by the state of California to conduct homestudies of adopting parents and to place children for adoption.

The use of the term "parties" herein shall refer to each and every party defined above.

Exhibit A

## II. DEFINITION OF TERMS

### A. Embryos

The embryos, which are the subject of this agreement, were conceived by the in-vitro fertilization of egg and sperm and may have involved one or more donors. Embryos will be referred to as the genetic parents' embryos in the possessive sense regardless of the use of a donor. Said embryos were subsequently frozen and stored by the genetic parents. The embryos are pre-born children who are endowed by God with unique characteristics and are entitled to the rights and protection accorded to all children, legally and morally.

### B. Adoption

The term adoption is used in this agreement in its literal sense, rather than in a legal sense. The parties to this agreement acknowledge that there are no existing laws relating to the adoption of embryos, although some states specifically recognize the transactional necessities required in transferring custody and/or ownership of embryos from the genetic parents to any other party. The terms donation and transfer are an inherent part of the term adoption as used herein.

Any child(ren) born as the result of embryos transferred and implanted in adopting mother under the terms of this agreement shall be referred to herein as adopted child(ren).

### C. Medical Terminology

Various medical terms are used in this agreement, including, but not limited to "selective reduction", "embryo transfer", "embryo implantation", "cryogenically preserved embryos", "in-vitro fertilization", "embryo viability", "thawing", "cryo-bank" and other terms. Such terms, unless specifically defined to the contrary, shall have the common and ordinary meaning accorded them in the field of fertility medicine.

### D. Ownership and Parental Rights

The terms ownership rights and parental rights may be used interchangeably in this agreement. The use of either term shall include the legal interpretation applicable to the other term as well as the term used.

## III. PREAMBLE

The parties believe that human life is created by God at the time of conception, whether in-vivo or in-vitro. The genetic parents, through the fertilization of eggs and sperm, have become responsible for the lives of pre-born children in the embryonic stage. The genetic parents desire to transfer the responsibility for nurturing their embryos through the gestational period and parenting the

child(ren) born as a result thereof to adopting parents selected or approved by them.

The adopting parents desire to accept the full moral and legal responsibility for parenting the embryos adopted hereunder and the child(ren) born therefrom, beginning with the implantation of the embryos in the adopting mother. THIS IS NOT A SURROGACY CONTRACT.

The parties understand that embryo adoption is a new, developing and unsettled area of the law and that few states have laws regulating the transfer or adoption of embryos. Notwithstanding the fact that the parties believe that embryos constitute life in being, in its earliest stage of development, many laws treat embryos as property subject to the ownership rights of the genetic parents or persons or organizations to whom the ownership rights have been legally transferred. The parties desire that this agreement shall, to the extent not previously proscribed by law, define their legal rights, duties and responsibilities in connection with the transfer and adoption of embryos. In the event that any new laws are established affecting the adoption, transfer or donation of embryos, it is the intention of the parties that such laws not supersede or alter the terms of this agreement.

The parties agree that the role of CAFS is to assume custody of the embryos transferred hereunder for the purpose of facilitating the adoption of such embryos by adopting parents or subsequent adopting parents. CAFS shall acquire no ownership interest in such embryos and will use its best efforts to implement the mutual agreements and intentions of the other parties hereto.

The parties understand that there is no certainty that any of the frozen embryos transferred hereunder will survive thawing. However, it is the intention of the parties that only those embryos, which the adopting parents are willing to have implanted, will be thawed and all viable embryos which survive thawing will be implanted in the adopting mother. The parties understand that the frozen embryos in varying number (typically one to three) are stored in straws and that the number of embryos which will be implanted may vary depending on the number of embryos which survive thawing. For example, if only one (1) embryo survives thawing from the first straw thawed, then the adopting parents will have the option of thawing additional embryos from the second straw, of which zero (0), one (1), two (2) or even three (3) embryos may be viable after thawing.

It is the intention of the parties that the rights of the genetic parents to each and every embryo which is viable after thawing, and therefore implanted in adopting mother, will be forever terminated. The genetic parents will, however, maintain their right to relinquish, as further defined herein, the remaining frozen embryos to subsequent adopting parents or to reclaim custody of the remaining frozen embryos, if any.

## IV. TRANSFER OF EMBRYOS

### A. Transfer

The genetic parents hereby transfer their 6 frozen embryos to CAFS, to be stored at a site designated by CAFS and approved by genetic parents. CAFS shall accept custody of the embryos transferred hereunder for the purpose of facilitating the adoption of such embryos by adopting parents or subsequent adopting parents. Genetic parents agree to execute a relinquishment of all of the identified frozen embryos to adopting parents prior to implantation of any embryos in adopting mother. Genetic parents understand that such relinquishment, an example of which is attached hereto as Exhibit A, will have the legal effect of relinquishing, transferring, assigning and releasing all of their ownership rights and interest in and to each and every such frozen embryo which survives thawing and is implanted in adopting mother.

Genetic parents agree that they shall have three (3) calendar days after executing said relinquishment to revoke the relinquishment and thereby prohibit the thawing and implantation of any of the transferred embryos. Any embryos transferred hereunder which are not thawed and implanted in adopting mother within six (6) months of the execution of the relinquishment shall remain subject to the right of genetic parents to revoke this agreement as provided hereunder.

The embryos which are the subject of this agreement are currently stored cryogenically at the Reproductive Associates, Inc. in Wilmington, Delaware and identified as follows:

_____

The genetic parents acknowledge that the number of embryos transferred hereunder may be more than the number of embryos that would be implanted in the adopting mother.

The genetic parents agree to execute whatever additional documents, releases, consents or forms as may be necessary to effectuate the intent of this agreement.

### B. Agreements of Adopting Parents

1. Adopting parents agree to have the embryos relinquished to them hereunder implanted in the adopting mother as soon as practical, but in no event more than six (6) months from the execution of such relinquishment. Adopting parents further agree that the number of embryos thawed and implanted shall not exceed the number of children the adopting mother is

willing to carry to term and deliver, and in no case more than three (3) embryos.

2. Adopting parents agree to implant all embryos which are viable after being thawed. Adopting parents further agree not to permit or undertake any procedure for eliminating or reducing the number of embryos which adhere to and are developing in the adopting mother.

3. Adopting parents agree to promptly advise genetic parents and CAFS of the results of any implantation of embryos, including the expected delivery date of the child(ren). Upon the birth of any child(ren) born to the adopting mother as a result of the implantation of embryos transferred hereunder, the adopting parents agree to notify the genetic parents and CAFS of the name, sex and birth date of each child.

4. Adopting parents agree to provide genetic parents with reasonable information on a periodic basis, no less frequently than once a year, on the health and emotional and physical progress of the adopted child(ren). Such information may, at the discretion of the adopting parents, be provided through CAFS.

## V. ROLE OF CAFS

The parties to this agreement acknowledge that CAFS has undertaken to assist the parties with the placement of the frozen embryos for adoption. CAFS shall use its best efforts to provide such services as are customary in an open agency adoption to both the genetic and adopting parents. In addition, CAFS shall use its best efforts to assist genetic parents in locating and qualifying subsequent adopting parents for frozen embryos which are not relinquished to and implanted in adopting mother.

The parties understand that CAFS is an agency, licensed by the State of California, to place children for adoption. Nothing in such license, however, relates to the placement of frozen embryos for adoption. The parties further understand that CAFS has performed or received a homestudy approving adopting parents for adoption. The parties agree that CAFS shall at all times act in accordance with the powers and directions given it under this agreement and in the best interests of the child(ren), whether born or pre-born, which are the subject of this agreement.

## VI. STATUS OF CHILDREN BORN FROM RELINQUISHED EMBRYOS

### A. Child(ren) of Adopting Parents

Any child(ren) born to the adopting mother as a result of the implantation of embryo(s) relinquished hereunder shall be morally and legally the adopted child(ren) of adopting parents. The child(ren) shall be deemed to have been

## IX. REPRESENTATIONS, WARRANTIES AND GUARANTEES

### A. Representations and Condition of Embryos

Genetic parents have made no representations to CAFS or adopting parents, or their attorneys or agents, with respect to the quality, grade or condition of the frozen embryos transferred hereunder. Genetic parents have fully disclosed any and all information which they have regarding the history and condition of the frozen embryos which are being transferred hereunder. Genetic parents specifically disclaim any and all warranties of any type regarding the transferred frozen embryos.

### B. Hold Harmless Agreement

Adopting parents accept the frozen embryos transferred and relinquished hereunder and acknowledge that there are no warranties or guarantees regarding such embryos. Specifically, adopting parents understand and agree that no viable embryo may survive the process of thawing, that no child(ren) may be born from any embryos implanted hereunder, that no embryo implanted hereunder may result in the live birth of a child and that any child born as a result of an embryo implanted hereunder may have unknown birth defects or handicaps. Adopting parents agree to hold genetic parents and CAFS harmless from any claims as a result of the transfer, implantation and/or birth of a child or children resulting from the embryos transferred and relinquished hereunder.

## X. TERMINATION OF AGREEMENT

Any termination of this agreement under the provisions thereof shall be effective only as to frozen embryos that have not been relinquished in accordance with Section IV.A. hereof. The terms of this agreement as to any embryos which have been thawed and implanted in adopting parents shall survive any termination hereunder.

### A. Termination of Agreement by Genetic Parents

Genetic parents may terminate this agreement as to any frozen embryos, which have not been relinquished, as provided hereunder. Such termination shall result in the return of any remaining frozen embryos to the custody of genetic parents at the expense of genetic parents. Adopting parents agree to cooperate fully in facilitating the return of any such frozen embryos to genetic parents. Any termination as provided hereunder must be in writing and delivered to adopting parents, with a copy to CAFS, in a manner at least as prompt as first- class U.S. mail.

### B. Termination of Agreement by Adopting Parents

Adopting parents may terminate this agreement as to any frozen embryos, which have not been thawed by notifying the genetic parents, in writing, of their desire to terminate the agreement. Such notification shall be delivered in

## IX. REPRESENTATIONS, WARRANTIES AND GUARANTEES

### A. Representations and Condition of Embryos

Genetic parents have made no representations to CAFS or adopting parents, or their attorneys or agents, with respect to the quality, grade or condition of the frozen embryos transferred hereunder. Genetic parents have fully disclosed any and all information which they have regarding the history and condition of the frozen embryos which are being transferred hereunder. Genetic parents specifically disclaim any and all warranties of any type regarding the transferred frozen embryos.

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Adopting parents accept the frozen embryos transferred and relinquished hereunder and acknowledge that there are no warranties or guarantees regarding such embryos. Specifically, adopting parents understand and agree that no viable embryo may survive the process of thawing, that no child(ren) may be born from any embryos implanted hereunder, that no embryo implanted hereunder may result in the live birth of a child and that any child born as a result of an embryo implanted hereunder may have unknown birth defects or handicaps. Adopting parents agree to hold genetic parents and CAFS harmless from any claims as a result of the transfer, implantation and/or birth of a child or children resulting from the embryos transferred and relinquished hereunder.

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Any termination of this agreement under the provisions thereof shall be effective only as to frozen embryos that have not been relinquished in accordance with Section IV.A. hereof. The terms of this agreement as to any embryos which have been thawed and implanted in adopting parents shall survive any termination hereunder.

### A. Termination of Agreement by Genetic Parents

Genetic parents may terminate this agreement as to any frozen embryos, which have not been relinquished, as provided hereunder. Such termination shall result in the return of any remaining frozen embryos to the custody of genetic parents at the expense of genetic parents. Adopting parents agree to cooperate fully in facilitating the return of any such frozen embryos to genetic parents. Any termination as provided hereunder must be in writing and delivered to adopting parents, with a copy to CAFS, in a manner at least as prompt as first- class U.S. mail.

### B. Termination of Agreement by Adopting Parents

Adopting parents may terminate this agreement as to any frozen embryos, which have not been thawed by notifying the genetic parents, in writing, of their desire to terminate the agreement. Such notification shall be delivered in

a manner at least as prompt as first-class U.S. mail, with a copy of such notification to CAFS. Adopting parents shall be responsible for the expenses of the return or forwarding of the frozen embryos to a cryo-bank designated by genetic parents.

## XI. MISCELLANEOUS TERMS AND PROVISIONS

**A. Confidentiality**

All parties to this agreement agree that any identifying information regarding the parties shall be confidential and may only be disclosed as necessary to effectuate the purposes hereof.

**B. Governing Law**

The parties agree that this agreement shall be construed in accordance with and governed by the law of the State of California.

**C. Construction**

The headings at the beginning of the paragraphs of this agreement are for convenience only and shall not affect, modify or control the meaning of the language in the text thereof.

**D. Binding Effect**

The parties intend to be fully bound, morally and legally, by the terms of this agreement. This agreement shall also be binding upon the parties' heirs, personal representatives and successors in interest.

**E. Legal Advice**

Each party to this agreement has had the opportunity to seek separate and independent legal counsel and advice concerning the terms of this agreement and the duties, responsibilities and conduct required by the respective parties.

**E. Notifications**

Any notifications required hereunder shall be made by means at least as prompt as first-class U.S. mail and shall be addressed to the parties at the addresses listed herein, or such revised addresses as are provided to the parties. Each party agrees to notify all other parties to this agreement of any change of address.

## XII. ENTIRE AGREEMENT

This agreement, together with any attachments or exhibits thereto, represents the entire agreement between the parties hereto. No prior oral or written and no other contemporaneous oral statements or agreements between or among the parties with respect to the subject matter of this agreement shall be of any force and effect. Any amendment or modification of the terms of this agreement shall be in writing and signed by all parties hereto.

GENETIC PARENTS:

[redacted] [redacted]

State of [redacted]
County of [redacted]

Subscribed and sworn to before me, this 10th day of December, 1999.

(notary seal)

Notary Public
My Comm. Exps. 3-11, 2001

ADOPTING PARENTS:

John Borden

Lucinda Borden

State of California
County of San Bernardino

Subscribed and sworn to before me, this 22nd day of November, 1999.

(notary seal)

TORRIE NOUWELS
COMM. #1117972
NOTARY PUBLIC - CALIFORNIA
SAN BERNARDINO COUNTY
My Comm. Expires Nov. 24, 2000

Notary Public

# EMBRYO RELINQUISHMENT

We, the genetic parents of certain frozen embryos transferred to Christian Adoption & Family Services, a licensed adoption agency in the State of California, under an Embryo Adoption Agreement entered into on or about 12/10, 1999 (hereinafter referred to as "the Agreement"), do hereby relinquish and surrender all such embryos which have not been previously thawed, consisting of 6 frozen embryos, to:
John & Lucinda Borden of Fontana, California (adopting parents) for the purpose of implantation in Lucinda Borden. This relinquishment shall be subject to the additional terms and conditions of the Agreement.

By signing this relinquishment, we forever terminate and surrender all of our parental rights to those embryos which are thawed within six (6) months from the date hereof, including any and all parental rights to children born as a result of the implantation of embryos in adopting mother during such six-month period.

Either or both of us shall have the right to rescind this relinquishment within three (3) days of the date hereof, by notifying Christian Adoption & Family Services by telephone at (714) 529-2949 (between the hours of 8:00 a.m. and 5:00 p.m. Pacific time) followed by confirmation in writing delivered to Christian Adoption & Family Services at 1698 Greenbriar Lane, Suite 219, Brea, California 92821, by first-class mail. If this relinquishment is not rescinded in accordance with this provision, it shall be irrevocable for a period of six (6) months from the date hereof.

[redacted] [redacted]

The foregoing instrument was signed on December 10th, 1999, by Timothy & Donna Zane (genetic parents) in our presence and we have signed the same as witnesses thereto.

Melissa Cox Melissa Cox
(Witness) (Witness)

State of [redacted]
County of [redacted]

Subscribed and sworn to before me, this 10th day of December, 1999.

Elaine P. Frick
Notary Public
My Comm. Exps. 5-11, 2001

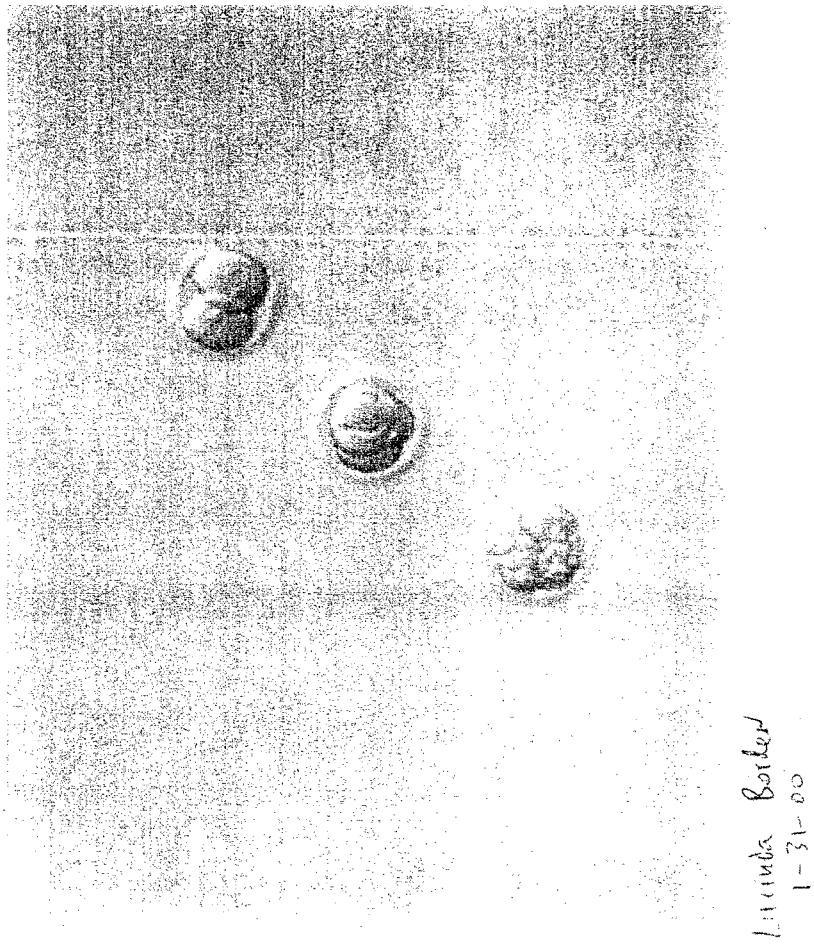



Exhibit B

Exhibit C

CERTIFICATION OF VITAL RECORD

# COUNTY of SAN BERNARDINO

DEPARTMENT OF PUBLIC HEALTH
351 MT. VIEW AVENUE, SAN BERNARDINO, CALIFORNIA 92415-0010

## CERTIFICATE OF LIVE BIRTH
STATE OF CALIFORNIA
USE BLACK INK ONLY

STATE FILE NUMBER: 1200036018332 (LOCAL REGISTRATION DISTRICT AND CERTIFICATE NUMBER)

| | | | | | |
|---|---|---|---|---|---|
| THIS CHILD | 1A. NAME OF CHILD — FIRST (GIVEN): LUKE | | 1B. MIDDLE: WILLIAM BRADFORD | 1C. LAST (FAMILY): BORDEN | |
| | 2. SEX: MALE | 3A. THIS BIRTH, SINGLE, TWIN, ETC.: TWIN | 3B. IF MULTIPLE, THIS CHILD 1ST, 2ND, ETC.: 1ST | 4A. DATE OF BIRTH — MM/DD/CCYY: 09/27/2000 | 4B. HOUR — (24 HOUR CLOCK TIME): 0754 |
| PLACE OF BIRTH | 5A. PLACE OF BIRTH — NAME OF HOSPITAL OR FACILITY: SAN ANTONIO COMMUNITY HOSPITAL | | 5B. STREET ADDRESS — STREET, NUMBER, OR LOCATION: 999 SAN BERNARDINO RD. | | |
| | 5C. CITY: UPLAND | | 5D. COUNTY: SAN BERNARDINO | 5E. PLANNED PLACE OF BIRTH: HOSPITAL | |
| FATHER OF CHILD | 6A. NAME OF FATHER — FIRST (GIVEN): JOHN | 6B. MIDDLE: WALLACE | 6C. LAST (FAMILY): BORDEN, II | 7. STATE OF BIRTH: CA | 8. DATE OF BIRTH: 11/18/1945 |
| MOTHER OF CHILD | 9A. NAME OF MOTHER — FIRST (GIVEN): LUCINDA | 9B. MIDDLE: KAY | 9C. LAST (MAIDEN): BLENDERMAN | 10. STATE OF BIRTH: CA | 11. DATE OF BIRTH: 01/01/1965 |
| INFORMANT CERTIFICATION | I CERTIFY THAT I HAVE REVIEWED THE STATED INFORMATION AND THAT IT IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE. | 12A. PARENT OR OTHER INFORMANT — SIGNATURE | | 12B. RELATIONSHIP TO CHILD: FATHER | 12C. DATE SIGNED: 09/28/2000 |
| CERTIFICATION OF BIRTH | I CERTIFY THAT THE CHILD WAS BORN ALIVE AT THE PLACE AND TIME STATED. | 13A. ATTENDANT OR CERTIFIER — SIGNATURE — DEGREE OR TITLE | | 13B. LICENSE NUMBER: A4760 | 13C. DATE SIGNED: 09/28/2000 |
| | 13D. TYPED NAME, TITLE AND MAILING ADDRESS OF ATTENDANT: R A ARMADA, DO, 585 MOUNTAIN AVE, UPLAND | | | 14. TYPED NAME AND TITLE OF CERTIFIER IF OTHER THAN ATTENDANT: CYNDY McLEAN, MSD REC MGR | |
| LOCAL REGISTRAR | 15A. DATE OF DEATH | 15B. STATE FILE NO. (STATE USE ONLY) | 16. LOCAL REGISTRAR — SIGNATURE | | 17. DATE ACCEPTED FOR REGISTRATION: 10/18/2000 |

1054878

CERTIFIED COPY OF VITAL RECORDS

STATE OF CALIFORNIA
COUNTY OF SAN BERNARDINO } SS

DATE ISSUED 12/29/2000

This is a true and exact reproduction of the document officially registered and issued on file in the VITAL RECORDS SECTION, SAN BERNARDINO DEPARTMENT OF PUBLIC HEALTH

THOMAS J. PHENDERGAST, M.D.
COUNTY HEALTH OFFICER
REGISTRAR OF VITAL STATISTICS

This copy not valid unless prepared on engraved Security paper bearing seal and signature of Registrar

ANY ALTERATION OR ERASURE VOIDS

Exhibit D

CERTIFICATION OF VITAL RECORD

# COUNTY of SAN BERNARDINO

DEPARTMENT OF PUBLIC HEALTH
351 MT. VIEW AVENUE, SAN BERNARDINO, CALIFORNIA 92415-0010

CERTIFICATE OF LIVE BIRTH
STATE OF CALIFORNIA
USE BLACK INK ONLY

STATE FILE NUMBER: 1200036018333
LOCAL REGISTRATION DISTRICT AND CERTIFICATE NUMBER

| | | | | | | |
|---|---|---|---|---|---|---|
| THIS CHILD | 1A. NAME OF CHILD — FIRST (GIVEN): MARK | | 1B. MIDDLE: WALLACE | | 1C. LAST (FAMILY): BORDEN | |
| | 2. SEX: MALE | 3A. THIS BIRTH (SINGLE, TWIN, ETC.): TWIN | 3B. IF MULTIPLE, THIS CHILD 1ST, 2ND, ETC.: 2ND | 4A. DATE OF BIRTH — MM/DD/CCYY: 09/27/2000 | 4B. HOUR — (24 HOUR CLOCK TIME): 0756 | |
| PLACE OF BIRTH | 5A. PLACE OF BIRTH — NAME OF HOSPITAL OR FACILITY: SAN ANTONIO COMMUNITY HOSPITAL | | | 5B. STREET ADDRESS — STREET, NUMBER, OR LOCATION: 999 SAN BERNARDINO RD. | | |
| | 5C. CITY: UPLAND | | | 5D. COUNTY: SAN BERNARDINO | 5E. PLANNED PLACE OF BIRTH: HOSPITAL | |
| FATHER OF CHILD | 6A. NAME OF FATHER — FIRST (GIVEN): JOHN | 6B. MIDDLE: WALLACE | | 6C. LAST (FAMILY): BORDEN, II | 7. STATE OF BIRTH: CA | 8. DATE OF BIRTH: 11/18/1945 |
| MOTHER OF CHILD | 9A. NAME OF MOTHER — FIRST (GIVEN): LUCINDA | 9B. MIDDLE: XAY | | 9C. LAST (MAIDEN): BLENDERMAN | 10. STATE OF BIRTH: CA | 11. DATE OF BIRTH: 01/01/1955 |
| INFORMANT CERTIFICATION | I CERTIFY THAT I HAVE REVIEWED THE STATED INFORMATION AND THAT IT IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE. | | 12A. PARENT OR OTHER INFORMANT — SIGNATURE: X | | 12B. RELATIONSHIP TO CHILD: FATHER | 12C. DATE SIGNED: 09/28/2000 |
| CERTIFICATION OF BIRTH | I CERTIFY THAT THE CHILD WAS BORN ALIVE AT THE DATE, HOUR AND PLACE STATED. | | 13A. ATTENDANT OR CERTIFIER — SIGNATURE — DEGREE OR TITLE: Cynthia McLean | | 13B. LICENSE NUMBER: A4760 | 13C. DATE SIGNED: 09/28/2000 |
| | 13D. TYPED NAME, TITLE AND MAILING ADDRESS OF ATTENDANT: R A ARMADA, DO, 585 MOUNTAIN AVE, UPLAND | | | | 14. TYPED NAME AND TITLE OF CERTIFIER IF OTHER THAN ATTENDANT: CYNDY McLEAN, MED REC MGR | |
| LOCAL REGISTRAR | 15A. DATE OF DEATH | 15B. STATE FILE NO. (STATE USE ONLY) | 16. LOCAL REGISTRAR — SIGNATURE: T. Hundersgast MD | | | 17. DATE ACCEPTED FOR REGISTRAT ON: 10/18/2000 |

10-5-877

CERTIFIED COPY OF VITAL RECORDS

STATE OF CALIFORNIA
COUNTY OF SAN BERNARDINO } SS

DATE ISSUED 12/29/2000

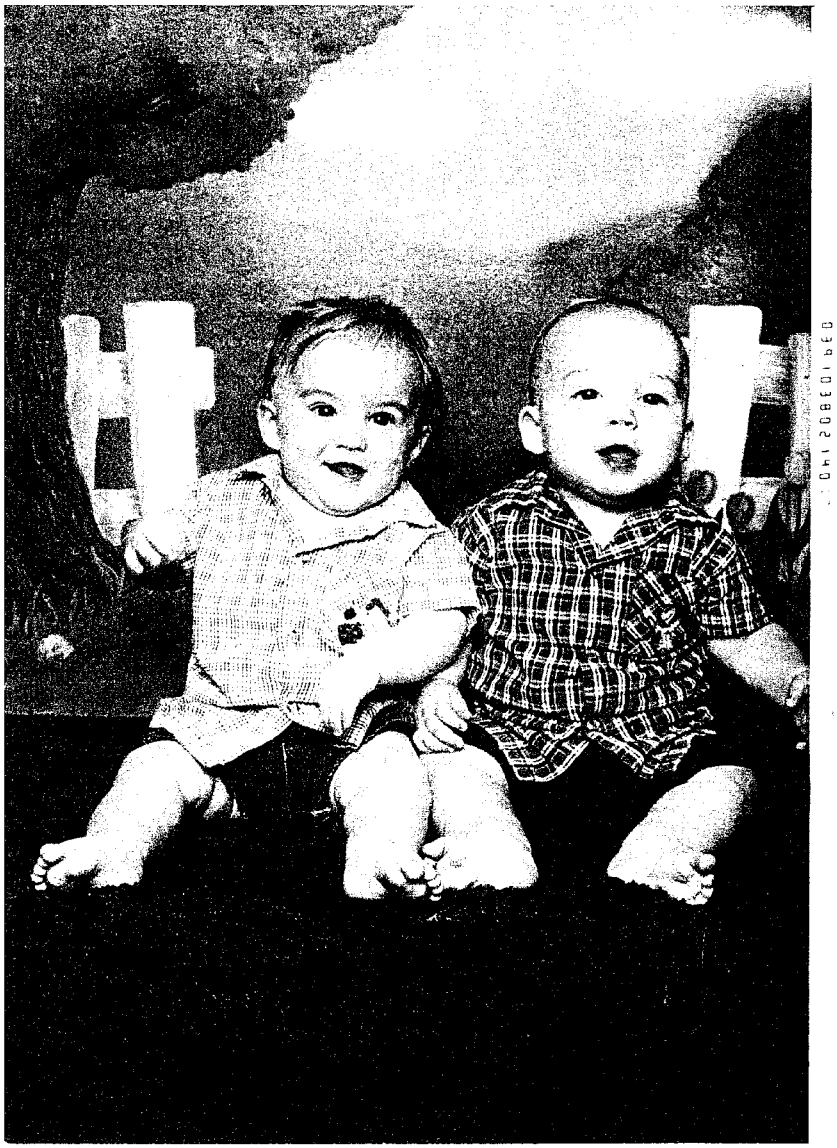
This is a true and exact reproduction of the document filed or registered and placed on file in the VITAL RECORDS SECTION, SAN BERNARDINO COUNTY DEPARTMENT OF PUBLIC HEALTH

T. Hundersgast MD
THOMAS J. HUNDERSGAST, M.D.
COUNTY HEALTH OFFICER
REGISTRAR OF VITAL STATISTICS

This copy not valid unless prepared on official security paper bearing seal and signature of Registrar.

ANY ALTERATION OR ERASURE VOIDS THIS CERTIFICATE

Exhibit E



Mr. SOUDER. Thank you very much, and we will have the record show that Mr. Borden also took the oath.

We are having a vote, of all times, right now over in another committee on drilling in the Arctic Wildlife Refuge, also a very close vote. I am going to yield the chair to Mr. Weldon. Actually, we will take the testimony of Ms. Davidson. We are clearly going to have a vote on the House floor as well. Then we will come back for questions.

I want to thank you both so much for coming forth today, and we will talk about that further.

Mr. WELDON [assuming Chair]. Members are advised we will take the testimony of Ms. Davidson and then recess for the vote.

Ms. Davidson, you may proceed with your testimony.

Ms. DAVIDSON. As the committee knows, my name is JoAnn Davidson. I am the program director of the Snowflakes Embryo Adoption Program for Nightlight Christian Adoptions.

I am here to let you know today that embryo adoption is not a theory and it's not an idea and it's not a hope, but it is happening right now in America. In fact, all 50 states permit living human embryo adoption and implantation. In fact, embryo adoption is proof positive that all embryos are not destroyed.

To date, the Snowflakes Program has seen eight babies born to six families. Mark, Luke, and Hannah are three of those babies, as you've met here today. 182 embryos in total from 28 genetic families have been adopted; 93 have survived the thaw, and we have the babies that we've mentioned here today, you've seen today, and other families. Twenty adopting families have gone through transfers. Nine of those families have babies. Five babies are currently waiting to be born and are gestating in the wombs of three very happy mothers.

Experience teaches us that at least 12,600 to 35,000 children could be adopted, thawed, and successfully born from human embryos residing in what many call frozen orphanages. At least 188,000 embryos from approximately 23,000 families are currently frozen, living in in vitro fertilization clinics throughout the United States.

An increasing number of genetic parents, presented with the dilemma of what to do with their frozen embryos, like the alternative of placing them with qualified families. Regardless of the medical or legal status of their embryos, these genetic parents are emotionally invested in their offspring and feel responsible for their welfare.

After recent publicity on ABC's Prime Time focusing on the dilemma that genetic parents face, the number of families enrolled in our program increased 35 percent. In essence, there are no excess living human embryos available for research since all should be entitled to an opportunity to live in a loving adoptive home. An estimated 6.5 to 10 million couples suffer from infertility. Many of these families could adopt and implant the existing population of frozen embryos less expensively than the costs associated with other in vitro fertilization processes.

Most of these infertile couples dearly want children and long to conceive. For these families, embryo adoption provides the benefits of pregnancy, pre-natal bonding, and child birth not found in tradi-

tional adoption, and also includes the satisfaction of parenting a waiting child. Embryo adoption is far less expensive than IVF treatments, and since the families are adopting and not creating embryos, they are helping to reduce, not contribute, to the supply of embryos in storage.

Embryo adoption involves a thorough screening process designed to ensure that embryos are placed with stable families meeting the expectations of genetic parents. Adoptive families participate in a standard home study, as required in all adoptions in the United States. They divulge medical, psychological, paternal, and background information. The adoption agency preparing the home study provides professional counseling, education to the adopting family regarding integrating the child into their home, parenting, and other issues unique to the family.

Properly freezing a living human embryo can preserve its life until it is properly thawed, but about 50 percent of living human embryos die in the process of freezing and thawing. While embryos may die in the adoption process, they are not destroyed intentionally. Harvesting the stem cells from living human embryos always kills that embryo. Therefore, we can say that in embryonic research the intent is necessarily to destroy the embryo. In adoption the intent is that every embryo be given the opportunity for life.

Embryo adoption solves multiple problems: families for children, children for families, and the number of embryos in storage tanks across the Nation is reduced. Adoption, not destruction of, frozen living human embryos is the best way to help infertile American couples and does no harm to anyone.

Therefore, independent of the legal question whether an embryo is or is not a legal person, we respectfully request, along with most Americans, and especially infertile Americans, that Congress not lift its existing ban against Federal funding for the destruction of human embryos for any purpose. Alternative sources of stem cells proven more effective are plentiful, and medical advances using umbilical, placenta, and adult cells are just beginning.

There are some who would say that they are going to be destroyed anyway. I'm here to tell you that's not necessary. We in America are greater than that. We can and ought to save every embryo. We can do this through educating the public about embryo adoption. We can do this by way of our IVF clinics including the adoption option in their consent procedures; then to enforce and encourage limitations on the numbers of embryos that are created.

Human embryo adoption is not about "dots on a paper," as Senator Harkin has referred to living human embryos. Rather, this debate is about whether we as an entire society want to federally fund destructive human experimentation of the littlest humans.

Here in this room and in homes across America we must decide whether we should compel every taxpayer to support destroying human embryos at a stage of development through which each one of us has passed. Are we going to accept the effect of genocide as medical therapy? Having looked into the eyes of eight precious newborns and frozen embryos, I, for one, will not.

I implore Congress to provide more funding for alternative sources of stem cells and extend to even the smallest of humans in America the right to life, liberty, and the pursuit of happiness through embryo adoption. Thank you very much.

[The prepared statement of Ms. Davidson follows:]

**Testimony of JoAnn L. Davidson**
**before the**
**United States House of Representatives Committee on Government Reform**
**Subcommittee on Criminal Justice, Drug Policy, and human Resources**
**Hearing on Embryonic Stem Cell Research**
July 17, 2001

My name is JoAnn L. Davidson. I am a resident of Balboa Island, California and hold a Bachelor's Degree in sociology from Texas A&M University. I am the Program Director for Snowflakes Embryo Adoption Program, a division of Nightlight Christian Adoptions, located at 801 East Chapman Avenue, Suite 106, Fullerton, California 92831. Nightlight has been involved in domestic adoptions since 1959 and international adoptions of children since 1992.

The Snowflakes Embryo Adoption Program derives its name from the idea that snowflakes like human embryos are frozen, unique and cannot be recreated. Nightlight developed the program in 1997 in response to two developments, together with the personal infertility experience of John and Marlene Strege.

The first development to influence Nightlight's decision was a British law passed on August 1, 1991, requiring the destruction of all frozen embryos unclaimed after five years.[1] It took effect on July 31, 1996,[2] leading to the extermination, according to a survey by Britain's Human Fertilization & Embryology Authority, of 3,300 frozen embryos.[3] The genetic parents of the remaining 6,000 embryos exercised their rights to extend storage for another five years or donate them.[4] Nightlight decided it wanted to do its part to prevent a similar massacre in the United States.

The second development is the rapid growth since the early-1980's of the in-vitro fertilization ("IVF") industry in the United States.[5] In the last two decades, it grew from one clinic to 360 by 1998.[6] In the late-1990s, it was estimated that the IVF industry was

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[1]Traci Watson, *Excess Embryos*, U.S. NEWS & WORLD REP. 10 (August 12, 1996); James Walsh, *A Bitter Embryo Imbroglio: Amid Dramatic Protests and Universal Unease, Britain Begins Destroying 3,300 Human Embryos*, TIME (August 12, 1996).
[2] Watson, *supra* note 1, at *10*.
[3] *Id.*
[4] Walsh, *supra* note 1.
[5]The world's first known baby born of in-vitro fertilization came into the world on July 25, 1978 in Oldham, England under the care of English Drs. Robert Edwards and Patrick Steptoe. Victor Cohn, *First U.S. Test-Tube Baby is Born; Norfok Test-Tube Baby First in United States*, WASHINGTON POST at A1 (December 29, 1981). The first IVF clinic in the United States, the Eastern Virginia Medical School, went into operation in March 1979. *Id.* After more than one year of experimentation, it announced the first successful pregnancy in the United States in May 1980. *Id.* Dr. Fred Worth was the attending pediatrician. *Id.* On December 28, 1981, the first baby was born in the United States from IVF treatment. *Id.*
[6] CENTER FOR DISEASE CONTROL, 1998 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 4 (2000) [hereinafter "CDC REPORT at _"]. According to the Society for Assisted Reproductive Technology ("SART"), the number of IVF clinics in 2001 is 371. Confirm by calling 205-978-5000 x 109.

earning revenues exceeding $350 million annually.[7] One observer estimated in 1999 that these IVF clinics store more than 150,000 frozen live humans with 19,000 added each year.[8] Anecdotal evidence suggests the number may be much higher.

Due to the tendency of fertility drugs given to women in IVF programs to produce more embryos than can safely be implanted at any one time, it has become common to freeze the unused embryos in a process called cryopreservation in order to preserve their lives for implantation at a later date.[9] Although this process relieves the woman of the cost and physical burden of further egg retrievals while preserving the lives of some of their embryos, the practical result is that the IVF industry regularly produces more human embryos than it implants, leading to an exploding frozen living human population.[10]

IVF clinics agree to store frozen embryos for a fixed period of time, usually five years.[11] Then, they offer the genetic parents the option of extending storage for a fee varying between $100 and $500 annually,[12] implanting the embryos, terminating them, or donating them for some purpose. Storage agreements with IVF clinics may include a presumption in favor of one of these alternatives if the genetic parents fail to act.

An increasing number of genetic parents presented with the dilemma of what to do with their frozen embryos would like the alternative of placing them with qualified families. Regardless of the medical or legal status of their embryos, these genetic parents are emotionally invested in their offspring and feel responsible for their welfare. As their storage contracts come up for renewal, they are looking for additional choices not offered by IVF clinics.

Fortunately, there are tremendous potential benefits of embryo adoption for infertile families. An estimated 6.5 to 10 million couples (or 13 to 20 million individuals) in the United States suffer from infertility.[13] Most of them dearly want children and long to conceive. Accordingly, many turn to the IVF industry, notwithstanding the expense, the

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[7] Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger*, 34 HOUS. L. REV. 609, 613-14 (1997).

[8] Lori B. Andrews, *Embryonic Confusion; When you Think Conception, You Don't Think Product Liability; Think Again*, WASHINGTON POST at B1, B4 (May 2, 1999).

[9] Samuel B. Casey, *How the Law Will Shape Our Life and Death Decisions: The Case of the Human Embryo* in BIOENGAGEMENT 151 (Nigel Cameron, Scott Daniels and Barbara White eds., 2000).

[10] *Id.*

[11] "The Ethics Committee finds that it is ethically acceptable for a program to consider embryos to have been abandoned if more than five years have passed since contact with the couple." *See* American Society for Reproductive Medicine, Ethics Committee, *Disposition of Abandoned Embryos* (1996) http://www.asrm.org/Media/Ethics/abandon.html (visited July 12, 2001).

[12] *See, e.g.*, Advanced Fertility Center of Chicago http://www.advancedfertility.com/ivfprice.html ($400 for one year) (visited July 12, 2001); ReproTech, Ltd. http://www.reprot.com/fees.html ($400 annually) (visited July 12, 2001); The Cleveland Clinic http://www.clevelandclinic.org/obgyn/fees.htm ($100 annually) (visited July 12, 2001); The Cooper Clinic for In-Vitro Fertilization, P.C. http://www.ccivf.com/pricing.html ($250 for six months) (visited July 12, 2001); Grand Rapids Fertility http://www.grandrapidsfertility.com/successcostofivf.htm ($800 for two years) (visited July 12, 2001).

[13] JOE S. MCILHANEY, M.D., 1001 HEALTH-CARE QUESTIONS WOMAN ASK 432-33 (1998); Dominick Vetri, *Reproductive Technologies and United States Law*, 37 INT'L & COMP. L. Q. 505 (1988).

low success rate, and their ethical reservations. For these people, child adoption is less attractive, because it does not involve pregnancy, prenatal bonding, or childbirth.

In contrast, embryo adoption involves all of these benefits, includes the satisfaction of parenting a waiting child, and is far less expensive than IVF treatments. The average expense of our embryo adoptions is between $7,000 and $10,000, compared to an average of nearly $50,000 for IVF treatments plus expensive medication.[14] Half of the couples that have participated in embryo adoption through the Snowflakes Program have become pregnant.

Embryo adoption is better than embryo donation because it involves a thorough screening process designed to ensure that embryos are placed with stable families meeting the expectations of genetic parents. It also protects against parenting paternally related children. Genetic parents complete an inventory of their financial, religious, educational and other preferences. We match these with input from the adopting parents.

Adoptive families participate in a standard home study, which can be used either for embryo or traditional adoption. They must also divulge thorough medical, psychological, paternal, and background information. The adoption agency preparing the homestudy provides professional counseling and education to the adoptive family regarding integrating the child into the home, parenting, and other issues unique to the family.

The Snowflakes Program promotes open adoption over closed adoption, because it is the most psychologically rewarding for all concerned. Open adoption necessarily involves selection of families through pictures and letters and usually, but not necessarily, involves knowledge by the genetic and adoptive parents of one another's last names and addresses. We recommend the latter because it enables children to become acquainted with their genetic parents and receive answers to the questions they naturally ask.

When we find a match between genetic and adoptive parents, we begin the formal adoption process, including drafting an adoption agreement. The latter provides, among other things, for the relinquishment of the genetic parents' rights over the embryo and states that the baby born will bear the name of the adoptive family and have inheritance rights through only the adoptive family.

Under well-established contract law principles, embryo adoption through an adoption agreement is permitted in all 50 states. Accordingly, the fact that the legal framework for embryo adoption is partially articulated in not more than a few states is less of a

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[14] The cost for IVF treatment varies dramatically depending upon the age of the woman and the clinic. According to calculations based on Center for Disease Control data, the average cycles of IVF treatment necessary for a live birth for those under 35 is 3.1; woman between 35 to 37, 3.8; woman between 38 and 40, 5.6; and woman over 40, 12.2. *See* CDC REPORT, *supra* note 6, at 47. The cost of IVF treatment, according to CNN and WebMD, is $9,990 per cycle. *See* Roxanne Nelson, *Financing Infertility* (1999) http://www.cnn.com/HEALTH/women/9905/19/financing.infertility/ (visited July 12, 2001). *See also* Daar, *supra* note 7, at 649 ("It is estimated that a single cycle of IVF can cost up to $10,000, and patients often undergo multiple cycles before a pregnancy is achieved.") Insurance is not ordinarily available for IVF treatments. *Id.* at 662.

concern.[15] The presumed mother of a child is his or her birth mother,[16] who in this case is also the adoptive mother.

Following adoption, Snowflakes arranges for shipment of the frozen living humans. Then, implantation proceeds. The adoptive family selects his or her own embryologist and other physicians who prepare the adopting woman's womb (which normally involves injections of inexpensive hormones such as estrogen and progesterone), thaw the embryos, and perform the transfer. The adoption agreement requires that any unused embryos be returned to their genetic parents. They may not be destroyed.

To date, the Snowflakes Program has been involved in the placement of eight babies born to six families across the United States. Hannah Strege, who you will meet shortly, was the first. Five children are in gestation in the wombs of three moms. Twenty-seven families have been matched. A total of 314 embryos from 35 families have been adopted, 182 thawed, and 93 survived and implanted.

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[15] A legal framework for embryo adoption exists in Florida, Louisiana, Oklahoma and Texas. Fla. Stat. Ann §§ 63.212(i)(2) provides that individuals may enter into a pre-planned adoption agreement wherein the mother agrees to become pregnant through "fertility techniques" including embryo adoption. The agreement must be reviewed and approved by a court of law to effect a final adoption. *Id.* La. Rev. Stat. Ann. § 9:126 requires "adoptive implantation" of embryos when the creators of the embryos are unidentifiable or no longer want the embryos. Embryo adoption is fulfilled when the couple "executes the notarial act of adoption of the ovum and birth occurs." La. Rev. Stat. Ann. § 9:130. *See also* 10 Okl. St. § 556 (written consent of husband and wife desiring to receive and donate embryo necessary; former also requires consent from physician to perform transfer and any judge of a court having adoption jurisdiction in the state); Tex. Fam. Code § 151.103 (written consent necessary of husband and wife desiring to receive embryo and of husband and wife desiring to donate embryo).

[16] *See, e.g.*, Ala. Code § 26-17-4 (establishing the birth mother as a child's mother); Cal. Fam. Code § 7610 (establishing the birth mother as a child's mother); Colo. Rev. Stat. § 19-4-104 (establishing the birth mother as a child's mother); Del. Code Ann. tit. 13, § 803 (establishing the birth mother as a child's mother); Fla. Stat. Ann §§ 742.11, 742.14, 742.17 (establishing child conceived by means of IVF as the child of the husband and wife consenting to IVF if both parties consent in writing; establishing child conceived from donated eggs or preembryos as the child of the gestating woman and her husband if both parties consent in writing; stating donor of embryo has no parental claim to resulting child); Haw. Rev. Stat. § 584-3 (establishing birth mother as a child's mother); 750 Ill. Comp. Stat. § 45/4 (establishing birth mother as a child's mother); Kan. Stat. Ann. § 38-1113 (establishing birth mother as a child's mother); Minn. Stat. § 257.54 (establishing birth mother as a child's mother); Mo. Ann. Stat. § 210.819 (establishing birth mother as a child's mother); Mont. Code Ann. § 40-6-104 (establishing birth mother as a child's mother); Nev. Rev. Stat. § 126.041 (establishing birth mother as a child's mother); N.H. Rev. Stat. Ann. § 168-B (establishing birth mother as legal mother of child; requiring husband to accept "legal rights and responsibilities of parenthood for any resulting child."); N.J. Stat. Ann. § 9:17-41 (establishing birth mother as a child's mother); N.M. Stat. Ann. § 40-11-4 (establishing birth mother as a child's mother); N.D. Cent. Code § 14-17-03 (establishing birth mother as a child's mother); Ohio Rev. Code Ann. § 3111.02 (establishing birth mother as a child's mother); 10 Okl. St. §§ 556, 7503-2.6 (establishing child "born of human embryo transfer donation . . . the same as a naturally conceived legitimate child of the husband and wife that consent to the human embryo transfer; recognizing mother as the woman having given birth to the child); Tex. Fam. Code Ann. §§ 151.001, 151.103 (establishing birth mother as the child's mother; establishing child resulting from a donated preimplantation embryo as the child of the birth mother; stating donor of embryo has no parental claim to resulting child); Va. §§ 20-49.1, 20-158 (establishing the birth mother as a child's mother); Wash. Rev. Code § 26.26.030 (establishing birth mother as a child's mother); Wyo. Stat. § 14-2-101 (establishing birth mother as a child's mother).

The Snowflakes Program only recently received publicity when ABC's PrimeTime featured it on April 12, 2001. After the program aired, the number of genetic parents that enrolled their frozen children in the Program increased 35 percent to roughly 67 with an average of seven embryos each in storage. The number of registered adoptive families also increased to roughly 70. Recently, we learned about a group of IVF practitioners considering disbanding, who would like to offer to each of their 500 clients the adoption option.

The potential growth of the Snowflakes Program is mind-numbing. We have doubled in size each year since the program started. This past year (2000), we increased our embryo adoptions 600 percent. We are scrambling now to develop a model, which other agencies can implement, to expand the embryo adoption concept.

Ultimately, no embryo will prove in "excess of the clinical need." Based upon our conservative estimate of 188,000 frozen human embryos currently stored in IVF clinics, a conservative thaw survival rate of 50 percent,[17] and a national pregnancy rate for IVF clinics of between 13.4% (over 40) to 37.2% (under 35),[18] between 12,600 and 35,000 children could be placed for adoption and born in the families of the 6.5 to 10 million infertile married couples in America who seek to raise children.

Every human embryo, even if he or she can no longer be cared for by their genetic parents, deserves to be nurtured and given a chance for a good life with an adoptive couple who will love and raise them to be welcome citizens of this country. Under these circumstances, a decision to authorize the federal funding of human embryo destruction is a decision to take the lives of at least 12,600 to 35,000 children who otherwise could have been born and raised by loving adoptive parents.

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[17] *See* IVF Phoenix Infertility Information Booklet ("Not all embryos survive the freeze-thaw process. A 50% survival rate is considered reasonable. After the thaw, embryos retaining 50 percent or more of the cells they had before freezing are cultured and placed back in the uterus via a tube inserted in the cervix. The number returned varies with the desires of the patient under the guidelines of age categories; under 35 years old, up to four embyos, 35 years and older, up to six embryos. National statistics for women 39 or less is 27% per embryo transfer, for women over 39, 14% per embryo transfer. Delivery rates will be lower due to miscarriage."); Michael J. Tucker, Ph.D., *The Freezing of Human Oocytes [Eggs]*, http://www.ivf.com/freezing.html ("Whether eggs are mature or not, standard cryopreservation technologies appear to have their ultimate limitations not only in terms of cryosurvival (% of eggs that are alive after thawing), but also more importantly in their lack of consistency. 50% cryosurvival may be an adequate overall outcome and is now commonly reported, but not if it is a statistic that is arrived at by 90-100% survival in one case, and 0-10% in the next. Consequently, radically different types of freezing protocol may provide the answer to increased consistent success. Different approaches have been applied, and include replacing the principal salts in the freezing solutions in an attempt to help reduce the stresses on the egg membranes during cryoprotectant exposure. This has provided significant improvements in mouse egg freezing, though it has yet to be applied clinically in the human."); Michelle F. Sublett, *Not Frozen Embryos: What Are They and How Should the Law Treat Them?* 38 CLEV. ST. L. REV. 585, 593 (1990) (overall, "there is less than a ten percent chance of creating a live birth from a frozen embryo.").

[18] CDC REPORT, *supra* note 6, at 47.

Therefore, independent of the legal question whether an embryo is or is not a "legal person" for this or another purpose,[19] we respectfully request, along with most Americans

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[19]Thirty-seven states and the District of Columbia recognize expressly or impliedly by statute, resolution, and/or court decision that "fertilization" or "conception" initiates the life of a human being. **Alabama:** Alabama Constitutional Convention Call (S.J. Res. 9, 1980 Ala. Acts 396) (seeking a federal constitutional amendment to protect "the lives of all human beings including unborn children at every stage of their biological development . . . from the moment of fertilization"); Trent v. State, 73 So. 834, 836 (Ala. Civ. App. 1916), cert. denied, 73 So. 1002 (Ala. 1917) ("[D]oes not the new being, from the first day of its uterine life, acquire a legal and moral status that entitles it to the same protection as that guaranteed to human beings in extra-uterine life?"'); Wolfe v. Isbell, 280 So.2d 758, 761 (Ala. 1973) ("[F]rom the moment of conception, the fetus or embryo is not a part of the mother, but rather has a separate existence within the body of the mother."); **Arizona:** Ariz. Rev. Stat. § 36-2152(I)(2) ("'Fetus' means any individual human organism from fertilization until birth."); Ariz. Rev. Stat. 13-1103(A)(5) (1989) (defining offense of manslaughter to include "[k]knowingly or recklessly causing the death of an unborn child at any stage of its development by any physical injury to the mother of such child. . . ."); Nelson v. Planned Parenthood Ctr. of Tucson, 505 P.2d 580, 586 (Ariz. App. 1973) ("One cannot gainsay a legislative determination that an embryonic or fetal organism is 'life,' Once begun, the inevitable result is a human being. . . ."); **Arkansas:** Ark. Const. Amend. 68, § 2 ("The policy of Arkansas is to protect the life of every unborn child from conception until birth."); Arkansas Constitutional Convention Call (Res. of Feb. 17, 1977, H.R.J. Res. 2) (requests Congress to call a convention to propose a constitutional amendment which would provide that every human being shall be deemed from the moment of fertilization to be a person and entitled to the right of life); **California:** Cal. Civ. Code § 43.1 ("A child conceived, but not yet born, is deemed an existing person, so far as necessary for its interests in the event of the child's subsequent birth."); Cal. Penal Code § 187(a) (West 1988) ("Murder is the unlawful killing of a human being, or a fetus, with malice aforethought"); Scott v. McPheeters, 92 P.2d 678, 681 (Cal.Ct.App. 1939) (it is "an established . . . fact" that "an unborn child is a human being separate and distinct from its mother"); **Colorado:** Colo. Rev. Stat. § 12-375.5-103; People v. Estergard, 457 P.2d 698,699 (Colo. 1969) (holding that state child support law included unborn children "upon conception and during pregnancy" because "the physical and mental conditions of the expectant mother are vital factors in the unfolding life of the child itself"); **Connecticut:** Simon v. Mullin, 380 A.2d 1353, 1357 (Conn. Super. Ct. 1977) ("The development of the principle of law that now permits recovery by or on behalf of a child born alive for prenatal injuries suffered at any time after conception, without regard to the viability of the fetus, is a notable illustration of the viability of our common law."); **District of Columbia:** Bonbrest v. Kotz, 65 F.Supp. 138, 140 (D.D. C. 1946) ("From the viewpoint of the civil law and the law of property, a child en ventre sa mere is not only regarded as [a] human being, but as such from the moment of conception—which it is in fact."); **Florida:** Day v. Nationwide Mut. Ins. Co., 328 So.2d 560, 561 (Fla. 2d DCA 1976) (rejecting viability requirement in case of prenatal injuries; ""Viability of course does not affect the question of the legal existence of foetus, and therefore of the defendant's duty. . . . Certainly the infant may be no less injured; and all logic is in favor of ignoring the stage at which it occurs."); **Georgia:** Morrow v. Scott, 7 Ga. 535, 537 (1849) ("In . . . general, a child is to be considered as in being from the time of its conception, where it will be for the benefit of such child to be so considered."); Hornbuckle v. Plantation Pipe Line Co., 93 S.E.2d 727, 728 (Ga. 1956) (rejecting viability requirement in case of prenatal injuries; dissent characterized majority opinion as holding, in effect, "that an infant becomes a 'person' from the moment of conception"); **Idaho:** Idaho Constitutional Convention Call (S. Con. Res. 132, 45th Legis. 2d Sess., 1980 Idaho Sess. Laws 1005) (seeking a federal constitutional amendment to protect personal rights "from the moment of conception"); Blake v. Cruz, 698 P.2d 315, 323 (Idaho 1984) (rejecting live birth requirement in wrongful death action where death occurs after viability); **Illinois:** 720 Ill. Comp. Stat. § 5/9-1.2(b)(1) (Smith-Hurd 1993) ("'Unborn child' shall mean any individual of the human species from fertilization until birth."); 720 Ill. Comp. Stat. §§ 5/9-1.2, 5/9-2.1, 519-3.2, 5/12-3.2, 5/12-4.4 (Smith-Hurd 1993) (amending criminal code to define broad range of crimes, including homicide, that can be committed against unborn child, regardless of gestational age); 720 Ill. Comp. Stat. § 510/1 (Smith-Hurd 1993) ("[T]he General Assembly of the State of Illinois doe solemnly declare and find . . . that the unborn child is a human being from the time of conception. . . ."); 740 Ill. Comp. Stat. 180/2.2 (Smith-Hurd 1993) (amending wrongful death statute to allow wrongful death action to be brought on behalf of an unborn child without regard to the stage of

pregnancy); **Indiana:** Ind. Code 35-41-1-25, 35-42-1-0.5, 35-42-1-1, 35-42-1-3, 35-42-1-4, 35-42-2-1.5, 35-50-2-9 (West 1997); Cheaney v. State 285 N.E.2d 265, 268 (Ind. 1972) *cert. denied*, 410 U.S. 991 (1973) ("It is now established that some sort of independent life begins at conception."); **Kansas:** State v. Harris, 136 P. 264, 267 (Kan. 1913) ("For many purposes the law regards the infant as alive from its conception."); **Kentucky:** Kentucky Constitutional Convention Call (H.R. Res. 7, 1978 Gen. Assembly, Reg. Sess., 1978 Ky. Acts 1401) (requests Congress to propose a convention for the sole purpose of passing an amendment to protect the unborn child); Ky. Rev. Stat. Ann. §§ 311.720 (5), (6) ("'Fetus' shall mean a human being from fertilization until birth"; "'Human being' shall mean any member of the species *homo sapiens* from fertilization until death."); Ky. Rev. Stat. Ann. § 311.710(5) (Michie/Bobbs-Merrill 1990) ("If . . . the United States constitution is amended or relevant judicial decisions are reversed or modified, the declared policy of this Commonwealth to recognize and to protect the lives of all human beings regardless of their degree of biological development shall be fully restored."); **Louisiana:** 1991 La. Acts § 1, No. 26 ("It is declared to be the public policy of the State of Louisiana that it has a legitimate compelling interest in protecting . . . the life of the unborn from the time of conception until birth. . . ."); Louisiana Constitutional Convention Call (Res. of July 16, 1976, S. Con Res. 70) (requests Congress to propose a convention for the sole purpose of passing an amendment to protect the unborn child); La. Rev. Stat. Ann. § 14:2(7) (West 1986) (defining "person" for purposes of criminal code to include "a human being from the moment of fertilization and implantation); La. Rev. Stat. Ann. § 9:121 ("A 'human embryo' . . . is an in vitro fertilized human ovum, with certain rights granted by law, composed of one or more living human cells and human genetic material so unified and organized that it will develop in utero into an unborn child."); La. Rev. Stat. Ann.§§ 14:32.5-32.8 (West 1992 Supp.) (defining fetal homicide offenses); Danos v. St. Pierre, 383 So.2d 1019, 1027 (La. Ct. App. 1980), *aff'd*, 402 So.2d 633 (La. 1981) (Lottinger, J., concurring) (Section 14.2(7) "reveals an express recognition by the legislature that life begins at the moment of conception. . . ."); **Maryland:** Vios. v. State, 246 A.2d 313 (Md. Ct. Spec. App. 1968) ("Pregnancy and life are simultaneous with the act of conception."); Damasiewicz v. Gosuch, 79 A.2d 550, 559 (Md. 1951) (recognizing cause of action for prenatal injuries); Group Health Ass'n v. Blumenthal, 453 A.2d 1198, 1207 (Md. 1983) (same); **Massachusetts:** Massachusetts Constitutional Convention Call (Act of June 8, 1977, H.R. 5984) (requests Congress to propose a convention to pass an amendment to protect the unborn child); Mass. Gen. Laws. Ch. 112, § 112:12K ("Unborn child, the individual human life in existence and developing from fertilization until birth."); Commonwealth v. Cass, 467 N.E.2d 1324, 1325 (Mass. 1984) (viable fetus is a person within meaning of vehicular homicide statute); **Michigan:** Womack v. Buchhorn, 187 N.W.2d 218, 222 (Mich. 1971) (recognizing cause of action for prenatal injuries and rejecting viability requirement because "a child has a legal right to begin life with a sound mind and body"); **Minnesota:** Minn. Stat. § 609.266(a) (West 1987 & 1992 Supp.) ("'Unborn child' means the unborn offspring of a human being conceived, but not yet born."); Minn. Stat. §§ 6.9.266, 609.2661 through 609.2665, 609.267, 609.2671 through 609.268 (West 1987 & 1992 Supp.) (homicide against an unborn child regardless of gestational age); Verkennes v. Corniea, 38 N.W.2d 838, 840 (Minn. 1949) ("A child en ventre sa mere is not only regarded as [a] human being, but as such from the moment of conception. . . ."); **Missouri:** Missouri Constitutional Convention Call (Res. of Apr. 24, 1975, S. Con. Res. 7) (requests Congress to propose a convention to pass an amendment to protect the unborn child); Mo. Rev. Stat. § 1.205.1(1) ("The life of each human being begins at conception"); Mo. Rev. Stat. § 188.015(6) (Vernon Supp. 1992) ("'Unborn child' shall include all unborn children or the offspring of human beings from the moment of conception until birth at every stage of biological development."); Rodgers v. Danforth, 486 S.W.2d 258, 259 (Mo. 1972) ("Medically, human life is a continuum from conception to death."); **Montana:** Mont. Code Ann. § 41-1-103 (1993) ("A child conceived but not yet born is to be deemed an existing person, so far as may be necessary for the child's interests in the event of its subsequent birth."); Mont. Code Ann. 50-20-102 (legislature reaffirms the tradition of the state of Montana to protect every human life, whether unborn or aged, healthy or sick); **Nebraska:** Nebraska Constitutional Convention Call (Res. of Apr. 21, 1978, Legis. Res. 152) (requests Congress to propose a convention to pass an amendment to protect the unborn child); Neb. Rev. Stat. §§ 28-326(4), (5) ("Pregnant means that condition of a woman who has unborn human life within her as the result of conception"; "Conception shall mean the fecundation of the ovum by the spermatozoa."); **Nevada:** Nevada Constitutional Convention Call (S.J. Res. 27, 60th Legis., 1979 Nev. Stat. 2014) (requests Congress to propose a convention to pass an amendment to protect the unborn child); White v. Yup, 458 P.2d 617, 623 (Nev. 1969) (recognizing cause of action for prenatal injuries); **New Hampshire:** Bennett v. Hymers, 147 A.2d 108, 110 (N.H. 1958) ("We

adopt the opinion that the fetus from the time of conception becomes a separate organism and remains so throughout its life."); Wallace v. Wallace, 421 A.2d 134, 136 (N.H. 1980) ("[L]ife begins at conception."); **New Jersey:** New Jersey Constitutional Convention Call (Act of Apr. 21, 1977, S. 1271) (requests Congress to propose a convention to pass an amendment to protect the unborn child); Smith v. Brennan, 157 A.2d 497, 502 (N.J. 1960) ("Medical authorities have long recognized that a child is in existence from the moment of conception. . . ."); **New York:** Byrn v. New York City Health & Hosps. Corp., 286 N.E.2d 887, 888 (N.Y. 1972), *appeal dismissed*, 410 U.S. 949 (1973) ("It is not effectively contradicted, if it is contradicted at all, that modern biological disciplines accept that upon conception a fetus has an independent genetic 'package' with potential to become a full-fledged human being and that it has an autonomy of development and character although it is for the period of gestation dependent upon the mother. It is human, if only because it may not be characterized as not human, and it is unquestionably alive."); Kelly v. Gregory, 125 N.Y.S.2d 696, 697 (N.Y. App. Div. 1953) (rejecting viability requirement in cause of action for prenatal injuries; "legal separability should begin where there is biological separability" and "separability begins at conception"); **North Dakota:** N.D. Cent. Code § 12.1-17.1-01(3) (Supp. 1991) ("'Unborn child' means the conceived but not yet born offspring of a human being."); N.D. Cent. Code § 12.1-17.1-02 through 12.1-17.1-06 (Supp. 1991) (amending criminal code to define broad range of crimes, including homicide, that can be committed against unborn child, regardless of gestational age); Hopkins v. McBane, 359 N.W.2d 862, 864 (N.D. 1984) ("A child conceived but not born is to be deemed an existing person so far as may be necessary for its interests in the event of its subsequent birth); **Ohio:** Ohio Rev. Code Ann. § 2919.16(A), -(K) ("'Unborn human' means an individual organism of the species *homo sapiens* from fertilization until live birth"; "'Fertilization' means the fusion of a human spermatozoon with a human ovum."); Williams v. Marion Rapid transit, 87 N.E.2d 334, 340 (Ohio 1949) ("[M]edical authority has recognized long since that the child is in existence from the moment of conception, and for many purposes its existence is recognized by the law."); **Oklahoma:** Okla. Stat. tit. 63 § 1-730 (West 1984) ("'Unborn child' means the unborn offspring of human beings from the moment of conception, through pregnancy, and until live birth including the human conceptus, zygote, morula, blastocyst, embryo and fetus"; "'Conception' means the fertilization of the ovum of a female individual by the sperm of a male individual."); **Oregon:** State v. Ausplund, 167 P. 1019, 1022-23 (Or. 1917) (When a virile spermatozoon unites with a fertile ovum in the uterus, conception is accomplished. Pregnancy at once ensues, and under normal circumstances continues until parturition. During all this time the woman is 'pregnant with a child' within the meaning of the [abortion] statute. She cannot be pregnant with anything else than a child. From the moment of conception a new life has begun."); **Pennsylvania:** Pa. Cons. Stat. Ann. tit. 18 § 3203 ("'Fertilization and 'conception' . . . shall mean the fusion of a human spermatozoon with a human ovum"; "'Unborn child' and 'fetus' . . . shall mean an individual organism of the species *homo sapiens* from fertilization until live birth."); Pennsylvania Constitutional Convention Call (H.R. 71, 1978 Gen. Assembly, 1978 Pa. Laws 1431) (requests Congress to propose a convention to pass an amendment to protect the unborn child); Amadio v. Levin, 501 A.2d 1085, 1087 (Pa. 1985) ("a child en ventre sa mere is a separate individual from the moment of conception"); **Rhode Island:** Rhode Island Constitutional Convention Call (Act of Apr. 21, 1977, H.R. 5150) (seeking a federal constitutional amendment affirming "every human being . . . from the moment of conception to be a person and entitled to the right to life"); Sylvia v. Gobeille, 220 A.2d 222, 223-24 (R.I. 1966) (noting "the medical fact that a fetus becomes a living human being from the moment of conception"); Presley v. Newport Hosp., 365 A.2d 748, 751 (R.I. 1976) ("from the moment of conception a separate organizsm with its own identity comes into existence"); **South Carolina:** S.C. Code Ann. §§ 44-41-10(f), -(g) ("'Pregnancy' means the condition of a woman carrying a fetus or embryo within her body as a result of conception"; "'Conception' means the fecundation of the ova by the spermatozoa."); **South Dakota:** S.D. Codified Laws § 26-1-2 (1992) ("A child conceived, but not born, is to be deemed an existing person so far as may be necessary for its interests in the event of its subsequent birth."); S.D. Codified Laws § 21-5-1 (1987) amending wrongful death statute to include "an unborn child" without regard to gestational age); **Texas:** Leal v. C.C. Pitts Sand and Gravel, Inc., 419 S.W.2d 820, 822 (Tex. 1967), *rev'g*, 413 S.W.2d 825 (Tex. Civ. App. 1967) *and app'g dissenting opinion of Justice Cadena*, 413 S.W.2d at 828 ("medical science . . . consider[s] that life begins at conception); **Utah:** Utah Constitutional Convention Call (H.R.J. Res. 28, 42nd Legis., Reg. Sess., 1977 Utah Laws 1317, 1318) (requests Congress to propose a convention to pass an amendment to protect the unborn child); Utah Code Ann. § 76-7-301.1 (1992) ("[U]nborn children have inherent and inalienable rights that are entitled to protection."; state has a "compelling interest in the protection of the lives of unborn children."); Utah Code

(especially infertile Americans), that Congress not lift its existing ban against federal spending for the destruction of human embryos for any purpose, including the lethal "harvesting" and medical experimentation upon the stem cells that compose each living human embryo.

Poll data educating Americans on the necessary consequence of embryo stem cell research, in particular, the destruction of embryos required to obtain their stem cells, reveals that 74 percent of Americans oppose use of tax dollars to support it.[20] The media, nevertheless, has tried to paint opposition to embryo stem cell research as another attempt to overturn *Roe v. Wade*.

This is unreasonable. At least fifteen states (including Utah) have expressed their legislative intent to outlaw harmful experiments on human embryos, regardless of how they are funded.[21] Thirty-seven states and the District of Columbia enforce tort, criminal and other laws declaring that human life begins at conception.[22] These laws have not affected the constitutionality of the pro-choice position. Likewise, a decision to fund or not to fund embryo stem cell research has no bearing on whether a mother has the right to terminate her pregnancy.

Human embryo adoption is not about abortion. It is not about hindering medical science, which has not exhausted potential advances with adult, placenta, and umbilical stem cells. It is not about "dots on a paper," as Sen. Harkin has referred to living human embryos, nor like "shooting gold fish in a barrel," as actress Mary Tyler Moore likened

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Ann. § 26-2-2(2) ("dead fetus" means a "product of human conception" . . . that was not born alive); **Virginia**: Kalafut v. Gruver, 389 S.E.2d 681, 683-84 (Va. 1990) ("[A]n action may be maintained for recovery of damages for any injury occurring after conception. . . ."); **Wisconsin:** Wis. Stat. Ann. § 939.75(1) ("'Unborn child' means any individual of the human species from fertilization until birth that is gestating inside a woman"), Wis. Stat. Ann. § 940.04(6) (West 1982) ("'Unborn child' means a human being from the time of conception until it is born alive."); Wis. Stat. Ann §§ 939.24, 939.25, 940.01, 940.08, 940.09, 940.24 (Wis. 1997) (criminal statutes addressing the unborn). *See also* Paul B. Linton, *Planned Parenthood v. Casey: The Flight from Reason in the Supreme Court*, 13 ST. LOUIS U. PUB. L. REV. 15, App. B (collecting legislation and case law relating to the unborn child); Clark D. Forsythe, *Human Cloning and the Constitution*, 32 VALPARAISO U. L. REV. 469, 501 nn.146-48 (1998).

[20] Press Release, National Conference of Catholic Bishops, Poll Shows Strong Opposition to Embryo Research Funding (July 25, 1995) (on file with author) (poll results taken from telephone survey conducted July 18-20 by the Tarrance Group).

[21] These states have expressed their legislative intent to restrict embryo research indirectly, banning all research on "live" embryos or fetuses. Ariz. Rev. Stat. § 36-2302; Fla. Stat. Ann. § 390.0111(6); 720 Ill. Comp. Stat. § 510/6(7); La. Rev. Stat. Ann. §§ 9:122, 14:87.2; Me. Rev. Stat. Ann. Tit. 22 § 1593; Mass. Gen. Laws Ann. Ch. 112 § 12j(a)(I); Mich. Comp. Laws Ann. §§ 333.2685, 333.2686, 333.2692; Minn. Stat. Ann. § 145.422; Mo. Rev. Stat. § 188.037; N.D. Cent. Code §§ 14-02.2-01, 14.02.2-02; N.M. Stat. Ann. § 24-9A-1 to 7; 18 Pa. Cons. Stat. Ann. § 3216(a); R.I. Gen. Laws § 11-54-1(a)-(c); S.D. Codified Laws §§ 34-14-16, 34-14-17; Utah Code Ann. § 76-7-310 ("Live unborn children may not be used for experimentation. . . ."); Utah Code Ann. § 76-7-31 ("Selling, buying, offering to sell and offering to buy unborn children is prohibited.") Courts have declared Arizona, Illinois, and Utah's imprecisely worded laws unconstitutional on grounds of vagueness. *See* Jane L. v. Bangerter, 61 F.3d 1493 (10th Cir. 1995), *rev'd on other grounds sub nom*, Leavitt v. Jane L., 518 U.S. 137 (1996); Lifchez v. Hartigan, 735 F.Supp. 1361 (N.D. Ill. 1990); Forbes v. Napolitano, 236 F.3d 1009 (9th Cir. 2000), *amended*, 247 F.3d 903 (9th Cir. 2000).

[22] *See supra* note 19.

# FACTS ABOUT LIVING HUMAN EMBRYOS

- All living human embryos **contain all the features of life** or are "totipotent."
- All living human embryos are composed of stem cells which themselves are "totipotent."
- "Harvesting" the stem cells from a living human embryo **always kills** that human embryo.
- **15 states have expressed their legislative intent to outlaw harmful experiments** on human embryos. For example, non-therapeutic experimentation upon human embryos in Pennsylvania is a felony.
- 37 states and the District of Columbia enforce laws declaring that **human life begins at conception or fertilization**. The geographical theory of life, *i.e.* that it commences only in certain locations like the womb, is not the law in any state.
- **Properly freezing a living human embryo can preserve its life until it is thawed**, but up to 50% of the human embryos die in the process of freezing and thawing.
- **Alternative sources of stem cells proven more effective are plentiful**. Medical advances using umbilical, placenta, and adult stem cells are being published weekly showing equal or more promising results than human embryo stem cells.

Appendix A

# FACTS ABOUT HUMAN EMBRYO ADOPTION

- **At least 188,000 human embryos are currently living in "frozen orphanages"** in the custody of *in vitro* fertilization clinics throughout the United States.
- Experience teaches that **12,600 to 35,000 children could be adopted, thawed and successfully born** from the at least 188,000 live human embryos residing in frozen orphanages.
- ***There are no "excess" living human embryos* available for research because all are entitled to the opportunity to live in a loving adoptive home.**
- **6.5 to 10 million couples are infertile** and could adopt and implant the existing population of frozen human embryos more inexpensively than utilize other *in-vitro* fertilization processes.
- **All 50 states and the District of Columbia permit living human embryo adoption and implantation**.
- **314 embryos from 35 families have been adopted**, 182 thawed, and 93 survived and implanted through the Snowflakes human embryo adoption program.
- **Adoption, not destruction of frozen living human embryos, is the best way to help infertile American couples and causes no harm to anyone else.**

Appendix B

Mr. WELDON. Thank you, Ms. Davidson.

The committee will stand in recess until the votes on the floor are finished. We will then reconvene for questioning of this panel.

[Recess.]

Mr. SOUDER [resuming Chair]. The subcommittee is now back in order.

I want to first say thank you to each of you for coming forth. It is a very difficult subject, and I very much respect your right to privacy. I know that Mrs. Strege commented on the Mary Tyler Moore statement about your children being like goldfish. I wondered, Mrs. Borden, if you had any kind of similar reaction to that, or what motivated you, in particular, to come forth today?

Ms. BORDEN. Actually, I heard Mary Tyler Moore on a different interview and didn't hear that one. What motivated me to come forward was the fact that I had heard so many different people on TV talking about, well, they're either going to be destroyed or we can do this wonderful thing and donate them to research where we'll destroy them, too. And I just kept thinking about all of the genetic families sitting in their living rooms watching TV with their children that they had tried so hard to conceive and making decisions about what to do with their leftover embryos, and nobody was telling them about the option of adoption. No one was telling them that this was life. But they were looking at the product of their embryos. They were looking at their children, like I look at Mark and Luke. That's what prompted me to come forward.

Mr. SOUDER. I sure hope—and it is hard for us to know what will happen in the final decisions of this administration, but I hope at a minimum, a bare minimum out of today, that you have helped draw attention to adoption as an option; that as we look at legislation, that we try to make sure that any clinic in America that offers this service to young mothers makes adoption-aware as part of the process. Because I know friends who are similar in your situation, including my sister who adopted children, who are looking all the time for the type of options that you two describe in your testimony.

Your willingness to come forward and to lose your privacy will, hopefully, at a minimum give many thousands of other families the opportunity that you have, by endorsing that awareness today. I praise you for your courage in coming out and losing your privacy, which, quite frankly, you may or may not ever get back. That is one of the difficult things, because you are interjected in a very huge, contentious national debate.

How do you feel, because many people, even pro-life people, approach me and say, "Well, these frozen embryos just aren't children." Yet, in your testimony, Mrs. Strege, you talk about—we heard one distinguished Member here today say that life can't be conceived in a petri dish, and that wasn't really life. Could you elaborate on that a little bit and where you think your children began and how, and watched them evolve?

Ms. STREGE. Right. I have pictures of my daughter over there. That was the day that she was thawed. The next picture is the next day, the day they transferred her into me. A physician told me that she had gone onto her next stage of human development—

that was outside of my body—called compaction, when those cells start to move to one side and a fluid-filled sac starts to form.

Furthermore, I'm the adoptive mom. The only thing I added to my daughter was oxygen, nutrients, a warm place to grow, and love. That's a scientific fact. So, I mean, you're going to have to tell me what I added to her to be a human life. She went into me as a human life, as an embryo. She came out of me as a human life, as an infant. She is now in her human developmental stage of toddlerhood. You know, I mean, you tell me what I added to her to make her a human life.

Mr. SOUDER. Ms. Davidson, could you talk a little bit about—have you made contacts with other groups around the country? I'm sorry I missed your testimony. I have the written testimony. What do you think are the best ways for us to advance here in Congress and through the administration adoption as an option? Because, as was stated earlier, there may not be excess embryonic children if adoption was, indeed, known as an option.

Ms. DAVIDSON. First of all, it would be that we let people know that this is an option. We can do that through the IVF clinics. I would like to see the IVF clinics being instructed to give informed consent to their clients, meaning that all their options are educated—that they are educated about all their options, that information is passed on in the process of the informed consent procedure that they do at this point in time.

Historically, we've seen clinics are offering destruction of the embryos, donation for research, continuing storage of the embryos, or using them for their own additional children later on. Those are four options. It is very simple to add line five and discuss embryo adoption and make them aware of them.

We can also expand adoption agencies. We have other agencies interested in expanding the program. The government funds adoption of children through States. We also have private entities doing adoptions, like ourselves. We can have state-funded adoption agencies that include embryo adoption. They are just another child waiting to be adopted.

Mr. SOUDER. This has obviously been a very contentious subject, deeply dividing Members who share the concern about research to help address these terrible diseases, but are divided on the question of human life and where the origins of life are. It would be best if we could go ahead with the research on everything non-embryonic, where we don't get into that division.

But, particularly to Mrs. Borden and Mrs. Strege, if the Members, some of whom may have been here today such as Senator Hatch and Congressman Gilman and Congressman Waxman, who didn't get a chance to hear your testimony, and other Members of Congress who haven't heard your testimony, would you be willing to meet with them so that they could meet your children and directly confront the consequences of a decision that would go forward with this kind of research?

Ms. BORDEN. Just tell us when and where.

Ms. STREGE. Yes.

Mr. SOUDER. Once again, I thank you for coming forth. I now yield to Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

As I am sitting here, first of all, I want to thank you all for coming. Thank you. As a parent, I can understand your joy, and children are truly gifts. There is no doubt about it.

On the other hand, I see children in my district. I so happen to represent Johns Hopkins, and I see so many children who are suffering. They are not the happy children that I see here today. They are children who have life-threatening illnesses, and parents struggle. It is a daily struggle to try to find cures to diseases that seem to have no cures.

So you can imagine the dilemma that we find ourselves in. On the one hand, we have the happy child and we have the happy parents. I have never been so struck by what happened just a few moments ago when you stood up and held your two beautiful children, and then just the idea that they could have not been here. So that has an effect on, I think, all of us.

But, at the same time, I think we all understand that in this life we have one life to live; this is no dress rehearsal, and this is life. So one of the things that I think we try to do is try to make life as best we can help to make it for every child, so that they all will have opportunity and we can nurture their nature.

Ms. Davidson, I just was wondering how this agency works. I mean, how is it financed? I am just curious.

Ms. DAVIDSON. This program at this point in time is not a moneymaking program. It's actually supported by our other adoptions and by private contributions. We are a domestic and international adoption agency as well. The program fees are paid by the adopting family. They are nominal fees that will, hopefully, just cover base expenses. We match just like in a traditional adoption. So our programs are run exactly like our other programs, but they are not moneymaking programs at all.

Mr. CUMMINGS. So can you give me an idea of—I mean, are these organizations that help fund it?

Ms. DAVIDSON. No, it's privately funded by the fees the adoption families pay, which is $3,500, is our fee, and then also by donations through other families, and then also supported at this point in time by the program, the other programs that we have, the fees that are paid for those other programs.

Mr. CUMMINGS. OK, now you may have said this a little bit earlier, but how do you all connect with getting the embryos? I mean, how does that work, you all getting the opportunity to even do what you do?

Ms. DAVIDSON. The genetic families call us and contact their fertility clinics and let them know that they are moving their embryos to an adopting family. We don't pursue relationships with any clinics. We don't have a contract with any clinics that they would refer families to us. We've had families who find us, like somebody said, through the Internet. Other families have heard about us through their clinic. Other families have heard about us through media or other sources, and have gone to their clinics and said, "We want to work with this program."

Mr. CUMMINGS. Is there any time limitation with regard to how old, I mean how long, the embryos have been frozen? Is there any limitation that you all have?

Ms. DAVIDSON. None at all. We believe all children should be given a chance to be born, and it doesn't matter if they were conceived 3 years ago or 10 years ago.

Mr. CUMMINGS. I am pretty sure our next panel will be able to answer some of these questions more from a scientific standpoint. So it is quite possible an embryo may have been conceived 7 or 8 years ago. Do you all have that kind of information available? In other words, when you all decide to work out the adoption process, is that information available as to how long—I see you all nodding your heads.

Ms. BORDEN. Yes.

Ms. STREGE. Yes.

Ms. DAVIDSON. They certainly know how old their siblings are.

Mr. CUMMINGS. You wanted to say something?

Ms. BORDEN. We were aware—we know Mark and Luke have siblings, genetic siblings, that are 18 months older than them. So we're aware of that.

Ms. STREGE. We have a confidentiality provision in our agreement, so I am unable to speak of anything prior to our adoption of our daughter.

Mr. CUMMINGS. OK. I understand.

Ms. Davidson, I guess one of the things that sort of is underlying all of our discussion is this idea that at some point it is assumed that these embryos would have been discarded, and I hate to even use that word; I really do, but, for lack of a better one. Does that make a difference to you? In other words, if the couple made a decision that they had all the children that they wanted to have, that they no longer wanted this embryo to exist, and they decided and they said to the clinic, "Look, we want to do away with—we want you to just get rid of these embryos," would that make a difference to you, in your opinion, the opinions that you've expressed today with regard to stem cell research?

Ms. DAVIDSON. Well, I would certainly be heartbroken that they decided to not give their child an opportunity to be born. I couldn't stand between them, obviously, to stop them from doing anything with their embryos, but I would certainly want to know that they were given all the options available to them. I can tell you, countless embryos have been destroyed that would have been placed for adoption had this program been established earlier. We have many families who contact us and say, "We just found out about you. We've been suffering and deliberating what choice we were going to make regarding our embryos for weeks, months, and years. We finally have an option that we can work with."

So I know that many families have made decisions and gone on and destroyed embryos or donated for research that maybe, had they had this opportunity in the past—we've only been offering this program for 4 years. There's only been really coverage and knowledge about our program for the last 2½, 3 years, as the program has been developing.

But I think that I would absolutely be heartbroken to know that they did not know all their options before they chose that.

Mr. CUMMINGS. Thank you very much.

Ms. DAVIDSON. Thank you.

Mr. SOUDER. I would like to clarify, Ms. Davidson, in answer to Congressman Cummings' question, do you as an adoption agency have a time limit or have you ever been told that there is any time limit for the storage of the frozen embryonic children? Like, for example, if one was 10 years old, would that make any difference to you? Do you know any scientific limitations at this point that your agency's ever been made aware of?

Ms. DAVIDSON. The scientific evidence that we do know of is that animal embryos have lived up to 25 years in storage, and that's the longest that technology has existed. That's the longest one that's been stored. They don't differentiate between that understanding of that information and humans, meaning they believe human embryos can last indefinitely in storage. It's not the storage time that affects them. It's the thawing and the freezing that is actually detrimental to the embryo.

Mr. SOUDER. Thank you.

Ms. DAVIDSON. I'm sorry, to continue, we don't differentiate. We don't have a time period where we cutoff saying any embryos older than such a date would be not willing to be placed through our embryo program.

Mr. SOUDER. Thank you. Congresswoman Davis is next. I am going to ask Congressman Weldon to take the chair again.

Mrs. JO ANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman. Again, I would like to thank you all for coming and testifying.

I would like to just say one thing. We heard from several Members here that we shouldn't stand in the way of science and research for stem cell research. I will speak for myself, and I think the bulk of us up here: We're not against stem cell research. It's the embryonic stem cell research. So the scientists can certainly do whatever they want with adult stem cells and anything else.

Ms. Davidson, my question to you is that Ms. Joan Samuelson, who is going to testify on our second panel, states in her testimony that, "No one can credibly argue that more than a small fraction of those embryos presently in storage would ever be adopted." Can you comment on that statement?

Ms. DAVIDSON. Well, our program grows exponentially. We see an increase—between 1999 and 2000, we had a 600 percent increase in the adoption placements that we did. It's still relatively small numbers in the grand scale, but I think a lot of the statistics are based on donor programs. You'll hear people say, well, only 5 percent of families in donor programs, in fertility clinics, are willing to participate in a donor program. Donor program and adoption are very different. The adoption program allows the family to select an adopting—it allows them to define what type of family their child will be placed with. That's not an option in the donor program. They're also allowed to have contact with the family. They're also allowed to know if a child or children were born to this program. These are all options available through adoption that aren't available through donor programs. So when somebody quotes the statistics of donor programs from a fertility clinic, they're not talking about adoption. They're a very different type program.

Mrs. JO ANN DAVIS OF VIRGINIA. I would like to go back and see if I can clarify something. I think when the gentleman was asking about the cost for adopting an embryo, you said roughly about

$3,500. I guess this question is for you two. You might know this. Does hospitalization cover your carrying the child?

Ms. BORDEN. Yes.

Mrs. JO ANN DAVIS OF VIRGINIA. As if it were any other pregnancies?

Ms. STREGE. Right.

Mrs. JO ANN DAVIS OF VIRGINIA. OK. Then my question is, this is roughly $3,500, and I guess I have heard statistics that the cost of adoption runs between—the reason a lot of people don't adopt is the cost runs between $10,000 to $20,000, is that correct?

Ms. DAVIDSON. It does on the East Coast.

Mrs. JO ANN DAVIS OF VIRGINIA. OK.

Ms. DAVIDSON. At our agency our fee for a domestic adoption is only $8,000.

Mrs. JO ANN DAVIS OF VIRGINIA. OK, but even at that, at $8,000, and you're saying $3,500 here. So this might be an opportunity for more families, more couples, to adopt children who right now can't because they can't afford the high cost of adoption.

Ms. DAVIDSON. They also have medical expenses that they have to pay for separately. We wanted to set our fees where it was financially viable for a family to go through this process.

Mrs. JO ANN DAVIS OF VIRGINIA. Right.

Ms. DAVIDSON. Once they've paid our fees and done their home study and paid their clinic to provide the frozen embryo transfer, they're looking at about $7,000 if they get pregnant on the first try, maybe $9,000 on a second. Again, that's still much below the IVF, the in vitro fertilization process of harvesting, fertilization, and doing transfers, which I think the average is about $17,000.

Ms. DAVIDSON. Did your insurance cover it?

Ms. BORDEN. My insurance ended up covering a lot more than I thought they would.

Ms. STREGE. My insurance did not because our initial physician would not participate in this. So we had to go outside of our plan and pay for it.

Mrs. JO ANN DAVIS OF VIRGINIA. I think I have time for one more question. This would be for you two moms. The pharmaceutical companies and many scientists would like free rein and taxpayer funding to destroy embryos for research. What would you say to the pharmaceutical lobbyists who have been demanding Federal funding on embryo destructive research? If they were to come into your offices—and they come into ours—what would you say to them?

Ms. STREGE. I would say to look at my daughter and tell me why she's expendable.

Ms. BORDEN. Just like my husband stated earlier, which son would you kill?

Mrs. JO ANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

Mr. WELDON [assuming Chair]. The Chair now recognizes the gentlelady from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, and thank you for your testimony, all of which I heard, by the way. I was in a side room listening to it all, even though I wasn't right here.

I just have a comment. I would say that you have beautiful children. You're blessed. All of us I think are blessed with the birth

of your children: the result of wonderful scientific research. I support the adoption program. I think that is a good program. I think it is an option that more people would know about. But it is one option that science has provided. I feel that presenting it as an either/or situation is not the real choice that we have to make.

I mean a hearing about this program is wonderful to have, and I think more people that hear about this, the better. But to say, then, that this precludes the use of embryos that are, in fact, regardless of whether or not there is this option, many will be destroyed, and that those could be used to save lives is what the essence of this hearing is about—not to say that you shouldn't have your children or that those opportunities shouldn't be available. Your children are not expendable, but there are situations where those embryos will be destroyed regardless of your programs and that we can save existing lives; we can save children that have juvenile diabetes. You know the whole litany, the diseases.

Yes, we should talk about adult stem cell research, explore it as far as we can. That is the wonder of scientific research right now. I just would say to you—and I am not asking for a response, but what I am saying to you is: Promote this program. It is a great program, and the option that you took should be available to others. Don't use it to preclude life-saving opportunities for others.

Thank you.

Ms. DAVIDSON. May we respond?

Mr. WELDON. Yes, go ahead.

Ms. DAVIDSON. Because I would definitely disagree. These children are not a product of some wonderful medical research. They're a product of the fact that a huge problem exists, that too many embryos have been created. These children were not created as wonderful new research. They were created as live children. This program does not exist to provide opportunities for new families to have children. This program exists to solve a problem that exists, and that's 188,000—conservative number—188,000 embryos that are in storage. I think there's a problem that we have that many children existing in clinics. This program is not here to provide a new way for families to get children. It's here to eliminate a problem that currently exists, in that there are children waiting to be born. It's no different than an orphanage, an orphanage that has never been really looked at as a really neat opportunity for somebody to add children to their families. It's been seen as a travesty that these children are not being parented.

Mr. WELDON. The gentlelady yields back. The Chair will now yield to himself.

I just want to reiterate a point that I made in my opening statement. It has been claimed that embryo stem cell research holds great promise, but when I look at the medical literature, I think it is highly speculative to make that kind of a statement. They do not, even as of yet, have an animal model where they have taken a rat or a mouse with a disease and taken an embryo stem cell and effectively treated that disease.

In the case of diabetes mellitus, juvenile diabetes mellitus, a model of that exists. There's a strain of mice that you can purchase, research labs can purchase, that are all diabetic. Adults themselves have been used to cure mice with that condition of their

diabetes mellitus. The attempt to duplicate that research using embryo stem cells failed.

The other additional point I want to make—and it is really a very critical point from a scientific perspective—is that embryo stem cell research has a potential huge problem, even if it were ever proved to be successful, of tissue rejection, whereas using adult stem cells from the patient is a way around the tissue rejection issue. So I think it is exaggeration to say that there is great potential for embryo stem cell research. I think it is not an exaggeration to say there is great potential for adult stem cell research.

I have a quick question for both Lucinda and Marlene. This was, I think, a pretty revealing thing for you to do, to come all the way to Washington and tell your personal story, as you have, in front of the TV cameras. I would assume neither of you have ever done anything of this sort before.

Could you just comment on what motivated you to agree to come and testify in this kind of an environment and get yourself and your family involved in a debate like this?

Ms. STREGE. You know, I guess for me I've seen these debates on C–SPAN at home, and no one is talking about infertility as a valid diagnosis. This is what needs to happen here. These embryos need to be adopted, and I just wanted, I guess, Americans to know that this is an option, because the media has been saying, well, they're just going to be destroyed anyway, that type of thing.

Also, we wanted to come here and meet with the President, too, so he could see our children and see that these are real people, these children.

Mr. WELDON. Are you scheduled to meet with the President?

Ms. STREGE. Well, we're here. [Laughter.]

We haven't had anything set up so far. So do you have any connections? [Laughter.]

Mr. WELDON. Well, I have been trying to get an appointment myself, and I haven't been able to get one. So I guess get in line. [Laughter.]

Lucinda, did you want to add to that at all?

Ms. BORDEN. For me, it was basically about the fact that all you hear is there's only the option of destroying or donating to science. Those don't respect the life that embryos are; adoption does. We wanted, I wanted people to know that this is out there and that my children came and were born through adoption, and that this option is a better choice in respect of the life that the embryos are, rather than manipulating them for research.

Mr. WELDON. I realize Matthew and Luke are kind of young.

Ms. BORDEN. Mark and Luke.

Mr. WELDON. Excuse me.

Ms. BORDEN. Everyone does that though.

Mr. WELDON. Mark, I'm sorry. Hannah is, I would assume, too young to have a comment at all? Does she understand any of this?

Ms. STREGE. Did you want to say anything, Hannah?

I can tell you, though, that for the last couple of nights we've been really kind of busy, and so I asked her kind of, "What do you want to pray for tonight?" And 2 nights in a row she said, "For the Snowflakes, Amen." So I guess that would be her comment.

Mr. WELDON. Thank you. The Chair now recognizes the gentlelady from New York, Mrs. Maloney.

Mrs. MALONEY. Thank you, Mr. Chairman, and I want to congratulate and applaud really all of the panelists for your very moving and informative statements today. I would also like to applaud the advance of science that has enabled us to have in vitro fertilization, that has enabled us to help families.

I want you to know that I am a co-sponsor of a bill by Representative Weiner called the Family Building Act, which would expand insurance coverage and funding and grants for families who want to follow the route of in vitro fertilization. I want to help these families in any way possible, and I also want to help other children with juvenile diabetes or other diseases with medical research.

I would like to really place into the record an analysis by the NIH—many of the items in it were sent to President Bush—which really states in so many words that the embryonic research is far more promising in the future than adult stem cell research. I support adult stem cell research and embryonic, but I think their statements about the promise for the future for healing juvenile diabetes, Parkinson's, and others is very, very promising.

I would like to really ask Ms. Davidson—and you have commented about your program, and I certainly support, as I said, this bill, the Family Building Act. It would help clinics such as yours, help other families. But some parents do not wish to donate all of their frozen embryos for adoption. Would you favor forcibly taking frozen embryos against the wishes of the parents and requiring them to donate them for adoption?

Ms. DAVIDSON. Absolutely not.

Mrs. MALONEY. You would not support that?

Ms. DAVIDSON. I wouldn't force anyone to give their children to somebody else, but I also wouldn't want them to destroy them.

Mrs. MALONEY. Well, now they can either freeze them and keep them for the future in case they want to have more children, correct?

Ms. DAVIDSON. Yes.

Mrs. MALONEY. They can donate them to other families and help them have children or they can donate them to science. From what I have read from various documents, there is an excess of embryos, much more than the demand for adoption and much more than the demand for people who think maybe 5 years from now I might want another child; let's keep this embryo frozen. But for those embryos that really will be discarded, would you object to them being used for solving some of the illnesses that society confronts?

Ms. DAVIDSON. Well, first of all, I don't think that there's such a number that they couldn't be placed for adoption. As I stated in my testimony, there are an estimated 12,000 to 35,000 kids that could be placed for adoption through this program.

Mrs. MALONEY. Are they on the waiting list at your program?

Ms. DAVIDSON. No, they're not.

Mrs. MALONEY. Well, I think that we need to get to the facts because, what I've read, that they're not there; that these embryos are there and people could access them if they so wished to have additional children.

Ms. DAVIDSON. And the number grows exponentially on a daily basis, the number of families that do sign up for the program. Again, I think it's a lot of education. There are a lot of clinics that don't have this information to provide to their clients, and it's very different than a donor program.

Mrs. MALONEY. Well, then, let's say, after the education, say we have passed the Family Building Act and have the funding to help the families have in vitro fertilization and help with the expenses of it, and there's still hundreds of thousands of embryos that are not being used.

Ms. DAVIDSON. I'm certainly for education. I think people need to understand what research looks like. I think people need to understand, when they donate their embryos for research, what occurs in the research labs. We talk about regulating what happens in a lab. I'm certainly happy to quit my job here and go be a policeman in a lab somewhere and say, "Nope, you can't do that any further because that's against legislation." But I can absolutely see the slippery slope that we're on, that as soon as we say, yes, it's OK to do this, then they grow them for a week; then they grow them for 2 weeks; then they grow them on beyond that.

Research, for most people, they don't even understand that. I am pro-education. Teach people all their options. Teach them what research looks like. When I heard that an embryo had grown outside of the womb in another country up to 19 weeks, I think a family who donates their embryos to research needs to know that their child may be grown up to 19 weeks outside the womb and then experimented on. I think people need to be educated. I think if people were truly educated about what research on an embryo would look like and feel like and be like for that child, they probably wouldn't decide that. Again, I'm very pro-education. I can't force a family to not chose to kill their children. I can't force a family not to select to let their embryo just die naturally or to place it in a research program, but I want them to know what their options are before they make that choice.

Mrs. MALONEY. Well, certainly a Federal role would help with your goals, which I support, of having standards, that everyone knows what they are. I predict that we probably agree more than we disagree. Personally, I don't support cloning and I don't support growing—as you mentioned, I support the embryonic research from the stem cells from the very beginning, which is what the guidelines are now. If we don't have Federal standards, then some of the things that people are concerned about may happen. So I think it is important that we have Federal standards that really put into place safeguards on some of these ethical problems or ethical challenges that you are putting forward.

Ms. DAVIDSON. And I hope that we can actually regulate private industries. We've done that a lot in the past, and maybe the government can step up and regulate the private industries that are doing research. But the issue here is: Are we going to federally fund this? And that's a bigger issue, and I am not for spending my tax dollars to fund the private agencies or private research facilities. I would encourage everyone who has a heart for donating for this research to do it out of their pocket, to definitely find—I mean, set up fundraisers and establish programs to develop money spe-

cific for the private funding for the private research facilities. Again, we're talking regulation of private industry. We can do that if——

Mrs. MALONEY. But wouldn't a Federal role——

Mr. WELDON. The gentlelady's time has expired.

Mrs. MALONEY. I thank the gentleman. My time has expired.

Mr. WELDON. The gentleman from New Jersey, Mr. Smith, is recognized for 5 minutes.

Mr. SMITH OF NEW JERSEY. Thank you, Mr. Chairman. I will keep it very brief, and I do thank you for yielding.

I want to thank our two families and the lady who has testified on behalf of Snowflakes Adoption for the extraordinary testimony you have provided. I have been in Congress 21 years, and I am not sure I have ever heard such compelling and such heart-warming information, that these tens of thousands of cryogenically frozen embryos have a fate other than destruction, destruction where they are just poured down the drain or destruction where they have their stem cells taken from them and they are killed. That, to me, is not a choice.

All of our legislation in the past that dealt with human subjects always tried to say that informed consent was required, and obviously, for anyone prior to birth informed consent or most children is very hard. Guardians, being parents, should be acting in their best interest. But when we passed the legislation, Mr. Chairman, back in the early 1980's—and I think this needs to be stated—one of those abuses by the National Institutes of Health and other researchers, for whom I in most instances have an enormous amount of respect, was a program whereby women who were intending on aborting were getting injected with the rubella virus or vaccine, I should say, and then when the baby was aborted later on, there was a determination whether or not chromosomal damage had occurred. That kind of human experimentation is outrageous. It is reminiscent of the kind of experimentation that has been done in other cultures.

We fought a war against a regime that felt that there were certain human beings who could be subjected to human experimentation that did not benefit them, but would benefit the whole of humanity, and, thankfully, their eugenics policy was roundly repudiated. But we see vestiges of that still in our research community, and we saw it with that NIH experiment, or experiments, with those children who were intended to be aborted.

That led to the legislation in the early eighties to protect human subjects, including the unborn and preborn. It seems to me that the application here is very clear and compelling. We now know, as a result of this hearing and your brave testimony, that there is an option of adoption. It's a pro-life, pro-family alternative to killing. My hope is that we will move very aggressively to make more Americans knowledgeable who have embryos in a frozen state that this is available.

You know, the previous speaker mentioned there is more than what is demanded for adoption. Nothing could be further from the truth. There are hundreds of thousands of couples who would like to adopt and can't in America. The waiting line is usually years, not measured in months or even a couple of years now, but in mul-

tiple years, sometimes as much as 6 to 8 years in order to obtain a child, to make an adoption plan for a child.

At the core of our adoption law, as well as the Hague Convention on Intercountry Adoption, is that whole concept of best interest of the child. It seems to me that we need a little more of that in this debate about these frozen embryos. What is in the best interest of those frozen embryos, all of whom have a great potential to grow and to be nurtured, to have a first date, to play soccer, to do all the things that we all come to take for granted, rather than saying those going down this aisle, they are for experimentation; those going down this aisle—and that is all left to the whim and caprice and decision of the families. It seems to me we need to have more—they are not property. There is a guardianship rightly by the parents, but they are not property that can be killed at will.

It seems to me the utilitarian ethic that has been talked about today does start us down a slippery slope because I noticed that Senator Hatch said how he is troubled by the work that is going on in the Jones Institute for Reproductive Medicine, where they are creating embryos. Why? If embryos are "expendable" and can be used for this purpose, then why not, if they are created for that reason or if they are in a cryogenic tank and it is in excess, to use the word of the day, of what the parents' needs are? It seems to me that they either have innate value or they don't, and we should be moving in that direction to protect them.

Let me also say—and this was mentioned by my colleague from Virginia, Ms. Davis—Ms. Samuelson in her statement, and I think this needs to be very much debated and discussed. "No one can credibly argue that more than a small fraction of those presently in storage would ever be adopted." Well, that is because nobody knows about it. The sooner that changes, the sooner that the genetic parents know about this, the better.

Thank you, Mr. Chairman, and I know my time is up. But I want to thank you so much for coming because, again, I think this is the turning point in this debate. What you have done on behalf of your children and their brothers and sisters yet to be born will change the entire nature of this debate, and I thank you.

Mr. WELDON. I want to thank the panel for their testimony. Your response to the questions has been most interesting. Thank you so much for providing the human side to this debate. Thanks for coming so far.

I would like the witnesses in the second panel now to please step forward. The witnesses on the second panel will include Nathan Salley, a leukemia patient; Mollie Singer, Juvenile Diabetes Research Foundation; Joan Samuelson of the Parkinson's Action Network; David Prentice, PhD, Indiana State University; Carl Hook, MD, with the Mayo Clinic, and Gerald Fischbach, MD, of Columbia University.

I would ask that you all remain standing so we can administer the oath. Do we have everybody here?

OK, it looks like we have two Ms. Singers. Is that right? Mollie and Jackie? Are they both going to provide testimony? Is that right? OK, great.

[Witnesses sworn.]

Mr. WELDON. Let the record show that the witnesses have all answered in the affirmative.

Please be seated.

We will now recognize the witnesses for their opening statements. I would like to thank them again for being here today. I would again ask that you limit your opening statements to 5 minutes and include any fuller statements you may wish to make in the record.

Mr. Salley, do you have an opening statement to give? You are recognized for 5 minutes.

**STATEMENTS OF NATHAN SALLEY, LEUKEMIA PATIENT; MOLLIE SINGER, JUVENILE DIABETES RESEARCH FOUNDATION; JACKIE SINGER, JUVENILE DIABETES RESEARCH FOUNDATION; JOAN SAMUELSON, PARKINSON'S ACTION NETWORK; DAVID A. PRENTICE, PROFESSOR OF LIFE SCIENCES, INDIANA STATE UNIVERSITY, AND ADJUNCT PROFESSOR OF MEDICAL AND MOLECULAR GENETICS, INDIANA UNIVERSITY SCHOOL OF MEDICINE; C. CHRISTOPHER HOOK, MD, MAYO CLINIC; AND GERALD D. FISCHBACH, MD, DEAN OF THE FACULTY OF MEDICINE, COLUMBIA UNIVERSITY**

Mr. SALLEY. My name is Nathan Salley. I am 16 years old and will be a junior next year at Faith Christian Academy. I live with my sister Meaghan and parents, Mark and Leslie Salley, in Arvada, CO. My father and mother are with me today.

I am living proof that there are promising and useful alternatives to embryonic stem cell research.

Mr. WELDON. Nathan, could you just pull that mic a little bit closer?

Mr. SALLEY. Yes.

Mr. WELDON. Just a little bit closer. That's great. Thanks.

Mr. SALLEY. OK. I'm living proof that there are promising and useful alternatives to embryonic stem cell research and that embryos do not need to be killed to achieve medical breakthroughs. My story begins at age 11 when I was ill for several months. My mother took me to doctors who told me that I was a victim of tonsillitis, fatigue, and infections. They were dead wrong. When I was finally checked for mononucleosis, they found something much worse. On March 4, 1997, I was diagnosed with acute myloid leukemia. The disease was at an advanced stage by the time of diagnosis.

For an exhausting 18 months I had chemotherapy for 86 to 94 hours each month and endured repeated spinal taps and bone marrow aspirations to check my progress. I lost my hair, energy, and appetite, but I tried hard to do as many things as I could, for life to be as normal as possible. Between chemotherapy treatments, I tried to play soccer and keep up with school.

Since being diagnosed more than 4 years ago, I have spent nearly 6 months as an in-patient at the hospital and made nearly weekly visits to this day as an out-patient. I missed much of school from sixth to ninth grade, and just when I thought the treatments were over and I was cured, I had a relapse.

Doctors informed me at age 14 that I needed a bone marrow transplant. They gave me three options: receive the bone marrow

from a donor relative, an unrelated donor, or cord blood. We found that nobody in my family was a match. We were ready to go ahead with the transplant from an adult donor who had what they call a 5 of 6 match with my proteins. However, at the last minute, a 6 of 6 matching cord blood unit from Spain became available.

Physicians assured us a cord blood transplant was my best chance for life. Dad signed consent forms for me to participate in the procedure. The forms said, "umbilical cord blood transplantation has been performed mainly in small children and one of the purposes of this study is to determine whether it can be performed safely in larger people."

At 14, I was among the oldest children to receive a transplant from an umbilical cord. More cells were going to be needed than were available in the cord blood unit. So the doctors told us about a second experimental procedure they felt should be used to expand the number of donated cord cells. We agreed and signed more medical consent forms.

Before the transplant could take place, I had to completely kill my own leukemia-producing marrow with 3 days of total body radiation, followed by even more intense chemotherapy. Then the transplant took place in two phases. I received about 60 percent of the donated cord blood cells on June 29, 1999, when they arrived from Spain. The remaining cells were sent to the lab to be expanded. I was transfused with these cells 10 days later on July 9, 1999.

It was an agonizing wait for my blood counts to begin to recover. Thankfully, I am in complete remission today. Regular blood tests continue to show no leukemia present in my body. The transplanted cells have built a brand-new marrow system and immune system for me.

When my transplant was performed by the doctors at Children's Hospital in Denver, I was just 1 of 7 patients to receive a cord blood transplant in 1999, and only the 13th person since the first cord blood transplant there in 1996.

As a result of this ground-breaking procedure, I am proof that the medical community does not need to destroy life to save it. I am told that the same cord blood stem cells that saved me are likely cures for other life-threatening diseases. People disagree about whether research using embryo stem cells also may yield medical benefits, but no one disputes that such research destroys embryos.

I am not a doctor, scientist, or theologian, but speaking as one cancer survivor who benefited from a cord cell treatment, it does not seem right to me to terminate living human embryos based on mere speculation that they could lead to cures when obvious alternatives are not yet exhausted.

All human life is fearfully and wonderfully made. My life is no more valuable before God than the life of an embryo. Everyone wants to live a complete and healthy life, but I do not believe killing a life to save it is right. Who, besides God, knows what an embryo may become? What we do know is that performing research on a 4-day-old embryo will ensure that it never becomes a 5-day-old embryo, much less a 25-year-old soccer player, a 30-year-old actor, a 50-year-old Congressman, or a 91-year-old former President.

Somehow the opportunity came to me from among countless others to be here today and tell my story. I have benefited from, and participated in, research on umbilical stem cells. Am I thankful to be alive today? Yes. Am I thankful that brilliant doctors and researchers discovered a treatment for my disease? Absolutely. Would I want human embryos unnecessarily killed when alternative research methods exist today? No.

So I urge this committee—and President Bush—not to allow taxpayers' money to fund destruction of live human embryos. Thank you.

[The prepared statement of Mr. Salley follows:]

**Testimony of Nathan Salley**
**before the**
**United States House of Representatives Committee on Governmental Reform**
**Subcommittee on Criminal Justice, Drug Policy, and Human Resources**
**Hearing on Embryonic Cell Research**
July 17, 2001

My name is Nathan Salley. I am 16 years old and I will be a junior next year at Faith Christian Academy. I live with my parents, Mark and Leslie Salley, in Arvada, Colorado. My father and mother are with me today.

I am honored to represent some of the children that proponents of embryonic stem cell research insist they are trying to save. Yet embryonic stem cell research did not save me—cord blood research did. I am living proof that there are promising and useful alternatives to embryonic stem cell research and that embryos do not need to be killed to achieve medical breakthroughs.

My story begins at the age of eleven when I was ill for several months. My mother took me to doctors, who told me that I was the victim of tonsillitis, fatigue and infections. They were dead wrong. When – at my mother's urging – I was finally checked for mononucleosis, they found something much worse. The doctor who called with the results of my blood test told us to get to the hospital immediately.

On March 4, 1997, I was diagnosed with Acute Myloid Leukemia. The disease was at an advanced stage by the time of diagnosis.

At age eleven, I knew nothing about leukemia. It was a terrible time, but I always tried to look on the bright side. Soccer teammates put my number "2" on their jerseys for the remainder of the season. Friends were very supportive, but the cancer treatment was awful. Cranial radiation exhausted me and chemotherapy caused me terrible nausea.

For eighteen months, I had chemotherapy for 86 to 94 hours each month and endured repeated spinal taps and bone marrow aspirations to check my progress. I lost my hair and appetite, but I tried hard to do as many things as I could – for life to be as normal as possible. Between chemotherapy treatments, I played soccer and kept up with school.

Since being diagnosed more than four years ago, I have spent nearly six months as an in-patient at the hospital and made nearly weekly visits to this day as an out-patient. I had to be homeschooled at the end of sixth grade, for all of seventh grade, for part of eighth grade and for part of my freshman year. I missed out on so many things with my friends that I could not begin to recount them. And, just when I thought the treatments were over and I was cured, I had a relapse.

Doctors informed me at age fourteen that I needed a bone marrow transplant. They gave me three options: receive the bone marrow from a donor relative, an unrelated donor, or cord blood. We found that nobody in my family was a match. We were ready to go ahead with a transplant

from an adult donor who had what they call a 5 of 6 match with my proteins. However, at the last minute, a 6 of 6 matching cord blood unit from Spain became available.

Cord blood transplants were becoming more widely used by 1999, but were still experimental. Physicians assured us a cord blood transplant was my best chance for life and would reduce the likelihood of rejecting the transplant. After prayerful consideration, my parents and I followed their advice. Dad signed consent forms for me to participate in the procedure, requiring us to acknowledge that "umbilical cord blood transplantation has been performed mainly in small children and one of the purposes of this study is to determine whether it can be performed safely in larger people."

At fourteen, I was among the oldest children to receive a transplant from a small umbilical cord. More cells were going to be needed than were available in the cord blood unit. So the doctors told us about a second experimental procedure they felt should be used to expand the number of donated cord cells. We agreed to this procedure and signed more medical consent forms.

The scariest one said, "You are being asked to participate in a research study involving an investigational technique where a portion of your cord blood transplant will be treated in a laboratory before it is given back to you. The goal of this study is to determine whether we can speed up your marrow recovery by increasing the number of cord blood-forming cells in the laboratory before you receive them . . . . Your doctors have shown that if cord blood cells are treated in the laboratory for 10 days with vitamins and growth factors, the number of stem cells which produce marrow recovery is substantially increased."

Before the transplant could take place my doctors had to completely kill my own leukemia-producing marrow with three days of total body radiation, followed by more intense chemotherapy. Then, the transplant took place in two phases. I received about 60 percent of the donated cord blood cells on June 29, 1999 when they arrived from Spain. The remaining cells were sent to the lab to be expanded. I was transfused with these cells ten days later on July 9, 1999.

It was an agonizing wait for my blood counts to begin to recover. I could not eat for two to three weeks. Thankfully, I am in complete remission today. Regular testing continues to show no leukemia present in my body. The transplanted cells have built a brand new bone marrow system for me.

When my transplant was performed by the doctors at Children's Hospital in Denver, I was just one of seven patients to receive a cord blood transplant in 1999. There have been just 36 total cord blood transplants at that hospital since the first one in 1996.

As a result of this groundbreaking procedure, I am proof that the medical community does not need to destroy life to save it. I am told that the same cord blood stem cells that saved me are likely cures for other life-threatening diseases. Differences of opinion exist about whether research using embryo stem cells may also yield medical benefits. But no one disputes that such research destroys embryos.

**Gerald D. Fischbach M.D.**
Vice President for Health and Biomedical Sciences
Columbia University and Dean of the Faculty of
Medicine

Subcommittee on Criminal Justice, Drug Policy and
Human Resources

July 17, 2001

Mr. Chairman, Congressman Cummings, Members of the Subcommittee, thank you for inviting me to testify before you today and address this critical scientific and medical research issue.

We are currently in the midst of a paralyzing debate that threatens to terminate the most promising type of stem cell research: the analysis of cells derived from excess fertilized eggs. Degenerative disorders are associated with the atrophy and ultimately the loss of crucial cells. Cells in the pancreas are lost in juvenile diabetes, dopamine neurons are lost in the midbrain of patients with Parkinson's disease, other types of neurons are lost in Alzheimer's disease, Amyotrophic Lateral Sclerosis and Huntington's disease, and heart cells are lost following a myocardial infarction. In the aggregate, degenerative disorders will become the number one public health problem facing this country in the 21st century. We have medicines that can treat some symptoms of degenerative disorders, but none that can stop the degenerative process or replace lost cells. Stem cells offer a new type of therapy, one in which damaged cells are replaced and tissues repaired. Restorative medicine promises to go beyond symptomatic treatments available today. We can actually begin to talk about halting degenerative disorders with greater confidence.

There is a great deal of confusion about the biology of stem cells, about current government regulations, and about prospects for the future. The issue before the President and the public is whether government funds should be used to support research on stem cells that are derived from excess fertilized eggs. It is not about governmental support for the derivation of these cells, which has been prohibited since 1995.

Mr. WELDON. Thank you, Nathan. We will now hear from Dr. Gerald Fischbach.

Dr. FISCHBACH. Thank you, Congressman Weldon, Congressman Cummings, and other members of the committee, for inviting me to appear before you and address these very promising medical therapies and difficult ethical issues. I am the dean of the faculty of medicine at Columbia University and past director of the National Institute of Neurological Disorders and Stroke.

Degenerative disorders are associated with the loss of cells. Cells in the pancreas that make insulin are lost in juvenile diabetes. Neurons that make dopamine are lost in the brains of patients with Parkinson's disease. Heart cells that pump blood are lost following an acute myocardial infarction. We have medicines that treat symptoms of degenerative disorders, but none of them stops the degeneration process itself, and none can replace the lost cells.

Stem cells offer a new type of therapy in which damaged cells are replaced and tissue repaired. Stem cells are very unusual cells. They are capable of self-replication and on cue they send out branches, so to speak, along different developmental pathways to form different types of cells. In that sense, they really are stem cells.

Three years ago was the first publication of the isolation of human embryonic stem cells, and the possibilities of expanded therapy with stem cell biology. It's remarkable, therefore, that we are in the midst of a debate that threatens to terminate research on embryonic stem cells, which many believe to be the most promising of all stem cell types.

The issue before the President and the public is whether government funds should be used to support research on human embryonic stem cells. It is not about government support for the derivation of the cells, a process that involves destruction of the embryos. Government-funded experiments on human embryos were prohibited in 1995. Recognizing this prohibition, but also recognizing the great potential of embryonic stem cells, the NIH issued guidelines last August that place severe restrictions on the methods of stem cell derivation. A working group composed of scientists, patients, ethicists, clinicians, and lawyers drafted the guidelines. They were subject to intense scrutiny, including congressional hearings, advice from the National Bioethics Advisory Commission, and publication in The Federal Register. Nevertheless, the debate continues and it has escalated since President Bush suspended the guidelines pending further review.

The guidelines should inform our debate about stem cell research. They state, "Researchers applying for NIH funds must provide assurance that the cells were isolated without Federal funds from embryos created for fertility treatment and that are no longer needed by the donors. At this early stage, the embryo is a hollow sphere containing about 100 to 200 cells, described as a pre-implantation embryo. Second, donation of an embryo must be voluntary with no financial inducements offered. Third, there must be a clear separation in time between the decision to create the embryo and the decision to donate."

The guidelines apply only to work supported by the Federal Government, but we should make no mistake about it: This research

is superb and it has an enormous impact on the private sector throughout the world. Indeed, the NIH guidelines are our best chance for monitoring the activity of private enterprises that might use embryos from other sources. It is better to train the spotlight of public scrutiny on embryo research than to allow this work to go on behind closed doors.

Alternatives to NIH guidelines have been discussed, but in my mind they are inadequate. One plan calls for the exclusive use of stem cells derived from adult tissues. However, the prevailing opinion of scientists in this field is that stem cells from adult tissues do not proliferate as robustly in tissue culture and they do not exhibit the same diversity of offspring as do embryonic stem cells. Both characteristics are essential for effective stem cell therapy.

Another alternative to NIH guidelines would allow research on human embryonic stem cells, but only those 10 or so cell lines that already exist. Unfortunately, this would cripple stem cell research. Cells from embryos are not all identical, and the same line may not be optimal for all disorders.

In sum, it is unethical in my mind to hold back our best efforts to help millions of Americans who suffer with rapidly progressive degenerative disorders. We do not have the knowledge or the time to suspend promising areas of research and continue this work with one hand tied behind our backs.

[The prepared statement of Dr. Fischbach follows:]

**Gerald D. Fischbach M.D.**
Vice President for Health and Biomedical Sciences
Columbia University and Dean of the Faculty of
Medicine

Subcommittee on Criminal Justice, Drug Policy and
Human Resources

July 17, 2001

Mr. Chairman, Congressman Cummings, Members of the Subcommittee, thank you for inviting me to testify before you today and address this critical scientific and medical research issue.

We are currently in the midst of a paralyzing debate that threatens to terminate the most promising type of stem cell research: the analysis of cells derived from excess fertilized eggs. Degenerative disorders are associated with the atrophy and ultimately the loss of crucial cells. Cells in the pancreas are lost in juvenile diabetes, dopamine neurons are lost in the midbrain of patients with Parkinson's disease, other types of neurons are lost in Alzheimer's disease, Amyotrophic Lateral Sclerosis and Huntington's disease, and heart cells are lost following a myocardial infarction. In the aggregate, degenerative disorders will become the number one public health problem facing this country in the 21st century. We have medicines that can treat some symptoms of degenerative disorders, but none that can stop the degenerative process or replace lost cells. Stem cells offer a new type of therapy, one in which damaged cells are replaced and tissues repaired. Restorative medicine promises to go beyond symptomatic treatments available today. We can actually begin to talk about halting degenerative disorders with greater confidence.

There is a great deal of confusion about the biology of stem cells, about current government regulations, and about prospects for the future. The issue before the President and the public is whether government funds should be used to support research on stem cells that are derived from excess fertilized eggs. It is not about governmental support for the derivation of these cells, which has been prohibited since 1995.

Recognizing the prohibition of government spending for research on human embryos, but also recognizing the great potential of isolated human embryonic stem cells, the National Institutes of Health (NIH) issued Guidelines last August that placed severe restrictions on the methods of stem cell derivation. NIH-supported researchers could use cells only if they were isolated as specified. The Guidelines underwent intense scrutiny before they were issued. This includes two congressional hearings and the convocation of a working group composed of scientists, patients, patient advocates, ethicists, clinicians, and lawyers. The group received advice from the National Bioethics Advisory Commission and a draft of the Guidelines was published in the *Federal Register* for public comment.

The main points of the Guidelines ought to inform the debate about stem cell research. First, researchers applying for NIH funding must provide assurance that the cells to be used were obtained without Federal funds and from excess fertilized eggs created for fertility treatment, and that said excess fertilized eggs are no longer needed by the individuals seeking such treatment. At this early stage, the excess fertilized egg is a hollow sphere containing about 100 cells. Second, all donors must provide consent and the donation must be voluntary with no inducements offered. Third, there must be a clear separation in time between the decision to create the fertilized egg for fertility treatment and the decision to donate.

The Guidelines apply only to work supported by the federal government, but the excellence of NIH supported researchers and the enormous impact of their work, has great influence on research conducted in the private sector throughout the world. The NIH guidelines are our best chance for monitoring the activity of private companies that might use embryos from other sources or might even produce embryos for the sole purpose of stem cell research. It is far better to focus the spotlight of public scrutiny on human embryo research than to allow this work to go on behind closed doors in privately funded labs. Simply stated, ignoring government-supported investigators is not good for business.

It may be that those who oppose embryonic stem cell research believe that it will increase the number of fertilized eggs destroyed. But this is not likely. Eggs created for in vitro fertilization must be produced in excess of what is needed for implantation

because only a small percentage of those introduced into a receptive uterus actually achieve a viable pregnancy. At the present time, the vast majority of frozen excess fertilized eggs are destroyed with the consent of both donors. A few are donated for medical research to help millions of suffering individuals. A small number are made available to other infertile couples, but of these, less than ten percent will be viable. It is estimated that about 100,000 frozen fertilized eggs exist today and implementing the NIH guidelines will not increase that number.

Alternatives to the NIH Guidelines have been discussed, but they are inadequate. One plan calls for the exclusive use of stem cells derived from adult tissues banning research on embryonic stem cells entirely. We have known for some time that stem cells are present in adult bone marrow and skin. The surprise in recent years is that stem cells are present in other adult tissues including the brain. However, it is generally believed that stem cells from adult tissues do not proliferate as robustly and they do not exhibit the same diversity of offspring as embryonic stem cells do. Both characteristics are essential for effective stem cell therapy. This hierarchy of stem cells must be taken into account as the debate intensifies.

It is irresponsible to claim that adult cells are superior to embryonic cells in their ability to proliferate or in the diversity of their descendants. This claim ignores hundreds, if not thousands, of published reports and the prevailing opinion of most scientists in the field. We must learn more about all types of stem cells, about the signals that stimulate them to divide, the signals that make them stop dividing, and the signals that steer them into one path of maturation or another. Breakthroughs cannot be predicted, and it is unethical to hold back our best effort while one hundred million of Americans continue to suffer with rapidly progressive degenerative disorders.

Another alternative to the NIH Guidelines would allow research on embryonic stem cells, but only on the 10 to 15 cell lines that already exist. Unfortunately this would cripple research on human embryonic stem cells. Stem cell lines derived from different fertilized eggs are not identical, and the same line may not be optimal for all disorders. Moreover, new cell lines, like any new medicine, must be tested for safety as well as efficacy. To maximize benefits and minimize adverse side effects, one must study many different cell lines. The FDA will demand nothing less. It is impossible to predict the

number of cell lines required, but it is a certain that with each success, the number of frozen fertilized eggs required will be dramatically reduced.

The United Kingdom, and most other European and Asian countries permit government funds to be used for embryonic stem cell research. Were we to ban this type of research, we would be one of the only scientifically advanced nations to do so. I respect the religious and ethical concerns some individuals have raised; however, I believe that the NIH guidelines do address those concerns. I do strongly disagree with those who argue that embryonic stem cell research is not needed, that adult stem research will provide the same scientific opportunities. This is just not so. Stem cells have the potential to usher in a new era of restorative medicine that was unimaginable just a few years ago, but we most push forward on multiple fronts. That is the only way we will be able to optimize the chance of relieving the suffering of so many Americans who suffer from degenerative disorders. Thank you.

Mr. WELDON. Thank you, Dr. Fischbach. We will now hear from Dr. David Prentice.

Dr. PRENTICE. Thank you, Mr. Chairman. Before my time starts, I might note for the record that during the Members' opening statements it tended to put the children to sleep; it's now the scientists' turn to do the same for the Members.

Mr. Chairman, Congressman Cummings, distinguished Members, many here support stem cell research. So do I. I don't know of anyone who does not support stem cell research. But the use of Federal funds to support human embryonic stem cell research is illegal, unethical, and unnecessary. Adult and other post-natal stem cells have vast biomedical potential to cure diseases such as diabetes, Parkinson's, heart disease, and other degenerative diseases. This biomedical potential is as great as, or greater than, the potential offered by human embryonic stem cell research.

Simply stated, adult stem cell research is a preferable alternative for progress in regenerative medicine and cell-based therapies because it does not pose the medical, legal, and ethical problems associated with human embryonic stem cell research. Current Federal law enacted by Congress is clear in prohibiting research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death. Human embryonic stem cell research requires the destruction of live human embryos to obtain their stem cells. It is a mistaken notion to think that there can be any meaningful separation between destroying the embryo and research that relies on this destruction. It is ethically wrong to harm or destroy some human lives for the potential benefit—and it is only a potential benefit—of others. This violates the basic tenet of the healing arts: First, do no harm.

The evidence indicates that the research is neither necessary nor ethical. Embryonic stem cell research takes a utilitarian view of human embryos: useful for a purpose and not valued in and of themselves. They are not viewed as people, but as property, a commodity. Dr. Erwin Chargaff, a renown biochemist, characterizes this attitude as "a kind of capitalist cannibalism."

The scientific record establishes that claims regarding the purported shortcomings of adult stem cells are not true, are not relevant to their therapeutic potential, and/or overstate the differences between adult stem cells and embryonic stem cells. Significantly, adult stem cells do exhibit pluripotency and they have the ability to transform from one cell type into another functional tissue. Moreover, an impressive volume of scientific literature attests to the fact that human adult stem cells, unlike human embryonic stem cells, are currently being used successfully with patients to combat many of the various diseases that embryonic stem cells only prospectively promise to treat, such as multiple sclerosis, lupus, various types of cancers, and cartilage diseases in children.

Animal research strongly suggests that more therapeutic applications of adult stem cell research will follow, including treatments for diabetes, Parkinson's, stroke, heart disease—to name a few. In sum, the scientific record indicates that the alleged shortcomings perceived in adult stem cell research either are illusory or will be overcome.

Finally, the potential biomedical application of embryonic stem cell research faces significant risks such as the tendency toward tumor formation as well as instability in gene expression, and embryonic stem cells face the very real possibility of immune rejection, while use of a patient's own adult stem cells is free from this problem. Hence, adult stem cells have many advantages as compared with embryonic stem cells for practical therapeutic application.

Thus, contrary to suggestions by supporters of human embryonic stem cell research, Federal funding of such research is not a necessary nor even a wise use of limited taxpayer dollars. Indeed, embryonic stem cells have not even shown their efficacy in animal models. Adult stem cell research is more promising, is demonstrably more successful at producing beneficial treatments that are actually in use today, and does not present the significant problems and uncertainties posed by human embryonic stem cell research. A viable, less morally problematic alternative to embryonic stem cells does exist. Adult and cord blood stem cells are making good on what are only promises of embryonic stem cells.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Prentice follows:]

SUMMARY of Testimony of Dr. 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

For The Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, U.S. House of Representatives

Hearing on "Opportunities and Advancements in Stem Cell Research", July 17, 2001

The use of federal funds to support human embryonic stem cell research is illegal, unethical, and unnecessary. Adult and other "post-natal" stem cells have vast biomedical potential to cure diseases such as diabetes, Parkinson's, heart disease, and other degenerative diseases. This biomedical potential is as great as *or greater than* the potential offered by human embryonic stem cell research. Simply stated, adult stem cell research is a preferable alternative for progress in regenerative medicine and cell-based therapies because it does not pose the medical, legal, and ethical problems associated with human embryonic stem cell research.

Current federal law enacted by Congress is clear in prohibiting "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death". Human embryonic stem cell research requires the destruction of live human embryos to obtain their stem cells. It is a mistaken notion to think that there can be any meaningful separation between destroying the embryo and research that relies on this destruction. It is ethically wrong to harm or destroy some human lives for the potential benefit of others. This violates the basic tenet of the healing arts: "first do no harm."

The evidence indicates that the research is neither necessary nor ethical. Embryonic stem cell research takes a utilitarian view of human embryos, useful for a purpose and not valued in and of themselves. They are not viewed as people, but as property, a commodity. Dr. Erwin Chargaff, renowned biochemist, characterizes this attitude as "a kind of capitalist cannibalism".

Recent scientific reports indicate that claims about the shortcomings of adult stem cells are not true, are not relevant to their therapeutic potential, and/or overstate the differences between adult stem cells and embryonic stem cells. Significantly, adult stem cells can be pluripotent and have the ability to transform from one cell type into another, functional tissue. The scientific record indicates that the alleged shortcomings perceived in adult stem cell research either are illusory or can be overcome.

Moreover, an impressive volume of scientific literature attests to the fact that human adult stem cells -- unlike human embryonic stem cells -- are currently being used successfully with patients to combat many of the very diseases that embryonic stem cells only prospectively promise to treat. Animal research strongly suggests that more therapeutic applications of adult stem cell research will follow.

Finally, the potential biomedical application of embryonic stem cell research faces significant risks such as the tendency toward tumor formation, as well as instability in gene expression. And, embryonic stem cells face the very real possibility of immune rejection, while use of a patient's own adult stem cells is free from this problem. Hence, adult stem cells have many advantages as compared with embryonic stem cells for practical therapeutic application.

Thus, contrary to suggestions by supporters of human embryonic stem cell research, federal funding of such research is not a necessary, nor even a wise, use of limited federal research dollars. Indeed, embryonic stem cells have not even shown their efficacy in animal models. Adult stem cell research is more promising, is demonstrably more successful at producing beneficial treatments that are actually in use today, and does not present the significant problems and uncertainties posed by human embryonic stem cell research. A viable, less morally problematic alternative to embryonic stem cells does exist. Adult and cord blood stem cells are making good on what are only promises of embryonic stem cells.

Testimony of Dr. David A. Prentice, Ph.D.
Professor of Life Sciences, Indiana State University
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The Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform, U.S. House of Representatives
Investigative Hearing on "Opportunities and Advancements in Stem Cell Research"
July 17, 2001

Mr. Chairman, Distinguished Members of the Subcommittee, thank you for the opportunity to testify today at this important hearing regarding stem cell research.

The use of federal funds to support human embryonic stem cell research is illegal, unethical, and unnecessary. Research using stem cells not derived from human embryos has confirmed what prior evidence had long suggested: that adult stem cells (and other "post-natal" stem cells)[1] have vast biomedical potential to cure diseases such as diabetes, Parkinson's, heart disease, and other degenerative diseases. This biomedical potential is as great as *or greater than* the potential offered by human embryonic stem cell research. Simply stated, adult stem cell research is a preferable alternative for progress in regenerative medicine and cell-based therapies for disease because it does not pose the medical, legal, and ethical problems associated with destructive human embryonic stem cell research.

Among the justifications stated in the Guidelines for pursuing human embryonic stem cell research was the allegedly limited potential of adult stem cells as compared to the purportedly enormous, yet speculative, potential of embryonic stem cells. In particular, NIH's response to comments urging the benefits of adult stem cell research highlighted four alleged shortcomings related to the biomedical potential of adult stem cells. 65 Fed. Reg. 51976. The agency stated that adult stem cells (1) had not been found in all cell types, (2) appear in limited numbers and can be difficult to harvest and grow in time for treatment, (3) are likely to pass on genetic defects, and (4) may not have the capacity to multiply as do "younger cells." *Id.* Recent scientific developments now support the contention, however, that these claims about the shortcomings of adult stem cells are not true, are not relevant to their therapeutic potential, and/or overstate the differences between adult stem cells and embryonic stem cells. Significantly, human adult stem cells can be pluripotent and have the ability to transform from one cell type into another, a fact largely unrecognized by the Guidelines. The scientific record

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[1] See Appendix B for a graphical representation of sources of stem cells and their potentials.

now indicates that the supposed shortcomings NIH perceived in adult stem cell research either are illusory or can be overcome.

Moreover, an impressive volume of scientific literature attests to the fact that human adult stem cells -- unlike human embryonic stem cells -- are currently being used successfully in clinical trials to combat many of the very diseases that embryonic stem cells only prospectively promise to treat. Animal research strongly suggests that more therapeutic applications of adult stem cell research will follow.

Finally, the potential biomedical application of human embryonic stem cell research faces risks that are unique to embryonic stem cells, such as the tendency toward tumor formation, as well as instability in gene expression. In addition, embryonic stem cells face the very real possibility of immune rejection, while use of a patient's own adult stem cells is free from this problem. Consequently, adult stem cells have several advantages as compared with embryonic stem cells in their practical therapeutic application for tissue regeneration.

Thus, contrary to the suggestions by supporters of destructive human embryonic stem cell research, federal funding of such research is not a necessary, or even a wise, use of limited federal research dollars. Other forms of stem cell research are more promising, are demonstrably more successful at producing beneficial treatments that are actually in use today, and do not present the significant problems and uncertainties (to say nothing of the ethical and legal problems) posed by destructive human embryonic stem cell research.

**1. Adult stem cells have been located in numerous cell and tissue types and can be transformed into virtually all cell and tissue types, including functional tissues**

Although it is true that human adult stem cells have not been found in *every* cell type, they have been found in many cell and tissue types including, but not limited to: brain (and other nervous system),[2] muscle,[3] retina,[4] pancreas,[5] bone marrow and peripheral blood,[6] cornea,[7]

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[2] *See, e.g.*, T.D. Palmer *et al.*, "Progenitor cells from human brain after death," 411 Nature 42 (May 3, 2001) (neural stem cells isolated and grown from human cadavers); S. Pagano *et al.*, "Isolation and Characterization of Neural Stem Cells from the Adult Human Olfactory Bulb," 18 Stem Cells 295 (July 2000) (identifying neural stem cells in a more accessible portion of the brain); Barnett *et al.*, "Identification of a human olfactory ensheathing cell that can effect transplant-mediated remyelination of demyelinated CNS axons," 123 Brain 1581 (Aug. 2000) (identifying human "olfactory ensheathing cell," the cell type which has been used successfully in animals to repair spinal cord damage); C.B. Johansson *et al.*, "Neural stem cells in the adult human brain"; 253 Exp. Cell Res. 733 (Dec. 1999) (discussing different regions in the adult brain in which stem cells have been isolated); *see also*, C.J. Hodge, Jr. and M. Boakye, "Biological Plasticity: The future of science in neurosurgery," 48 Neurosurgery 2 (Jan. 2001) (reviewing science regarding the plasticity of neural cells in humans and animals); *see generally*, App. A, Refs. 113-143 (collecting published papers using non-embryonic neural stem cells from human adults and animals).

blood vessels (endothelial cells),[8] fat,[9] dental pulp,[10] spermatogonia,[11] and placenta.[12] In essence, where scientists have devoted time and resources to the identification of human adult (and other non-embryonic) stem cell types, they have generally found them.

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3 *See, e.g.,* P. Manasché *et al.* "Myoblast transplantation for heart failure," 357 Lancet 279 (Jan. 27. 2001) (using isolated human muscle cells in a clinical trial); J. T. Williams *et al.*, "Cells isolated from adult human skeletal muscle capable of differentiating into multiple mesodermal phenotypes," 65 Am. Surg. 22 (Jan. 1999); *see generally*, App. A, Refs. 146-161 (collecting published papers using non-embryonic muscle stem cells from humans and animals).

4 Tropepe *et al.*, "Retinal stem cells in the adult mammalian eye," 287 Science 2032 (Mar. 17, 2000) (identifying retinal stem cells in humans and other mammals).

5 *See, e.g.,* V. Gmyr *et al.*, "Adult human cytokeratin 19-positive cells reexpress insulin promoter factor 1 in vitro: Further evidence for pluripotent pancreatic stem cells in humans," 49 Diabetes 1671 (Oct. 2000); S. Bonner-Weir *et al.*, "In vitro cultivation of human islets from expanded ductal tissue," 97 Proc. Natl. Acad. Sci. USA 7999 (July 5, 2000); *see also* P. Serup, O.D. Madsen, and T. Mandrup-Poulsen; "Islet and stem cell transplantation for treating diabetes"; 322 British Medical Journal 29 (Jan. 6, 2001) (reviewing animal and human stem cell developments for biomedical potential to treat diabetes).

6 *See e.g.,* A. A. Kocher *et al.*, "Neovascularization of ischemic myocardium by human bone-marrow-derived angioblasts prevents cardiomyocyte apoptosis, reduces remodeling and improves cardiac function," 7 Nature Medicine 430 (April 2001) (experiment using bone marrow cells); *see generally*, App. A, refs. 169-219 (collecting papers using non-embryonic human and animal adult bone marrow and peripheral blood stem cells).

7 *See* R. J-F. Tsai *et al.*; "Reconstruction of damaged corneas by transplantation of autologous limbal epithelial cells," 343 New England J. of Medicine 86 (2000); I. R. Schwab *et al.*; "Successful transplantation of bioengineered tissue replacements in patients with ocular surface disease," 19 Cornea 421 (July 2000); K. Tsubota *et al.*; "Treatment of severe ocular-surface disorders with corneal epithelial stem-cell transplantation," 340 New England J. of Medicine 1697 (June 3, 1999); *see generally*, App. A, Refs. 67-74 (collecting published papers using non-embryonic human corneal stem cells).

8 *See, e.g.,* T. Asahara *et al.*, "Isolation of Putative Progenitor Endothelial Cells for Angiogenesis," 275 Science 964 (Feb. 14, 1997).

9 *See* P.A. Zuk *et al.*, "Multilineage cells from human adipose tissue: Implications for cell-based therapies," 7 Tissue Engineering 211 (2001).

10 *See* S. Gronthos *et al.*, "Postnatal human dental pulp stem cells (DPSCs) *in vitro* and *in vivo*," 97 Proc. Natl. Acad. Sci. USA 13625 (Dec. 5 2000).

11 *See* F. Izadyar *et al.*, "Spermatogonial stem cell transplantation" 169 Mol. Cell Endocrinology 21 (Nov. 27 2000); D.S. Johnston *et al.*, "Advances in spermatogonial stem

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Moreover, experiments using animals have recently isolated many additional adult stem cell and tissue types, including, but not limited to: skin,[13] liver,[14] and mammary gland.[15] Given the impressive pace of adult stem cell identification in the past few years -- which invariably followed the pattern of (1) identification and isolation of the stem cell in animals, followed by (2) identification and isolation of the stem cell in humans -- the imminent identification and isolation of the human adult stem cells of these cell and tissue types is highly likely.

Even more important than the identification of human adult stem cells in most cell types is the fact that adult stem cells can regenerate healthy tissue and many can transform from one cell type into another. Thus, many types of human adult stem cells -- including stem cells from fat -- exhibit the ability to transform from one tissue type into many others. For example, plentiful adult stem cells from fat have been transformed into cartilage, muscle, and bone.[16] Readily accessible human adult bone marrow stem cells have been transformed into smooth muscle,[17] cardiac tissues,[18] neural cells,[19] liver,[20] bone,[21] cartilage,[22] and fat.[23] Human adult

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cell transplantation," 5 Rev. Reprod. 183 (Sept. 2000) (reviewing advances in spermatogonial stem cell transplantation since 1994).

12 Based on press releases from AnthroGen indicating that scientists have isolated stem cells in placenta that have been induced to form bone, nerve, cartilage, bone marrow, muscle, tendon, and blood vessel. This press release is available at <http://www.mcpf.org/ AnthroGen%20Discovery.htm>. AnthroGen has also posted articles based on that press release at <http://www.anthrogenesis.com/page411559.htm>.

13 *See, e.g.*, H. Oshima *et al.*, "Morphogenesis and renewal of hair follicles from adult multipotent stem cells," 104 Cell 233 (Jan. 2001) (studies showing that the skin/hair follicle cell is multipotent and can form epidermis, hair follicles, sebaceous glands, and all structures of the hairy skin).

14 *See, e.g.*, N. N. Malouf *et al.*, "Adult-derived stem cells from the liver become myocytes in the heart in vivo," 158 American Journal of Pathology, 1929 (June 2001); *see generally,* App. A, refs. 220-225(collecting papers discussing liver stem cells).

15 *See* N. D. Kim, "Stem cell characteristics of transplanted rat mammary clonogens, 260 Exp. Cell Res. 146 (Oct. 10. 2000).

16 *See* P.A. Zuk *et al.*, *supra* at n. 8.

17 O. N. Koc and H. M. Lazarus, "Mesenchymal stem cells: heading into the clinic," 27(3) Bone Marrow Transplant 235-239 (Feb. 2001).

18 D. Orlic *et al.*, "Bone marrow cells regenerate infarcted myocardium," 410 Nature 701 (Apr. 5 2001).

19 J.Sanchez-Ramos *et al.*, "Adult bone marrow stromal cells differentiate into neural cells in vitro," 164 Experimental Neurology 247 (Aug. 2000); D. Woodbury *et al.*, "Adult rat and human bone marrow stromal cells differentiate into neurons," 61 J. Neuroscience Research

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neural stem cells have been reprogrammed to form skeletal muscle,[24] and have the ability to form all neural types.[25] Human adult stem cells from skeletal muscles can be coaxed into forming skeletal myotubes, smooth muscle, bone, cartilage, and fat.[26] Human adult stem cells from human dental pulp can be induced to differentiate into tooth structures.[27] And stem cells from placenta are reported to have been induced to form bone, nerve, cartilage, bone marrow, muscle, tendon, and blood vessels.[28] (Please see Appendix C for a graphical representation of some adult stem cells discovered and potential transformations into other tissue types based on the literature.)

In fact, animal research indicates that adult neural and bone marrow stem cells may be able to generate virtually all adult tissues, including heart, lung, intestine, kidney, liver, nervous system, muscle, and the gastrointenstinal tract (including esophagus, stomach, intestine, and colon).[29] Clarke suggests that "stem cells in different adult tissues may . . . have a developmental repertoire close to that of [embryonic stem] cells."[30] The recent rapid pace of discovery of adult stem cells for a variety of tissue types, combined with their ability to form many, if not all, adult tissues, suggests that adult stem cells will ultimately be found in or be capable of transforming into every significant tissue type.

In particular, the Guidelines evince concern that no pancreatic or cardiac adult stem cells had been identified. 65 Fed. Reg. 51976. In fact, however, human pancreatic and cardiac stem

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364 (Aug. 15, 2000); E. Mezey and K. J. Chandross, "Bone marrow: a possible alternative source of cells in the adult nervous system," 405 Eur. J. Pharmacol. 297 (Sept. 29, 2000).

20 N. Theise *et al.*, "Liver from bone marrow in humans," 32 Hepatology 11 (July 2000).

21 M. F. Pittenger *et al.*, "Multilineage potential of adult human mesenchymal stem cells," 284 Science 143 (Apr. 2, 1999).

22 *Id.*

23 *Id.*

24 R. Galli *et al.*, "Skeletal myogenic potential of human and mouse neural stem cells," 3 Nature Neuroscience 986 (Oct. 2000).

25 Pagano, *supra* at n. 1.

26 Williams, *supra* at n. 2.

27 S. Gronthos *et al.*, *supra* at n. 9.

28 *See* AnthroGen press release, *supra* at n. 11.

29 *See* D.L. Clarke *et al.*; "Generalized potential of adult neural stem cells" 288 Science 1660 (June 2, 2000); D.S. Krause *et al.*, "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell," 105 Cell 369 (May 4, 2001).

30 Clarke *et al.*, *supra* at n. 28.

cells *have* been identified. Indeed, scientists have actually reversed diabetes in mice using the animal's own adult pancreatic stem cells.[31] This animal research has led to evidence of adult human pancreatic stem cells, which have been grown in culture and induced to differentiate into insulin-producing cells.[32] In fact, in 1999, well before the NIH published the Guidelines, the NIH was funding research involving insulin-producing adult human pancreatic stem cells.[33] These cells are available for use in potential technologies to reverse diabetes in humans.

Recent evidence also indicates the ability of stem cells to transform into heart cells. Added to the numerous studies done in animals since 1995, these reports indicate that adult stem cells from skeletal muscle, bone marrow, liver, and the heart itself have the capacity to regenerate cardiac tissue and repair heart damage.[34] More recently, new evidence has emerged suggesting the existence of a human heart stem cell.[35] This research promises potential biomedical application to treat heart disease. In fact, myoblast transplantation has already been used in the first successful clinical application of human adult stem cells for treatment of cardiac damage.[36]

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[31] *See* V. K. Ramiya *et al.*, "Reversal of insulin-dependent diabetes using islets generated in vitro from pancreatic stem cells," 6 Nature Medicine 278 (March 2000).

[32] *See* references cited in n. 4, *supra.*

[33] *See* Grant Number 5R21DK57173-02 to Lawrence K. Olson, Michigan State University, "Pluripotent Human Pancreatic Ductal Cells," Project Start Date, September 30, 1999 (available at NIH website).

[34] *See, e.g.*, B. Pouzet *et al.*, "Factors affecting functional outcome after autologous skeletal myoblast transplantation," 71 Ann Thorac Surg 844 (Mar. 2001); B. Pouzet *et al.*, "Intramyocardial transplantation of autologous myoblasts : can tissue processing Be optimized?," 102 Circulation 210 (Nov. 7, 2000); M. Scorsin *et al.*, "Comparison of the effects of fetal cardiomyocyte and skeletal myoblast transplantation on postinfarction left ventricular function," 119 J. Thorac. Cardiovasc. Surg. 1169 (June 2000); P.D. Kessler and B.J. Byrne, "Myoblast cell grafting into heart muscle: cellular biology and potential applications," 61 Ann. Rev. Physiol. 219 (1999); K. A. Jackson *et al.*, "Regeneration of ischemic cardiac muscle and vascular endothelium by adult stem cells," 107 Journal of Clinical Investigation 1395 (June 2001); D. Orlic *et al.*, *supra* at n. 17; J-S. Wang *et al.*, "Marrow stromal cells for cellular cardiomyoplasty: Feasibility and potential clinical advantages," 120 The Journal of Thoracic and Cardiovascular Surgery 999 (Nov. 2000).

[35] *See* A. P. Beltrami *et al.*, "Evidence That Human Myocytes Divide After Myocardial Infarction," 344 New England Journal of Medicine 1750 (June 7, 2001) (research indicating that the adult human heart may have its own stem cell).

[36] *See* P. Menasché *et al.*, "Myoblast transplantation for cardiac repair," 357 Lancet 279 (Jan. 27, 2001); P. Menasché *et al.*, ["Autologous skeletal myoblast transplantation for cardiac insufficiency. First clinical case."], 94 Arch Mal Coeur Vaiss 180 (Mar. 2001) (Original title and article in French).

Contrary to the impression created by advocates of destructive human embryonic stem cell research, these results for adult stem cell research are far *more* promising than any results obtained thus far through embryonic stem cell research. Indeed, researchers have yet to publish *any* evidence that human pancreatic cells can be generated from human embryonic stem cells, and have yet to show any evidence that human cardiac cells generated from embryonic stem cells in culture can form functional tissue in the body. The case for diverting scarce research dollars away from promising avenues of research and instead into human embryonic stem cell research in order to "cure" diabetes or heart disease is weak indeed.

**2. Adult stem cells can be reproduced to create a "virtually limitless" supply**

Contrary to the assumptions expressed in the Guidelines, recent scientific evidence indicates the ability of adult stem cells to rapidly expand and implies that adult stem cells can be produced in ample quantities for biomedical applications. To be sure, adult stem cells are present in finite amounts throughout the human body, but the supply of human adult stem cells immediately available is much greater than previously thought.[37] Moreover, the number of available adult stem cells can be expanded greatly in culture. In March of 2000, researchers identified the conditions necessary to allow for a large-scale expansion (a billion-fold in a few weeks) of adult stem cells in culture.[38] Other researchers have confirmed the ability to rapidly and significantly expand the numbers of adult stem cells in culture, so that sufficient numbers of a variety of adult stem cells can be produced for clinical applications.[39]

Thus, scientific reports make clear that adult stem cells are readily accessible, can create a "virtually limitless" supply, and can even be transformed into other tissue types with use of a simple protocol.[40] Indeed, animal studies indicate that a *single* stem cell is sufficient to

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[37] *See, e.g.*, , J. D. Cashman and C. J. Eaves, "High marrow seeding efficiency of human lymphomyeloid repopulating cells in irradiated NOD/SCID mice," 96 Blood 3979 (Dec. 1 2000).

[38] D. Colter *et al.*, "Rapid Expansion of recycling stem cells in cultures of plastic-adherent cells from human bone marrow," 97 Proc. Natl. Acad. Sci. USA 3213 (Mar. 28, 2000).

[39] *See, e.g.* Cashman, *supra* at n. 36; L. Kobari *et al.*, "In vitro and in vivo evidence for the long-term multilineage (myeloid, B, NK, and T) reconstitution capacity of ex vivo expanded human CD34(+) cord blood cells," 28 Exp. Hematol. 1470 (Dec. 2000); G. L. Gilmore *et al.*, "Ex vivo expansion of human umbilical cord blood and peripheral blood CD34(+) hematopoietic stem cells," 28 Exp. Hematol. 1297 (Nov. 2000); G. Bhardwaj *et al.*, "Sonic hedgehog induces the proliferation of primitive human hematopoietic cells via BMP regulation" 2 Nature Immun. 172 (2001); A. Villa *et al.*, "Establishment and properties of a growth factor-dependent, perpetual neural stem cell line from the human CNS," 161 Exp. Neurol. 67 (Jan. 2000); D. Woodbury *et al.*, *supra* at n. 18; T. Ueda *et al.*, "Expansion of human NOD/SCID-repopulating cells by stem cell factor, Flk2/Flt3 ligand, thrombopoietin, IL-6, and soluble IL-6 receptor" 105 J. Clin. Invest. 1013 (April 2000).

[40] D. Woodbury, *supra* at n. 18.

repopulate adult bone marrow,[41] generate nerves,[42] and participate in tissue repair in a variety of tissues throughout the body.

In a nutshell, the arguments for federal funding of destructive human embryonic stem cell research rely on an outdated understanding that markedly underestimates the number of adult stem cells present in an adult human and the efficiency with which those cells can be reproduced. Studies published since the close of the Guidelines' comment period indicate that there will be no shortage of adult stem cells for clinical use.

### 3. The pluripotent nature of adult stem cells alleviates concerns about the difficulty of harvesting neural stem cells from humans

As discussed above, adult stem cells show great potential to transform from one tissue type into multiple other tissue types. Thus, at least some adult stem cells can be pluripotent in the sense that they can develop into cells and tissues of the three primary germ layers -- the ectoderm, the mesoderm, and the endoderm. For example, as noted above, human adult bone marrow stem cells have the capacity to transform into the following tissue types: muscle, cardiac blood vessels, neural cells, liver, bone, cartilage, and fat. *See supra*, § 1. Animal research suggests that the bone marrow stem cell could transform into virtually all tissue types.[43] Such research also indicates that adult neural stem cells have the ability to transform into virtually all tissue types.[44]

The Guidelines evinced a concern that adult neural stem cells were impracticable in clinical application because neural cells would be difficult to harvest. A finding of pluripotency for adult stem cells would make this and similar concerns irrelevant. If neural stem cells can easily be created from readily accessible adult bone marrow stem cells in human beings,[45] it will

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[41] *See* D.S. Krause *et al.*, "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell," 105 Cell 369 (May 4, 2001); M. Yagi *et al.*, "Sustained ex vivo expansion of hematopoietic stem cells mediated by thrombopoietin," 96 Proc. Natl. Acad. Sci. USA 8126 (July 1999).

[42] *See* N. Uchida *et al.*, "Direct isolation of human central nervous system stem cells," 97 Proc. Natl. Acad. Sci. USA 14720 (Dec. 19, 2000); S. Shihabuddin *et al.*, "Adult spinal cord stem cells generate neurons after transplantation in the adult dentate gyrus," 20 J Neuroscience 8727 (Dec. 2000).

[43] *See generally*, App. A, refs. 160-207. Even the staunchest supporters of embryonic stem cell research concede that "[b]one marrow stem cells probably can form any cell type." G. Vogel, "Can Adult Stem Cells Suffice?" 292 Science 1820 (June 8, 2001) (quoting Dr. Douglas Melton).

[44] *See, e.g.*, Clarke, *supra* at 28.

[45] *See, e.g.*, D. Woodbury, *supra* at n. 18.

not matter whether the harvesting of neural cells directly from adult humans would require difficult procedures such as surgery.

Aside from creating neural cells through a transformation of cell type, adult brain cells have also been isolated at locations that are more accessible and safer to harvest.[46] Indeed, researchers have determined that human adult neural stem cells can be isolated from cadavers.[47] Thus, as with other concerns discussed above, the suggestion that adult stem cell research and clinical applications suffer from a lack of adequate supply is not supported by the available evidence.

**4. Treatments using adult stem cells will not be prohibited by risks of "duplicating genetic error"**

The Guidelines asserted that adult stem cells are likely to be ineffective at combating genetic diseases because the patient's own stem cells would likely contain the same genetic error, making cells from the patient inappropriate for transplantation. But evidence from clinical studies to date belies this assertion. The first successful human gene therapy used "remedied" adult stem cells -- not embryonic stem cells -- to cure severe combined immunodeficiency syndrome.[48] Not only can genetic error be remedied while adult stem cells are in culture, but in many cases the correction of the genetic defect may not be necessary to effect a cure with adult stem cells. For example, patients with systemic lupus have been treated with their own adult bone marrow stem cells which repaired organ damage that was previously considered permanent. This repair occurred without correcting the genetic defect present in the bone marrow cells.[49]

In sum, a patient's genetic deficiency does not preclude the use of his or her own stem cells for therapeutic purposes. In fact, as discussed below, the use of one's own stem cells is medically and scientifically preferable to the use of embryonic stem cells derived from another human being, because the transplantation of embryonic stem cells may carry with it a severe risk of immune rejection and tumor formation.

**5. Adult stem cells have been used in many clinical trials with great success**

Contrary to the impression created by advocates of destructive human embryonic stem cell research, the biomedical potential of embryonic stem cells remains entirely speculative, because such cells have *never* been successfully used in clinical applications with human

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[46] Pagano, *supra* at n. 1.

[47] Palmer, *supra* at n. 1.

[48] M. Cavazzana-Calvo *et al.*, "Gene therapy of human severe combined immunodeficiency (SCID)-X1 disease," 288 Science 669 (Apr. 28, 2000).

[49] A.E. Traynor *et al.*, "Treatment of severe systemic lupus erythematosus with high-dose chemotherapy and haemopoietic stem-cell transplantation: a phase I study," 356 Lancet 701 (Aug. 26, 2000).

patients. *See infra*, § 7. By contrast, adult stem cells already have been used in a variety of human clinical trials and applications with considerable success. Indeed, because researchers have found that stem cells in the bone marrow were the chief therapeutic agent in whole marrow transplants, many treatments which previously relied on transplant of unfractionated bone marrow now use transplants of bone marrow stem cells instead. Such treatments include applications for various types of cancer, including but not limited to: brain tumors,[50] retinoblastoma,[51] ovarian cancer,[52] various solid tumors,[53] testicular cancer,[54] multiple myeloma and leukemias,[55] breast cancer,[56] neuroblastoma,[57] non-Hodgkin's lymphoma,[58] and renal cell carcinoma.[59] Adult stem cells have also been used in treatment of autoimmune diseases such as multiple sclerosis, systemic lupus, rheumatoid arthritis, and juvenile rheumatoid arthritis,[60] immunodeficiencies and anemias,[61] stroke,[62] and cartilage and bone diseases.[63] Adult stem cells have been used to regenerate corneas, restoring sight to previously blind patients,[64] and also to combat blood and liver diseases.[65] Recently the positive results from the first successful human trials of adult stem cells to treat cardiac damage were published.[66]

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[50] App. A, refs. 1-3.

[51] *Id.* at refs. 4-5.

[52] *Id.* at refs. 6-7.

[53] *Id.* at refs. 8-13.

[54] *Id.* at refs. 14-15.

[55] *Id.* at refs. 16-27.

[56] *Id.* at refs. 28-31.

[57] *Id.* at ref. 32.

[58] *Id.* at refs. 33-35.

[59] *Id.* at refs 36-37.

[60] *Id.* at refs. 38-51.

[61] *Id.* at refs. 53-62.

[62] *Id.* at ref. 52.

[63] *Id.* at refs. 65-66.

[64] *Id.* at refs. 67-74.

[65] *Id.* at refs. 75-76.

[66] *See* P. Menasché, *supra* at n. 35; *see generally*, App. A, Refs. 78-82 (collecting reports regarding clinical treatment of heart damage using non-embryonic human stem cells).

Simply stated, adult stem cells are already being used in a wide array of human clinical trials, with many therapeutic applications having moved well beyond the experimental stage. Thus, adult stem cells are presently providing the results only promised by advocates of destructive embryonic stem cell research. There can be little doubt that as we learn more about adult stem cells, they will be even more successfully employed to fight the diseases noted above and to combat other diseases and conditions, such as diabetes and paralysis.

**6. Adult stem cells have been used successfully in treatment of numerous animal models of disease**

The scientific record provides strong evidence for the conclusion that adult stem cells will be applied to biomedical technologies to treat a host of other human diseases and conditions. Adult and other non-embryonic stem cells have already been used successfully in treatment of various animal models of disease, including nerve and spinal cord damage,[67] retinal damage,[68] Parkinson's disease,[69] heart damage,[70] muscular dystrophy,[71] diabetes,[72] stroke,[73] and liver disease.[74] Adult stem cells also appear to possess an ability to "home" to sites of damaged tissue in the body, repairing damaged tissue and even attacking tumors.[75]

There is every reason to believe that these studies will yield positive results in human application as well. As these studies move from animal models to clinical application, adult stem cells will be our best hope for fighting those diseases in the near term.

**7. By contrast, human embryonic stem cells have never successfully been used in clinical trials, have had lackluster success in combating animal models of disease, and carry significant risks, including immune rejection, tumor formation, and genomic instability**

Human embryonic stem cells have never been used successfully in clinical trials. Thus, unlike adult stem cells, their biomedical potential is purely speculative. And any speculative clinical use remains a distant hope. Indeed, in contrast to human adult stem cells, human

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[67] App. A. at refs. 116, 125, 126, 131, 136, 137, and 215.

[68] *Id.* at ref. 138.

[69] *Id.* at ref. 115.

[70] *Id.* at refs. 148-150, 152-153, 159-161, 170-172, and 178.

[71] *Id.* at refs. 151, 155, 156.

[72] *Id.* at ref. 168.

[73] *Id.* at refs. 173, 174, 246.

[74] *Id.* at ref. 223.

[75] *Id.* at refs. 118, 151, 169, 173, 180, 181, and 246.

embryonic stem cells have not been successfully coaxed to transform into pure populations of most cell and tissue types, even in treatment of animal models of disease.[76]

Although human embryonic stem cells may exhibit impressive plasticity due to their potency, this plasticity has proven to be a double-edged sword, as embryonic stem cells have been difficult to control in laboratories.[77] The inability to successfully control embryonic stem cells in the controlled atmosphere of a laboratory does not suggest that they have a high probability of successful use in therapeutic treatments. In contrast, adult stem cells have proven to be relatively easy to control.

Fetal tissue transplants provide a cautionary example of the potential for problems using developmentally-young cells such as embryonic stem cells, which are difficult to direct along specific and controlled developmental pathways. In one instance, fetal tissue derived from early fetuses was transplanted into an individual's brain, resulting in no viable neurons but instead producing non-specific differentiation into numerous non-brain tissues within the patient's brain.[78]

Moreover, in the most extensive controlled study of fetal brain tissue transplantation for Parkinson's disease, the transplants showed little or no benefit to most patients. Fetal brain tissue was transplanted into the brains of patients to regenerate or replace the cells missing or damaged due to Parkinson's disease, the theory being that these young cells would take over

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[76] In fact, these experiments have yielded disastrous results, as implanted embryonic stem cells have literally killed the cells of their host after transplantation. *See, e.g.*, G. Vogel, "Stem Cells: New excitement, persistent questions," 290 Science 1672 (Dec 1, 2000) (describing an experiment performed at Geron Corp. implanting human embryonic stem cells into rats, where the implanted embryonic stem cells "did not readily differentiate," and instead caused the neural cells "near them . . . to die"). In stark contrast, experiments in which human *adult* bone marrow stem cells were injected into rat brains to repair damaged brain tissue -- experiments performed over 3 years ago -- yielded remarkably successful results. *See, e.g.*, S.A. Azizi *et al.*, "Engraftment and migration of human bone marrow stromal cells implanted in the brains of albino rats-similarities to astrocyte grafts," 95 Proc. Natl. Acad. Sci. USA 3908 (March 1998) (reporting that human bone marrow stromal cells had the ability to repair damaged rat brain tissue without inflammatory response or rejection).

[77] *See, e.g.*, M. Schuldiner *et al.*, "Effects of eight growth factors on the differentiation of cells derived from human embryonic stem cells," 97 Proc. Natl. Acad. Sci. USA 11307 (Oct. 10, 2000) (study using human embryonic stem cells indicated that "none of the eight growth factors tested directs a completely uniform and singular differentiation of cells"); G. Vogel, *supra* at n. 42 ("And so far, reports of pure cell populations derived from either human or mouse ES cells are few and far between -- fewer than those from adult cells.").

[78] R. D. Folkerth, R. Durso, "Survival and proliferation of nonneural tissues, with obstruction of cerebral ventricles, in a parkinsonian patient treated with fetal allografts," 46 Neurology 1219 (May 1996).

production of the missing brain chemical dopamine. However, there were horrific results for some patients, with transplanted fetal cells going out of control and producing irreversible and devastating changes in the patients' brains.[79]

Significantly, embryonic stem cells also face a substantial risk of immune rejection, similar to the risks present in organ transplantation.[80] These risks include the rejection of the transplanted tissue, as well as the possibility of the transplant attacking the host, or even forming tumors.[81] In stark contrast, the re-transplantation of a patient's own adult stem cells carries with it no risk of immune rejection since the cells are the patient's own.

Scientists have not developed an effective strategy to combat the problems of tumor formation and immune rejection. Until they do, human embryonic stem cells have no realistic potential to be used for therapeutic purposes.

Indeed, advocates of destructive embryonic stem cell research have recently stated that embryonic stem cell regenerative technologies will, by themselves, be *unable to provide effective therapeutic treatments*. Instead, they claim, embryonic stem cell technology must be applied to human embryos produced by cloning if it is to achieve biomedical application.[82] The reason is simple: although human embryonic stem cells exhibit tremendous plasticity, they lead to immune

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[79] *See* C. R. Freed *et al.*, "Transplantation of embryonic dopamine neurons for severe Parkinson's disease," 344 New England Journal of Medicine 710 (Mar. 8, 2001); G. Kolata, "Parkinson's Stem Cell Implants Yield Nightmarish Side Effects," New York Times (March 8, 2001).

[80] *See, for discussion*, Serup, *supra* at n. 4; J. Thomson *et al.*, "Embryonic Stem Cell Lines Derived from Human Blastocysts," 282 Science 1145 (Nov. 6, 1998) (noting that strategies need to be developed to "prevent immune rejection of transplanted [embryonic stem] cells"); *see also*, Thomas Okarma, Prepared Witness Testimony before the Subcommittee on Health (hearings regarding H.R. 1644, Human Cloning Prohibition Act of 2001) (June 20, 2001) (noting the "need" for cloning, given the risks of immune rejection that embryonic stem cells face when implanted into a host), *available at* <http://energycommerce.house.gov/107/hearings /06202001Hearing291/Okarma450print.htm>.

[81] *See, e.g.*, Johns Hopkins Medical Institutions Office of Communications and Public Affairs, "New Lab-Made Stem Cells May Be Key To Transplants," (Dec. 25, 2000) (quoting embryonic stem-cell researcher Dr. Michael Shamblott as stating, when "coaxing [embryonic stem cells] to differentiate -- to form nerve cells and the like -- you risk contaminating the newly differentiated cells with the stem cells. . . . Injected into the body, stem cells can produce tumors"); G. Vogel, "Can Adult Stem Cells Suffice?," *supra* at n. 42 ("E[mbryonic ]S[tem] cells have a disturbing ability to form tumors, and researchers aren't yet sure how to counteract that").

[82] *See* Okarma, *supra* at n. 79 ("Somatic cell nuclear transfer [*i.e.*, cloning] is *essential* if we are to achieve our goals in regenerative medicine.") (emphasis added).

rejection. A cloned embryo, however, has the same genetic code as the donor, and thus transplantation of a pluripotent cell from this embryo into its "original" may "avoid complications due to immune response rejection."[83] Thus, embryonic stem cell research may be merely a tool to understanding how pluripotent cells function, a stepping stone to open the door for what some call "therapeutic cloning."[84]

But this door is closed, providing further confirmation that the NIH should not waste precious research dollars funding speculative embryonic stem cell research that will never result in effective medical treatments. The Bush Administration has announced its opposition to human cloning for any purpose, including research purposes.[85] If the ultimate goals and hypothetical applications of human embryonic stem cell research depend on cloning, which is directly contrary to the position of this Administration, it would be wholly inappropriate -- and directly contrary to the Administration's policy on cloning -- to fund embryonic stem cell research.

Finally, the Guidelines assert that adult stem cells may be more difficult to grow and may contain more DNA abnormalities than younger, embryonic stem cells. Although these assertions are of questionable merit, it is important to note that embryonic stem cells in fact suffer from these defects that the Guidelines attribute to adult stem cells alone.

As demonstrated above, adult stem cells have proven to be relatively easy to grow. *See supra*, § 2. In contrast, even proponents of embryonic stem cell research have noted that embryonic stem cells are "tedious to grow," and that "simply keeping human embryonic stem

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[83] *Id.*

[84] Mr. Okarma explains the process as follows: "Once we fully understand re-programming[, the process of making a differentiated cell a pluripotent cell,] we will be able to develop specific cells[, using the knowledge that will be acquired from studying embryonic stem cells,] for transplantation without immune rejection." *Id.* Thus, advocates of destructive human embryonic stem cell and cloning research seek to learn technologies from cells created through the destruction of human embryos that then can be applied to technologies using clones -- individuals who will necessarily be destroyed as they are used for research purposes -- all in an attempt to avoid immune rejection and tumor formation, *side effects to regenerative therapies that are already avoidable by employing effective autologous transplants using adult stem cells. See, e.g.,* Azizi, *supra* at n. 75.

[85] Claude Allen, Prepared Witness Testimony before the Subcommittee on Health (hearings regarding H.R. 1644, Human Cloning Prohibition Act of 2001) (June 20, 2001) (speaking on behalf of the administration, stating that "we oppose the use of human somatic cell nuclear transfer cloning techniques either to assist human reproduction or to develop cell- or tissue-based therapies," because cloning "would pose deeply troubling moral and ethical issues for humankind").

cells alive can be a challenge."[86] Not only is there difficulty in consistently coaxing human embryonic stem cells to differentiate into the desired cell and tissue type, but also there is the more fundamental problem of keeping embryonic stem cell lines alive.

In addition, embryonic stem cells face the risk of mutation with every successive generation. Thus, "[c]ells derived from stem cells that have replicated through many generations will have accumulated mutations and be susceptible to cancer or have decreased viability."[87] The phenomenon of mutation is controlled by the number of divisions a cell line has undergone, and not its chronological age.[88] Thus, an embryonic stem cell line, kept alive in a lab for successive generations, has an equal or greater chance of exhibiting undesirable characteristics compared to the adult stem cells harvested from a patient for purposes of autologous transplantation.

Moreover, a study published in the July 6th issue of the journal *Science* points to potentially significant problems with the possibility of using embryonic stem cells for "therapeutic" treatments.[89] In the study, mice were cloned from mouse embryonic stem cells, and even apparently healthy cloned animals had abnormalities that would be difficult to detect but could lead to disastrous disorders later in life. The abnormalities could be traced back to the embryonic stem cells themselves; gene expression of the embryonic stem cells "was found to be extremely unstable", even in the laboratory culture dish. It was noted that the problems likely reflect changes that occurred during culture even from a single embryonic stem cell. This instability in gene expression suggests that using embryonic stem cells to treat health disorders may not work nearly so well as some scientists have suggested, and would likely limit any use of embryonic stem cells in clinical applications.

**Conclusion: Compared with embryonic stem cells, adult stem cells have at least as great, if not greater, potential for biomedical application, but without the medical risks or the ethical controversy**

The biomedical potential of adult stem cells is enormous. Adult stem cells have already been used successfully in treatments for diseases such as multiple sclerosis, lupus, renal cell carcinoma, and breast cancer, with encouraging results. Moreover, animal models using adult stem cell treatments indicate that therapeutic treatments for pernicious diseases such as diabetes,

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[86] G. Vogel, "Stem cells: New excitement, persistent questions," *supra* at n. 75 (quoting Dr. Peter Andrews of University of Sheffield, England).

[87] L. Roccanova, P. Ramphal, P. Rappa III, "Mutation in Embryonic Stem Cells," 292 Science 438 (Apr. 20, 2001).

[88] *Id.* (citing J. Smith, O. M. Pereira-Smith, 273 Science 63).

[89] D. Humpherys *et al.*; "Epigenetic Instability in ES Cells and Cloned Mice"; 293 Science 95 (July 6, 2001).

heart disease, Parkinson's, and stroke are well within the vast therapeutic capabilities of adult stem cells.

Additionally, science is continuing to discover human adult stem cells for an increasing number of cell and tissue types. Furthermore, studies of the pluripotent nature of human adult stem cells as readily accessible as stem cells from fat or bone marrow are yielding impressive results, and strongly suggest that some adult stem cells have the capacity to transform into all significant cell and tissue types. This transformative power of adult stem cells, unrecognized by the Guidelines, has caused one reviewer to remark that "[r]ecent studies have revealed that much of this remarkable developmental potential of embryonic stem cells is retained by small populations of cells within most tissues in the adult."[90] In this respect, recent evidence indicates overlapping genetic programs in hematopoietic and neural stem cells, leading some researchers to propose that some genes are functionally conserved "to participate in basic stem cell functions, including stem cell self-renewal."[91] One recent review proposes that "rather than referring to a discrete cellular entity, a stem cell most accurately refers to a biological function that can be induced in many distinct types of cells, even differentiated cells."[92] The authors liken the circulatory system to a "stem cell highway" in which adult stem cells may migrate from tissue to tissue, taking "on-ramps" and entering tissues to generate appropriate cell types in response to homing and growth signals ("billboards") as required, with all choices reversible. Critics of adult stem cell research have attempted to discredit the findings, claiming that adult stem cell studies are published in journals that are not peer-reviewed. This is simply false. The remarkable achievements with adult stem cells are published in the most prestigious scientific and medical journals in the world, as well as peer-reviewed scientific specialty journals; indeed, these are the same journals in which proponents of embryonic stem cell research have published their own findings (please see Appendix D for a sample listing of journals.)

Whereas human adult stem cells continue to surpass the Guidelines' expectations and amaze observers, embryonic stem cells have yet to live up to their billing as the new fountain of youth. Embryonic stem cells have proven to be difficult to work with, and carry with them significant risks that cast doubt upon their therapeutic viability.[93] Indeed, some now say that human cloning might be necessary if embryonic stem cells could ever have clinical application to human beings -- a result that is directly contrary to the stated policy positions of this Administration. The shortcomings of embryonic stem cells, contrasted with the capability of adult stem cells, have led scientists to conclude that "adult stem cells have several advantages as

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[90] M. S. Rao and M. P. Mattson, "Stem cells and aging: expanding the possibilities"; 122 Mech. Ageing Dev. 713 (May 31, 2001)

[91] Terskikh AV *et al.*; "From hematopoiesis to neuropoiesis: Evidence of overlapping genetic programs"; 98 Proc. Natl. Acad. Sci. USA 7934 (July 3, 2001).

[92] Blau *et al.*; "The Evolving Concept of a Stem Cell: Entity or Function?"; 105 Cell 829 (June 29, 2001)

[93] *See generally*, G. Vogel, "Stem cells: New excitement, persistent questions," *supra* at n. 75.

compared with embryonic stem cells in their practical therapeutic application for tissue regeneration."[94]

Finally, it is worth noting that the National Bioethics Advisory Commission ("NBAC"), which recommended federally funding research using embryonic stem cells under the assumption that embryonic stem cells "offer greater promise of therapeutic breakthroughs," noted that "the derivation of stem cells from embryos . . . is justifiable *only if no less morally problematic alternatives are available for advancing the research.*"[95] There can be little doubt at this time that adult stem cells provide equal, if not greater, potential for biomedical application as compared with embryonic stem cells. Thus, applying NBAC's own standard, the scientific record indicates that federal funding of destructive human embryonic stem cell research is not justifiable. Indeed, less morally problematic alternatives for advancing the research *are* available, due to the stunning promise of research using adult stem cells.

Mr. Chairman, Distinguished Members, I thank you for the opportunity to provide testimony on this important issue, and I would be pleased to answer any questions.

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[94] T. Asahara, C. Kalka, and J. M. Isner, "Stem cell therapy and gene transfer for regeneration," 7 Gene Ther. 451 (March 2000); *See generally*, Do No Harm: The Coalition of Americans for Research Ethics, "Stem Cell Report: Advances in Alternatives to Embryonic Stem Cell Research," available at <http://www.stemcellresearch.org/stemcellreport.htm> (collecting press reports and scientific articles that suggest adult stem cell research is scientifically preferable to embryonic stem cell research).

[95] National Bioethics Advisory Commission, "Ethical Issues in Human Stem Cell Research," at 53 (Sept. 1999) (emphasis added).

# APPENDIX A

Selected References Documenting the Scientific Advances in Stem Cell Research using Stem Cells which are not derived from embryos.

The majority of the sources cited in this reference list are articles published in peer-reviewed scientific and medical journals. Some are reviews of scientific research. This document is organized by subject area, so some references may appear more than once.

## I. CURRENT CLINICAL APPLICATIONS SUCCESSFULLY USING HUMAN ADULT STEM CELLS TO COMBAT DISEASES AND CONDITIONS

### A. CANCER TREATMENTS

#### (1) Brain Tumors


1. Dunkel, IJ; "High-dose chemotherapy with autologous stem cell rescue for malignant brain tumors"; Cancer Invest. 18, 492-493; 2000.

2. Abrey, LE *et al.*; "High dose chemotherapy with autologous stem cell rescue in adults with malignant primary brain tumors"; J. Neurooncol. 44, 147-153; Sept.. 1999.

3. Finlay, JL; "The role of high-dose chemotherapy and stem cell rescue in the treatment of malignant brain tumors: a reappraisal"; Pediatr. Transplant 3 Suppl. 1, 87-95; 1999 (a review of high-dose chemotherapy and stem cell transplant for children with brain tumors).


#### (2) Retinoblastoma


4. Hertzberg, H *et al.*; "Recurrent disseminated retinoblastoma in a 7-year-old girl treated successfully by high-dose chemotherapy and CD34-selected autologous peripheral blood stem cell transplantation"; Bone Marrow Transplant 27(6), 653-655; March 2001.

5. Dunkel, IJ *et al.*; "Successful treatment of metastatic retinoblastoma"; Cancer 89, 2117-2121; Nov. 15, 2000.


#### (3) Ovarian Cancer


6. Stiff, PJ *et al.*; "High-dose chemotherapy and autologous stem-cell transplantation for ovarian cancer: An autologous blood and marrow transplant registry report"; Ann. Intern. Med. 133, 504-515; Oct. 3, 2000.

7. Schilder, RJ and Shea, TC; "Multiple cycles of high-dose chemotherapy for ovarian cancer"; Semin. Oncol. 25, 349-355; June 1998.


#### (4) Solid Tumors


8. Nieboer P *et al.*; "Long-term haematological recovery following high-dose chemotherapy with autologous bone marrow transplantation or peripheral stem cell transplantation in patients with solid tumours"; Bone Marrow Transplant 27, 959-966; May 2001

9. Waldmann, V *et al.*; "Transient complete remission of metastasized merkel cell carcinoma by high-dose polychemotherapy and autologous peripheral blood stem cell transplantation"; Br. J. Dermatol. 143, 837-839; Oct. 2000.

**10.** Blay, JY *et al.*; "High-dose chemotherapy with autologous hematopoietic stem-cell transplantation for advanced soft tissue sarcoma in adults"; J. Clin. Oncol. 18, 3643-3650; Nov. 1, 2000.

**11.** Lafay-Cousin, L *et al.*; "High-dose thiotepa and hematopoietic stem cell transplantation in pediatric malignant mesenchymal tumors: a phase II study"; Bone Marrow Transplant 26, 627-632; Sept.. 2000.

**12.** Michon, J and Schleiermacher, G.; "Autologous haematopoietic stem cell transplantation for paediatric solid tumors"; Baillieres Best Practice Research in Clinical Haematology 12, 247-259; March-June, 1999.

**13.** Schilder, RJ *et al.*; "Phase I trial of multiple cycles of high-dose chemotherapy supported by autologous peripheral-blood stem cells"; J. Clin. Oncol. 17, 2198-2207; July 1999.

**(5) Testicular Cancer**

**14.** Bhatia, S *et al.*; "High-dose chemotherapy as initial salvage chemotherapy in patients with relapsed testicular cancer"; J. Clin. Oncol. 18, 3346-3351; Oct. 19, 2000.

**15.** Hanazawa, K *et al.*; "Collection of peripheral blood stem cells with granulocyte-colony-stimulating factor alone in testicular cancer patients"; Int. J. Urol. 7, 77-82; March 2000.

**(6) Multiple Myeloma; Leukemias**

**16.** Laughlin, MJ *et al.*; "Hematopoietic engraftment and survival in adult recipients of umbilical-cord blood from unrelated donors"; New England J. of Medicine 344, 1815-1822; June 14, 2001.

**17.** Tabata M *et al.*; "Peripheral blood stem cell transplantation in patients over 65 years old with malignant lymphoma--possibility of early completion of chemotherapy and improvement of performance status"; Intern Med 40, 471-474; June 2001

**18.** Koizumi M *et al.*; "Successful treatment of intravascular malignant lymphomatosis with high-dose chemotherapy and autologous peripheral blood stem cell transplantation"; Bone Marrow Transplant 27, 1101-1103; May 2001

**19.** Ohnuma, K *et al.*; "Cord blood transplantation from HLA-mismatched unrelated donors as a treatment for children with haematological malignancies"; Br. J. Haematol. 112(4), 981-987; March 2001.

**20.** Lindahl, J *et al.*; "High-dose chemotherapy and APSCT as a potential cure for relapsing hemolysing AILD"; Leuk. Res. 25(3), 267-270; March 2001.

**21.** Bensinger, WI *et al.*; "Transplantation of bone marrow as compared with peripheral-blood cells from HLA-identical relatives in patients with hematologic cancers"; New

England J. of Medicine 344, 175-181; Jan. 18, 2001 (review of new procedures involving stem cell transplantation).

**22.** Margolis, J *et al.*; "New approaches to treating malignances with stem cell transplantation"; Semin. Oncol. 27, 524-530; Oct. 2000.

**23.** Gorin, NC *et al.*; "Feasibility and recent improvement of autologous stem cell transplantation for acut myelocytic leukaemia in patients over 60 years of age: importance of the source of stem cells"; Br. J. Haematol. 110, 887-893; Sept. 2000.

**24.** Marco, F *et al.*; "High Survival Rate in Infant Acute Leukemia Treated With Early High-Dose Chemotherapy and Stem-Cell Support"; J. Clin. Oncol. 18, 3256-3261; Sept. 15, 2000.

**25.** Nagler, A *et al.*; "Second allogeneic stem cell transplantation using nonmyeloablative conditioning for patients who relapsed or developed secondary malignancies following autologous transplantation"; Exp. Hematol. 28, 1096-1104, Sept. 1, 2000

**26.** Bruserud, O *et al.*; "New strategies in the treatment of acute myelogenous leukemia: mobilization and transplantation of autologous peripheral blood stem cells in adult patients"; Stem Cells 18, 343-351; 2000 (Review of autologous stem cell treatment strategies noting a variety of positive results).

**27.** Vesole, DH *et al.*; "High-Dose Melphalan With Autotransplantation for Refractory Multiple Myeloma: Results of a Southwest Oncology Group Phase II Trial"; J. Clin. Oncol. 17, 2173-2179; July 1999.

(7) **Breast Cancer**

**28.** Damon, LE *et al.*; "High-dose chemotherapy and hematopoietic stem cell rescue for breast cancer: experience in California"; Biol. Blood Marrow Transplant 6, 496-505; 2000.

**29.** Paquette, RL *et al.*, "Ex vivo expanded unselected peripheral blood: progenitor cells reduce posttransplantation neutropenia, thrombocytopenia, and anemia in patients with breast cancer", Blood 96, 2385-2390; Oct. 2000.

**30.** Stiff, P *et al.*; "Autologous transplantation of ex vivo expanded bone marrow cells grown from small aliquots after high-dose chemotherapy for breast cancer"; Blood 95, 2169-2174; March 15, 2000.

**31.** Koc, ON *et al.*; "Rapid Hematopoietic Recovery After Coinfusion of Autologous-Blood Stem Cells and Culture-Expanded Marrow Mesenchymal Stem Cells in Advanced Breast Cancer Patients Receiving High-Dose Chemotherapy"; J. Clin. Oncol. 18, 307-316; Jan. 2000.

**(8) Neuroblastoma**

**32.** Kawa, K *et al.*; "Long-Term Survivors of Advanced Neuroblastoma With MYCN Amplification: A Report of 19 Patients Surviving Disease-Free for More Than 66 Months"; J. Clin. Oncol. 17:3216-3220; Oct. 1999.

**(9) Non-Hodgkin's Lymphoma**

**33.** Josting, A; "Treatment of Primary Progressive Hodgkin's and Aggressive Non-Hodgkin's Lymphoma: Is There a Chance for Cure?"; J. Clin. Oncol. 18, 332-339; 2000.

**34.** Kirita, T *et al.*; "Primary non-Hodgkin's lymphoma of the mandible treated with radiotherapy, chemotherapy, and autologous peripheral blood stem cell transplantation"; Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod. 90, 450-455; Oct. 2000.

**35.** Yao, M *et al.*; "Ex vivo expansion of CD34-positive peripheral blood progenitor cells from patients with non-Hodgkin's lymphoma: no evidence of concomitant expansion of contaminating bcl2/JH-positive lymphoma cells"; Bone Marrow Transplant 26, 497-503; Sept.. 2000.

**(10) Renal Cell Carcinoma**

**36.** Childs, R *et al.*; "Regression of Metastatic Renal-Cell Carcinoma after Nonmyeloablative Allogeneic Peripheral-Blood Stem-Cell Transplantation"; New England J. of Medicine 343, 750-758; Sept. 14, 2000.

**37.** Childs, RW; "Successful Treatment of Metastatic Renal Cell Carcinoma With a Nonmyeloablative Allogeneic Peripheral-Blood Progenitor-Cell Transplant: Evidence for a Graft-Versus-Tumor Effect"; J. Clin. Oncol. 17, 2044-2049; July 1999

**B. TREATMENTS FOR AUTOIMMUNE DISEASES**

**Multiple Sclerosis, Systemic Lupus Erythematosus, Juvenile Rheumatoid Arthritis, Rheumatoid Arthritis**

**38.** Mancardi GL *et al.*; "Autologous hematopoietic stem cell transplantation suppresses Gd-enhanced MRI activity in MS"; Neurology 57, 62-68; July 10, 2001 (describing use of combined therapy with using a patient's own stem cells for treatment of severe cases of multiple sclerosis. Treatment decreased tissue damage in the patients, and had the capacity to completely suppress further tissue damage, an effect that is sustained with time.)

**39.** Verburg, RJ *et al.*; "High-dose chemotherapy and autologous hematopoietic stem cell transplantation in patients with rheumatoid arthritis: results of an open study to assess feasibility, safety, and efficacy"; Arthritis Rheum. 44(4), 754-760; April 2001.

**40.** Wulffraat, NM *et al.*; "Prolonged remission without treatment after autologous stem cell transplantation for refractory childhood systemic lupus erythematosus"; Arthritis Rheum. 44(3), 728-731; March 2001.

**41.** Rosen, O *et al.*; "Autologous stem-cell transplantation in refractory autoimmune diseases after in vivo immunoablation and ex vivo depletion of mononuclear cells"; Arthritis Res. 2, 327-336; 2000.

**42.** Rabusin, M *et al.*; "Immunoablation followed by autologous hematopoietic stem cell infusion for the treatment of severe autoimmune disease"; Haematologica 85(11 Suppl.), 81-85; Nov.. 2000.

**43.** Papadaki, HA *et al.*; "Assessment of bone marrow stem cell reserve and function and stromal cell function in patients with autoimmune cytopenias"; Blood 96, 3272-3275; Nov. 1, 2000.

**44.** Traynor, AE *et al.*; "Treatment of severe systemic lupus erythematosus with high-dose chemotherapy and haemopoietic stem-cell transplantation: a phase I study"; Lancet 356, 701-707; Aug. 26, 2000.

**45.** Burt, RK and Traynor, AE; "Hematopoietic Stem Cell Transplantation: A New Therapy for Autoimmune Disease"; Stem Cells17, 366-372; 1999 (review of stem cell treatments to combat juvenile rheumatoid arthritis; multiple sclerosis; rheumatoid arthritis; systemic lupus erythematosus).

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**48.** Martini, A *et al.*; "Marked and sustained improvement 2 years after autologous stem cell transplant in a girl with system sclerosis"; Rheumatology 38, 773; Aug. 1999.

**49.** Hawkey, CJ *et al.*; "Stem cell transplantation for inflammatory bowel disease: practical and ethical issues"; Gut 46, 869-872; June 2000.

**50.** Burt, RK *et al.*; "Autologous hematopoietic stem cell transplantation in refractory rheumatoid arthritis: sustained response in two of four patients"; Arthritis & Rheumatology 42, 2281-2285; Nov. 1999.

**51.** Burt, RK *et al.*, "Gene-marked autologous hematopoietic stem cell transplantation of autoimmune disease"; J. of Clinical Immunology 20, 1-9; Jan. 2000.

## C. TREATMENTS FOR STROKE

**52.** Kondziolka, D *et al.*; "Transplantation of cultured human neuronal cells for patients with stroke"; Neurology 55, 565-569; Aug. 2000.

## D. TREATMENTS FOR IMMUNODEFICIENCIES

**53.** Ziegner, UH *et al.*; "Unrelated umbilical cord stem cell transplantation for X-linked immunodeficiencies"; J Pediatr 138(4), 570-573; April 2001.

**54.** Amrolia, P. *et al.*; "Nonmyeloablative stem cell transplantation for congenital immunodeficiencies"; Blood 96, 1239-1246; Aug. 15, 2000.

## E. TREATMENTS FOR ANEMIAS

**55.** Ayas M *et al.*; "Congenital sideroblastic anaemia successfully treated using allogeneic stem cell transplantation"; Br J Haematol 113, 938-939; June 2001

**56.** Anagnostopoulos A *et al.*; "High-dose chemotherapy followed by stem cell transplantation in patients with resistant Waldenstrom's macroglobulinemia"; Bone Marrow Transplant 27, 1027-1029; May 2001

**57.** Gurman, G *et al.*; "Allogeneic peripheral blood stem cell transplantation for severe aplastic anemia"; Ther. Apher. 5(1), 54-57; Feb. 2001.

**58.** Steen, RG *et al.*; "Improved cerebrovascular patency following therapy in patients with sickle cell disease: initial results in 4 patients who received HLA-identical hematopoietic stem cell allografts"; Ann. Neurol. 49(2), 222-229; Feb. 2001.

**59.** Gonzalez, MI *et al.*; "Allogeneic peripheral stem cell transplantation in a case of hereditary sideroblastic anaemia"; British J. of Haematology 109, 658-660; 2000.

**60.** Kook, H *et al.*; "Rubella-associated aplastic anemia treated by syngeneic stem cell transplantations"; Am. J. Hematol. 64, 303-305; Aug. 2000.

**61.** Wethers, DL; "Sickle cell disease in childhood: Part II. Diagnosis and treatment of major complications and recent advances in treatment"; Am. Fam. Physician 62, 1309-1314; Sept.. 15, 2000.

**62.** Yesilipek *et al.*; "Peripheral stem cell transplantation in a child with amegakaryocytic thrombocytopenia"; Bone Marrow Transplant 26, 571-572; Sept.. 2000

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**63.** Fujii, N *et al.*; "Allogeneic peripheral blood stem cell transplantation for the treatment of chronic active epstein-barr virus infection"; Bone Marrow Transplant 26, 805-808; Oct. 2000.

**64.** Okamura, T *et al.*; "Blood stem-cell transplantation for chronic active Epstein-Barr virus with lymphoproliferation"; Lancet 356, 223-224; July 2000.

## G. TREATMENTS FOR CARTILAGE AND BONE DISEASES

**65.** Robinson, D *et al.*; "Characteristics of cartilage biopsies used for autologous chondrocytes transplantation"; Cell Transplant 10(2), 203-208; March-April 2001.

**66.** Horwitz, EM *et al.*; "Transplantability and therapeutic effects of bone marrow-derived mesenchymal cells in children with osteogenesis imperfecta"; Nat. Med. 5, 309-313; March 1999.

## H. TREATMENTS FOR CORNEAL SCARRING

**67.** James SE *et al.*; "The Potential for Eye Bank Limbal Rings to Generate Cultured Corneal Epithelial Allografts"; Cornea 20, 488-494; July 2001
(Confluent sheets of cultured corneal epithelial cells, suitable for grafting, can be produced from limbal tissue taken from eye bank organ-cultured corneas, although it takes longer, on average, to reach confluence (17–21 days) than an equivalent sample from a fresh eye (9–12 days).)

**68.** Anderson, DF *et al.*; "Amniotic Membrane Transplantation After the Primary Surgical Management of Band Keratopathy"; Cornea 20(4), 354-361; May 2001.

**69.** Anderson, DF *et al.*; "Amniotic membrane transplantation for partial limbal stem cell deficiency"; Br. J. Ophthalmol. 85(5), 567-575; May 2001.

**70.** Henderson, TR *et al.*; "The long term outcome of limbal allografts: the search for surviving cells"; Br. J. Ophthalmol. 85(5), 604-609; May 2001.

**71.** Daya, SM and Ilari, FA; "Living related conjuctival limbal allograft for the treatment of stem cell deficiency"; Opthalmology 180, 126-133; Jan. 2001.

**72.** Schwab, IR *et al.*; "Successful transplantation of bioengineered tissue replacements in patients with ocular surface disease"; Cornea 19, 421-426; July 2000.

**73.** Tsai *et al.*; "Reconstruction of damaged corneas by transplantation of autologous limbal epithelial cells."; New England J. of Medicine 343, 86-93; 2000.

**74.** Tsubota, K *et al.*; "Treatment of severe ocular-surface disorders with corneal epithelial stem-cell transplantation"; New England J. of Medicine 340, 1697-1703; June 3, 1999.

### I. TREATMENTS FOR BLOOD AND LIVER DISEASE

**75.** Matthes-Martin, S *et al.*; "Successful stem cell transplantation following orthotopic liver transplantation from the same haploidentical family donor in a girl with hemophagocytic lymphohistiocytosis"; Blood 96, 3997-3999; Dec. 1, 2000.

**76.** Sezer, O *et al.*; "Nov.el approaches to the treatment of primary amyloidosis"; Exper. Opin. Investig. Drugs 9, 2343-2350; Oct. 2000.

### J. TREATMENTS FOR SEVERE COMBINED IMMUNODEFICIENCY SYNDROME (SCIDS)

**77.** Cavazzana-Calvo, M *et al.*; "Gene therapy of human severe combined immunodeficiency (SCID)-X1 disease"; Science 288, 669-672; April 28, 2000.

### K. TREATMENTS TO REPAIR HEART DAMAGE AFTER HEART ATTACK

**78.** Menasché, P *et al.* "Myoblast transplantation for heart failure." Lancet 357, 279-280; Jan. 27, 2001.

**79.** Menasché, P *et al.* ["Autologous skeletal myoblast transplantation for cardiac insufficiency. First clinical case."] [article in French] Arch. Mal. Coeur Vaiss 94(3), 180-182; March 2001.

**80.** "Doctor Puts Arm Muscle Cells Into Patient's Heart"; Associated Press; May 30, 2001.

**81.** "First Percutaneous Endovascular Case of Heart Muscle Regeneration Completed with Bioheart's MyoCell(TM) Product"; PRNewswire; May 30, 2001.

**82.** El Oakley, RM *et al.*; "Myocyte transplantation for cardiac repair: A few good cells can mend a broken heart"; Annals of Thoracic Surgery 71, 1724 –1733; 2001.

### L. GROWTH OF SKIN FROM HAIR FOLLICLE STEM CELLS

**83.** Coghlan, Andy; "Hair today, skin tomorrow"; New Scientist 170, 19; June 30, 2001

## II. OTHER GENERAL REFERENCES RELATED TO CLINICAL USES AND ABILITIES OF HUMAN STEM CELLS DERIVED FROM NON-EMBRYO SOURCES

**84.** Rao, MS and Mattson, MP; "Stem cells and aging: expanding the possibilities"; Mech. Ageing Dev. 122(7), 713-734; May 31, 2001 (reviewing uses of adult stem cells, noting their remarkable plasticity).

**85.** Koc, ON and Lazarus, HM; "Mesenchymal stem cells: heading into the clinic"; Bone Marrow Transplant 27(3), 235-239; Feb. 2001 (reviewing clinical role and potential therapeutic role of mesenchymal stem cells).

**86.** Globerson, A; "Haematopoietic stem cell ageing"; Nov.artis Found Symp. 235, 85-96; discussion 96-100, 101-4; 2001 (discussing the effectiveness of using haematopoietic stem cells of older patients and alternatives).

**87.** Rice, AM *et al.*; "Prior cryopreservation of ex vivo-expanded cord blood cells is not detrimental to engraftment as measured in the nod-scid mouse model"; J Hematother. Stem Cell Res. 0(1), 157-165; Feb. 2001 (discussing the ability to preserve and use cord blood).

**88.** Humpe, A *et al.*; "Successful transplantation and engraftment of peripheral blood stem cells after cryopreservation, positive and negative purging procedures, and a second cryopreservation cycle"; Ann. Hematol. 80(2), 109-112; Feb. 2001 (discussing the ability to cryopreserve peripheral stem cells while maintaining their effectiveness).

**89.** Dempke, W *et al.*; "Human hematopoietic growth factors: old lessons and new perspectives"; Anticancer Res. 20(6D), 5155-5164; Nov.-Dec. 2000 (general review of growth factors used in hematopoietic stem cell transplants).

**90.** Surbek, DV and Holzgreve, W; "Fetal cells from cord blood as stem cell source: current status and possible implications in gynaecologic oncology"; Eur. J. Gynaecol. Oncol. 22(1), 6-12; 2001 (review of the increasing use of umbilical cord blood for transplants and the banking of cells).

**91.** Dreger, P and Schmitz, N; "Allogeneic transplantation of blood stem cells: coming of age?"; Ann. Hematol. 80(3), 127-136; March 2001 (clinically oriented overview on current results and perspectives of allogeneic peripheral blood stem cell transplantation, with particular focus on reconstitution of hematopoiesis and the immune system, graft-versus-host disease, graft-versus-leukemia effects, intensity-reduced conditioning, and graft engineering).

**92.** Cashman, JD and Eaves, CJ; "High marrow seeding efficiency of human lymphomyeloid repopulating cells in irradiated NOD/SCID mice"; Blood 96, 3979-3981; Dec. 1, 2000 (noting that previously reported human stem cell frequencies and their in vivo self-renewal activity have been markedly underestimated).

**93.** Kobari, L *et al.;* "In vitro and in vivo evidence for the long-term multilineage (myeloid, B, NK, and T) reconstitution capacity of ex vivo expanded human CD34(+) cord blood cells"; Exp. Hematol. 28, 1470-1480; Dec. 2000 (reporting evidence for expansion protocol to maintain cord blood stem cells for clinical applications).

**94.** Bacigalupo, A *et al.*; "Bone marrow or peripheral blood as a source of stem cells for allogeneic transplants"; Curr. Opin. Hematol. 7, 343-347; Nov. 2000 (study noting the comparative advantages of peripheral blood stem cell transplants versus bone marrow in warding off recurrence of disease).

**95.** Bush, NE *et al.*; "Conditional and unconditional estimation of multidimensional quality of life after hematopoietic stem cell transplantation: a longitudinal follow-up of 415 patients"; Biol. Blood Marrow Transplant 6, 576-591; 2000 (noting that the quality of life for adult patients who received hematopoietic stem cell transplants is similar to the normal population).

**96.** Fu, S and Liesveld, J; "Mobilization of hematopoietic stem cells"; Blood Rev 14, 205-218; Dec. 2000 (review of techniques to mobilize hematopoietic bone marrow stem cells into peripheral blood).

**97.** Gilmore, GL *et al.*; "Ex vivo expansion of human umbilical cord blood and peripheral blood CD34(+) hematopoietic stem cells"; Exp. Hematol. 28, 1297-1305; Nov. 1, 2000 (reporting technique to expand numbers of human hematopoietic stem cells in culture).

**98.** Gluckman, E; "Current status of umbilical cord blood hematopoietic stem cell transplantation"; Exp. Hematol. 28, 1197-1205; Nov. 1, 2000 (extensive review "confirm[ing] the potential benefit of using umbilical cord blood hematopoietic stem cells for allogeneic transplants").

**99.** Steward, CG; "Stem cell transplantation for non-malignant disorders"; Baillieres Best Pract. Res. Clin. Haematol. 13, 343-363; Sept.. 2000 (review of potentials for stem cell transplantation).

**100.** Slavin, S; "New strategies for bone marrow transplantation"; Curr. Opin. Immunol. 12, 542-551; Oct. 2000 (review of potentials for stem cell transplantation).

**101.** McNiece, I *et al.*; "Increased expansion and differentiation of cord blood products using a two-step expansion culture"; Exp. Hematol. 28, 1181-1186; Oct. 2000 (study reporting technique to quickly expand numbers of cord blood cells in culture, allowing adequate numbers for treatment of adult patients).

**102.** Lewis, ID and Verfaillie, CM; "Multi-lineage expansion potential of primitive hematopoietic progenitors. Superiority of umbilical cord blood compared to mobilized peripheral blood"; Exp. Hematol. 28, 1087-1095; Sept.. 1, 2000 (discussing superiority of cord blood's expansion potential).

**103.** Cho, RH and Muller-Sieburg, CE; "High frequency of long-term culture-initiating cells retain in vivo repopulation and self-renewal capacity"; Exp. Hematol. 28, 1080-1086; Sept.. 1, 2000.

**104.** Jacobs, P *et al.*; "Allogeneic stem cell transplantation. An economic comparison of bone marrow, peripheral blood, and cord blood technologies"; Int. J. Technol. Assess Health Care 16, 874-884; Summer 2000 (discussing economic benefits of stem cell treatment).

**105.** Saba, N *et al.*; "Overview of autologous stem cell transplantation"; Critical Reviews of Oncology and Hematology 36, 27-48, Oct. 2000 (review concluding that blood stem cell transplants show faster recovery, less transplant problems, shorter hospital stay, and reduced cost compared to bone marrow transplants).

**106.** Ringden, O *et al.*, "Peripheral blood stem cell transplantation from unrelated donors: a comparison with marrow transplantation"; Blood 94, 455; July 15, 1999 (finding that allogeneic peripheral blood stem cell transplants as good or better than bone marrow).

**107.** Hester, J; "Peripheral blood stem cell collection: the interaction of technology, procedure, and biological factors"; Transfus. Sci. 23, 125-132; Oct. 2000 (review of current protocols allowing better methods for collection of stem cells from peripheral blood).

**108.** Kessinger, A; "Collection of autologous peripheral blood stem cells in steady state"; Baillieres Best Pract. Res. Clin. Haematol. 12, 19-26; March-June, 1999.

**109.** Korbling, M; "In vivo expansion of the circulating stem cell pool"; Stem Cells 16 Suppl. 1, 131-138; 1998.

**110.** Kessinger, A and Sharp, JG; "Mobilization of blood stem cells"; Stem Cells 16 Suppl. 1, 139-143; 1998.

**111.** Huhn, RD; "Umbilical cord blood stem cell transplantation and banking"; N J Med. 97, 53-57; Sept.. 2000 (review of cord blood stem cell transplants)

**112.** "Bibliography. Current world literature. Hematopoietic stem cell transplantation"; Curr. Opin. Hematol. 7, B171-189; Nov. 2000.

## III. POTENTIAL CLINICAL APPLICATIONS OF ADULT STEM CELLS: ANIMAL AND HUMAN POST-NATAL STEM CELL RESEARCH RELATING TO VARIOUS CELL AND TISSUE TYPES

### A. BRAIN AND CENTRAL NERVOUS SYSTEM STEM CELLS

**113.** Palmer, TD *et al.*; "Progenitor cells human brain after death"; Nature 411, 42-43; May 3, 2001.

**114.** Geschwind, DH *et al.*; "A genetic analysis of neural progenitor differentiation"; Neuron 29(2), 325-339; Feb. 2001.

**115.** Fallon, J *et al.*; "*In vivo* induction of massive proliferation, directed migration, and differentiation of neural cells in the adult mammalian brain"; Proc. Natl. Acad. Sci. USA 97, 14686-14691; Dec. 19, 2000 (growth factor successfully used to stimulate brain stem cells to reverse brain damage that is similar to Parkinson's disease).

**116.** Shihabuddin, S *et al.*; "Adult spinal cord stem cells generate neurons after transplantation in the adult dentate gyrus"; J. Neuroscience 20, 8727-8735; Dec. 2000.

**117.** Uchida, N *et al.*; "Direct isolation of human central nervous system stem cells"; Proc. Natl. Acad. Sci. USA 97, 14720-14725; Dec. 19, 2000.

**118.** Aboody, KS *et al.*; "From the cover: neural stem cells display extensive tropism for pathology in adult brain: evidence from intracranial gliomas"; Proc. Natl. Acad. Sci. USA 97, 12846-12851; Nov. 7, 2000 (study reporting that implanted neural stem cells show the ability to migrate extensively throughout the brain to reach sites of damage).

**119.** Taupin, P *et al.*; "FSF-2-responsivie neural stem cell proliferation required CCg, a Nov.el autocrine/paracrine cofactor"; Neuron 28, 385-397; Feb. 2001.

**120.** Hodge, CJ Jr. and Boakye, M; "Biological Plasticity: The future of science in neurosurgery"; Neurosurgery 48, 2-16; Jan. 2001 (reviewing stem cell plasticity).

**121.** Galli, R. *et al.*, "Skeletal myogenic potential of human and mouse neural stem cells", Nature Neuroscience 3, 986-991; Oct. 2000 (reporting on the ability of human and mouse adult neural cells to transform into skeletal muscle cells).

**122.** Toda, H *et al.*; "Neurons generated from adult rat hippocampal stem cells form functional glutamatergic and GABAergic synapses *in vitro*"; Experimental Neurology 165, 66-76; Sept. 2000.

**123.** Villa, A *et al.*; "Establishment and properties of a growth factor-dependent, perpetual neural stem cell line from the human CNS"; Exp. Neurol. 161, 67-84; Jan. 2000

**124.** Clarke *et al.*; "Generalized potential of adult neural stem cells"; Science 288, 1660-1663; June 2, 2000 (research with mice indicating that adult stem cells from brain can grow into

a wide variety of organs, including heart, lung, intestine, kidney, liver, nervous system, muscle, and other tissues).

**125.** Magavi *et al.*; "Induction of neurogenesis in the neocortex of adult mice"; Nature 405, 951-955; June 22, 2000 (reporting that adult stem cells in brain stimulated to grow and replace damaged brain tissue).

**126.** Bjorklund, A and Lindvall, O; "Self-repair in the brain"; Nature 405, 892-893, June 22, 2000 (same).

**127.** Kondo, T and Raff, M; "Oligodendrocyte precursor cells reprogrammed to become multipotent CNS stem cells"; Science 289, 1754-1757; Sept. 8, 2000.

**128.** Johansson, CB *et al.*; "Neural stem cells in the adult human brain"; Exp. Cell Res. 253, 733-736; Dec. 1999.

**129.** Johansson, CB *et al.*; "Identification of a neural stem cell in the adult mammalian central nervous system"; Cell 96, 25-34; Jan. 1999

**130.** Bjornson *et al.*; "Turning brain into blood: a hematopoietic fate adopted by adult neural stem cells in vivo"; Science 283, 534-537; Jan. 22, 1999.

**131.** Barnett *et al.*; "Identification of a human olfactory ensheathing cell that can effect transplant-mediated remyelination of demyelinated CNS axons"; Brain 123, 1581-1588, Aug. 2000 (reporting on the isolation of the human adult stem cell that has been able to repair nerve axons in rat spinal cords).

**132.** Pagano, S *et al.*; "Isolation and Characterization of Neural Stem Cells from the Adult Human Olfactory Bulb"; Stem Cells 18, 295-300; July 2000.

**133.** Schwarz EJ *et al.*; "Multipotential marrow stromal cells transduced to produce L-DOPA: engraftment in a rat model of Parkinson disease"; Hum Gene Ther 10, 2539-2549; Oct 10, 1999

**134.** Kopen, GC *et al.*; "Marrow stromal cells migrate throughout forebrain and cerebellum, and they differentiate into astrocytes after injection into neonatal mouse brains"; Proc. Natl. Acad. Sci. USA 96, 10711-10716; Sept. 14, 1999 (injected stem cells show the ability to migrate throughout the hosts brain without damaging it).

**135.** Foster, GA and Stringer, BM; "Genetic regulatory elements introduced into neural stem and progenitor cell populations"; Brain Pathol. 9, 547-567; July 1999 (review of methods that enable cell immortalization, purification and safety mechanisms, and genetic therapy using neural stem cells).

**136.** Yandava, BD *et al.*; " 'Global' cell replacement is feasible via neural stem cell transplantation: evidence from the dysmyelinated shiverer mouse brain"; Proc. Natl. Acad. Sci. USA 96, 7029-7034; June 8, 1999 (adult neural stem cell transplantation repairing tissue damage caused by a condition similar to Parkison's).

**137** Ramer, MS *et al.*; "Functional regeneration of sensory axons into the adult spinal cord"; Nature 403, 312-316; Jan. 20, 2000.

**138.** Young, MJ *et al.*; "Neuronal differentiation and morphological integration of hippocampal progenitor cells transplanted to the retina of immature and mature dystrophic rats"; Molecular and Cellular Neurosciences 16, 197-205; Sept. 2000 (reporting that injected adult neural stem cells migrate to damaged retina in rats and take on the characteristics of retinal cells).

**139.** Flax, JD *et al.*; "Engraftable human neural stem cells respond to developmental cues, replace neurons, and express foreign genes"; Nature Biotechnol. 16, 1033; Nov. 1998.

**140.** Przyborski, SA *et al.*; "Developmental regulation of neurogenesis in the pluripotent human embryonal carcinoma cell line NTERA-2"; Eur. J. Neurosci. 12, 3521-3528; Oct. 2000.

**141.** Tuszynski, MH; "Intraparenchymal NGF infusions rescue degenerating cholinergic neurons"; Cell Transplant 9; 629-636; Sept.-Oct. 2000.

**142.** Smith, DE *et al.*; "Age-associated neuronal atrophy occurs in the primate brain and is reversible by growth factor gene therapy"; Proc Natl Acad Sci USA 96, 10893-10898; Sept. 14, 1999.

**143.** Raymon, HK *et al.*; "Immortalized human dorsal root ganglion cells differentiate into neurons with nociceptive properties"; J. Neurosci 19, 5420; July 1, 1999 (reporting the establishment of human neural cell lines, the establishment of immortalized human CNS cell lines, and their ability to differentiate into functional sensory neurons).

### B. RETINAL STEM CELLS

**144.** Ahmad, I *et al.*; "Identification of neural progenitors in the adult mammalian eye"; Biochem. Biophys. Res. Commun. 270, 517-521; April 13, 2000

**145.** Tropepe *et al.*; "Retinal stem cells in the adult mammalian eye"; Science 287, 2032-2036, March 17, 2000 (isolation of retinal stem cell in humans, as well as other animals).

## C. MUSCLE STEM CELLS

**146.** Lee, J-Y *et al.*; "Effect of Bone Morphogenetic Protein-2-Expressing Muscle-Derived Cells on Healing of Critical-Sized Bone Defects in Mice"; The Journal of Bone and Joint Surgery 83-A, 1032-1039; July 2001
(describing gene therapy with muscle-derived cells that have been genetically engineered to express growth factor BMP-2; used to treat nonhealing bone defects. The muscle-derived cells appear to include stem cells, which are easily obtained with muscle biopsy and could be used in gene therapy.)

**147.** Menasché P *et al.*; [Autologous skeletal myoblast transplantation for cardiac insufficiency. First clinical case] [Article in French] Arch. Mal. Coeur Vaiss 94(3):180-182; March 2001

**148.** Pouzet B *et al.*; "Factors affecting functional outcome after autologous skeletal myoblast transplantation." Ann. Thorac. Surg. 71(3):844-850; March 2001 (study noting that ability of animal adult stem cells to repair damaged heart tissue).

**149.** Menasché P *et al.*; "Myoblast transplantation for heart failure"; Lancet 357(9252):279-280; Jan. 27, 2001 (evidence of improved function human heart after myoblast transplantation).

**150.** El Oakley, RM *et al.*; "Myocyte transplantation for cardiac repair: A few good cells can mend a broken heart"; Ann. Thorac. Surg. 71, 1724 –1733; 2001.

**151.** Torrente, Y *et al.*; "Intraarterial injection of muscle-derived $CD34^+Sca\text{-}1^+$ stem cells restores dystrophin in *mdx* mice"; J. of Cell Biology 152, 335-348; Jan. 22, 2001

**152.** Scorsin M *et al.*; "Comparison of the effects of fetal cardiomyocyte and skeletal myoblast transplantation on postinfarction left ventricular function"; J. Thorac. Cardiovasc. Surg. 119; 1169-1175; June 2000.

**153.** Pouzet B *et al.*; "Intramyocardial transplantation of autologous myoblasts : can tissue processing Be optimized?"; Circulation 102; III210-215; Nov. 7, 2000 (reporting that autologous skeletal myoblast (SM) transplantation improves function of infarcted myocardium in rats).

**154.** Jackson, K *et al.*; "Hematopoietic potential of stem cells isolated from murine skeletal muscle"; Proceedings National Academy of Sciences USA 96, 14482-14486; Dec. 7, 1999. [NOTE: may have been due to hematopoietic stem cell contamination! personal communication, M. Goodell]

**155.** Lee, JY *et al.*; "Clonal isolation of muscle-derived cells capable of enhancing muscle regeneration and bone healing"; J. Cell Biology 150, 1085-1100; Sept. 4, 2000 (reporting that intravenous injection of muscle-derived adult stem cells back into the mice resulted in muscle regeneration and partial restoration of dystrophin expression in the mice, and

that the transplantation of these cells engineered to secrete a bone protein results in their differentiation into bone cells and acceleration of healing of a skull defect in immunodeficient mice).

**156.** Gussoni, E *et al.*; "Dystrophin expression in the mdx mouse restored by stem cell transplantation"; Nature 401, 390-394; Sept. 23, 1999 (similar findings as ref. 146, additionally finding that normal haematopoietic cells partially restored dystrophin expression in the affected muscle and that the inherent developmental potential of adult stem cells isolated from diverse tissues is greater than previously anticipated).

**157.** Williams, JT *et al.*; "Cells isolated from adult human skeletal muscle capable of differentiating into multiple mesodermal phenotypes"; Am. Surg. 65, 22; Jan. 1999.

**158.** Kessler, PD and Byrne, BJ; "Myoblast cell grafting into heart muscle: cellular biology and potential applications"; Ann. Rev. Physiol. 61, 219; 1999.

**159.** Ray, C.J. Chiu *et al.*; "Cellular Cardiomyoplasty: Myocardial Regeneration With Satellite Cell Implantation"; Ann. Thorac. Surg. 60:12-18; 1995.

**160.** Dorfman, J *et al.*; "Myocardial tissue engineering with autologous myoblast implantation"; J. Of Thorac. And Cardio. Surg. 116, 744-751; Nov. 1998.

**161.** Atkins, B *et al.*; "Intracardiac Transplantation of Skeletal Myoblasts Yields Two Populations of Striated Cells In Situ"; Ann. Thorac. Surg. 67, 124-129; 1999.

**D. SKIN STEM CELLS**

**162.** Oshima, H *et al.*; "Morphogenesis and renewal of hair follicles from adult multipotent stem cells"; Cell 104, 233-245; Jan. 2001.

**163.** Taylor, G; "Involvement of follicular stem cells in forming not only the follicle but also the epidermis"; Cell 102, 451-461; Aug. 2000.

**E. PANCREATIC STEM CELLS**

**164.** Serup, P *et al.*; "Islet and stem cell transplantation for treating diabetes"; British Medical J. 322, 29-32; Jan. 6, 2001 (review of possible stem cell treatments for diabetes, suggesting that adult stem cells show more promise).

**165.** Cheung, AT *et al.*; "Glucose-dependent insulin release from genetically engineered K cells"; Science 290; 1959-1962; Dec. 8, 2000.

**166.** Gmyr, V *et al.*, "Adult human cytokeratin 19-positive cells reexpress insulin promoter factor 1 in vitro: Further evidence for pluripotent pancreatic stem cells in humans"; Diabetes 49, 1671-1680; Oct. 2000.

**167.** Bonner-Weir, S *et al.*; "In vitro cultivation of human islets from expanded ductal tissue"; Proc. Natl. Acad. Sci. USA 97, 7999-8004; July 5, 2000 (reporting that cultured human pancreatic ductal cells formed islet buds and secreted insulin).

**168.** Ramiya, VK *et al.*; "Reversal of insulin-dependent diabetes using islets generated in vitro from pancreatic stem cells"; Nature Medicine 6, 278-282; March 2000.

**F. BONE MARROW and PERIPHERAL BLOOD STEM CELLS**

**169.** Krause, DS *et al.*; "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell"; Cell 105, 369-377; May 4, 2001.

**170.** Jackson, KA *et al.*; "Regeneration of ischemic cardiac muscle and vascular endothelium by adult stem cells"; J. of Clinical Investigation 107, 1395-1402; June 2001 (reporting that adult bone marrow stem cells could form functional heart muscle and blood vessels in mice which had heart damage).

**171.** Orlic, D *et al.*; "Bone marrow cells regenerate infarcted myocardium"; Nature 410, 701-705; April 5, 2001 (reporting that that locally delivered bone marrow cells can generate de Nov.o myocardium, ameliorating the outcome of coronary artery disease).

**172.** Kocher, AA *et al.*; "Neovascularization of ischemic myocardium by human bone-marrow-derived angioblasts prevents cardiomyocyte apoptosis, reduces remodeling and improves cardiac function"; Nature Medicine 7, 430-436; April 2001.

**173.** Chen, J *et al.*; "Therapeutic benefit of intravenous administration of bone marrow stromal cells after cerebral ischemia in rats"; Stroke 32, 1005-1011; April 2001 (study indicates that bone marrow stem cells may be able to be used to reverse the effects of strokes).

**174.** Li, Y *et al.*; "Adult bone marrow transplantation after stroke in adult rats"; Cell Transplant 10(1), 31-40; Jan.-Feb. 2001.

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**176.** Moutsatsos, IK *et al.*; "Exogenously regulated stem cell-mediated gene therapy for bone regeneration"; Mol Ther 3(4), 449-461; April 2001.

**177.** Glimm, H *et al.*; "Previously undetected human hematopoietic cell populations with short-term repopulating activity selectively engraft NOD/SCID-beta2 microglobulin-null mice"; J. Clin. Invest. 107, 199-206; Jan. 2001.

**178.** Wang, J-S *et al.*; "Marrow stromal cells for cellular cardiomyoplasty: Feasibility and potential clinical advantages"; The J. of Thorac. And Cardio. Surg. 120, 999-1006; Nov. 2000.

**179.** Bhardwaj, G *et al.*; "Sonic hedgehog induces the proliferation of primitive human hematopoietic cells via BMP regulation"; Nature Immun. 2, 172-180; 2001 (reporting that human and animal adult stem cells were shown to be able of extensive proliferation in culture, providing potentially unlimited supplies of adult stem cells for clinical treatments).

**180.** Brazelton, TR *et al.*; "From marrow to brain: expression of neuronal phenotypes in adult mice"; Science 290, 1775-1779; Dec. 1, 2000 (reporting that adult stem cells from mouse bone marrow injected into mouse blood stream could be found developing neuron characteristics in brain, "demonstrat[ing] a remarkable plasticity of adult tissues with potential clinical applications").

**181.** Mezey, E *et al.*; "Turning blood into brain: Cells bearing neuronal antigens generated in vivo from bone marrow"; Science 290, 1779-1782; Dec. 1, 2000 (same).

**182.** Cashman, JD and Eaves, CJ; "High marrow seeding efficiency of human lymphomyeloid repopulating cells in irradiated NOD/SCID mice"; Blood 96, 3979-3981; Dec. 1, 2000 (finding that previously reported human stem cell frequencies and their in vivo self-renewal activity have been markedly underestimated).

**183.** Goan *et al.*; "Donor stromal cells from human blood engraft in NOD/SCID mice"; Blood 96, 3971-3978; Dec. 1, 2000.

**184.** Liechty, KW *et al.*; "Human mesenchymal stem cells engraft and demonstrate site-specific differentiation after in utero transplantation in sheep"; Nature Medicine 6, 1282-1286; Nov. 2000.

**185.** Lagasse, E *et al.*; "Purified hematopoietic stem cells can differentiate into hepatocytes in vivo"; Nature Medicine 6, 1229-1234; Nov. 2000 (reporting that the intravenous injection of adult bone marrow stem cells in a mouse model of tyrosinemia type I rescued the mouse and restored biochemical function of its liver).

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**187.** Varnum-Finney, B *et al.*; "Pluripotent, cytokine-dependent, hematopoietic stem cells are immortalized by constitutive Notch1 signaling"; Nature Medicine 6, 1278-1281; Nov. 2000

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**191.** Sanchez-Ramos, J *et al.*; "Adult bone marrow stromal cells differentiate into neural cells in vitro"; Experimental Neurology 164, 247-256; Aug. 2000 (study showing that human and mouse bone marrow stem cells able to form nerve cells).

**192.** Woodbury, D *et al.*; "Adult rat and human bone marrow stromal cells differentiate into neurons"; J. Neuroscience Research 61, 364-370; Aug. 15, 2000 (reporting that adult human bone marrow stem cells can create a "virtually limitless supply" of nerve cells, and that the adult stem cells "grow rapidly in culture, precluding the need for immortalization, and differentiate into neurons exclusively with use of a simple protocol").

**193.** Cao, H *et al.*; "In vitro generation of dendritic cells from human blood monocytes in experimental conditions compatible for in vivo cell therapy"; J. Hematother. Stem Cell Res. 9, 183-194; April 2000.

**194.** Theise, N *et al.*; "Liver from bone marrow in humans"; Hepatology 32, 11-16; July 2000 (reporting that human bone marrow stem cells can form liver).

**195.** Alison, M *et al.*; "Cell differentiation: hepatocytes from non-hepatic adult stem cells"; Nature 406, 257; July 20, 2000.

**196.** Theise, N *et al.*; "Derivation of hepatocytes from bone marrow cells in mice after radiation-induced myeloablation"; Hepatology 31, 235-240; Jan. 2000

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**198.** Petersen, B *et al.*; "Bone marrow as a potential source of hepatic oval cells"; Science 284, 1168-1170; May 14, 1999.

**199.** Lian, JB *et al.*; "Marrow transplantation and targeted gene therapy to the skeleton"; Clin. Orthop. 379 Supp., S146-155; Oct. 2000 (review of bone marrow as a source of cells for nervous system).

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2000 (reporting identified conditions that allow large-scale expansion of human adult stem cells in culture, making these cells an almost unlimited source).

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**204.** Pittenger, MF *et al.*; "Multilineage potential of adult human mesenchymal stem cells"; Science 284, 143-147; April 2, 1999 (reporting that adult stem cells could be stimulated to form either bone, cartilage, or fat cells, and that these cells appear to have the potential to form other tissues as well, including tendon and muscle).

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**206.** Makino S *et al.*; "Cardiomyocytes can be generated from marrow stromal cells in vitro"; J. Clin. Invest. 103, 697–705; March 1999

**207.** Pereira RF *et al.*; "Marrow stromal cells as a source of progenitor cells for nonhematopoietic tissues in transgenic mice with a phenotype of osteogenesis imperfecta"; Proc. Natl. Acad. Sci. USA 95, 1142–1147; February 1998

**208.** Asahara, T *et* al.; "Isolation of Putative Progenitor Endothelial Cells for Angiogenesis"; Science 275, 964-967; Feb. 14, 1997.

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**210.** Yagi, M *et al.*; "Sustained ex vivo expansion of hematopoietic stem cells mediated by thrombopoietin"; Proc. Natl. Acad. Sci. USA 96, 8126–8131; July 1999.

**211.** Bhatia, M *et al.*; "Purification of primitive human hematopoietic cells capable of repopulating immune-deficient mice"; Proc. Natl. Acad. Sci. USA 94, 5320–5325; May 1997 (reporting that a single human marrow stromal cell has the ability to repopulate bone marrow of mice).

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**213.** Eglitis, MA *et al.*; "Targeting of marrow-derived astrocytes to the ischemic brain"; Neuroreport 10, 1289; April 26, 1999 .

**214.** Deans, RJ and Moseley, AB, "Mesenchymal stem cells. Biology and potential clinical uses", Experimental Hematology 28, 875-884; Aug., 2000 (reporting that multiple tissue types can be derived from bone marrow stem cells, with many potential clinical uses).

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**216.** Bruder, SP *et al.*; "Bone regeneration by implantation of purified, culture-expanded human mesenchymal stem cells"; J. Orthop. Res. 16, 155; 1998.

**217.** Ringden, O *et al.*, "Peripheral blood stem cell transplantation from unrelated donors: a comparison with marrow transplantation"; Blood 94, 455; July 15, 1999.

**218.** Jaiswal, N *et al.*; "Osteogenic differentiation of purified, culture-expanded human mesenchymal stem cells in vitro"; J. Cell Biochem. 64:295-312; 1997 (reporting that human bone marrow cells induced to form bone in culture).

**219.** Bruder, SP *et al.*; "Growth kinetics, self-renewal, and the osteogenic potential of purified human mesenchymal stem cells during extensive subcultivation and following cryopreservation", J Cell Biochem 64, 278; 1997 (reporting that bone marrow cells maintain potential after long-term cryopreservation).

**G. LIVER STEM CELLS**

**220.** Malouf, NN *et al.*; "Adult-derived stem cells from the liver become myocytes in the heart in vivo"; American J. of Pathology 158, 1929-1935; June 2001 (reporting that adult stem cells from liver could transform into heart tissue when injected into mice, demonstrating "that adult-derived stem cells, like their embryonic counterparts, are pluripotent").

**221.** Suzuki, A *et al.*; "Flow-cytometric separation and enrichment of hepatic progenitor cells in the developing mouse liver"; Hepatology 32, 1230-1239; Dec. 2000.

**222.** Shafritz, DA; "Rat liver stem cells: Prospects for the future"; Hepatology 32, 1399-1400; Dec. 2000 (commentary on future prospects of liver stem cell research for therapeutic application).

**223.** Lagasse, E *et al.*; "Purified hematopoietic stem cells can differentiate into hepatocytes in vivo"; Nature Medicine 6, 1229-1234; Nov. 2000.

**224.** Kubota, H and Reid, LM; "Clonogenic hepatoblasts, common precursors for hepatocytic and biliary lineages, are lacking classical major histocompatibility complex class I antigen"; Proc. Natl. Acad. Sci. USA 97, 12132-12137; Oct. 24, 2000.

**225.** Strain, AJ and Crosby, HA; "Hepatic stem cells"; Gut 46, 743-745; 2000 (general reference collecting research regarding liver stem cells).

### H. STEM CELLS FROM HEART, BLOOD VESSELS, and HEART VALVES

**226.** Beltrami, AP *et al.*; "Evidence That Human Cardiac Myocytes Divide after Myocardial Infarction"; *New England J. of Medicine* 344, 1750-1757; June 7, 2001 (research indicating that the human heart contains its own adult stem cell, which could possibly be stimulated to grow and repair damage after a heart attack).

**227.** Shum-Tim, D *et al.*; "Tissue engineering of autologous aorta using a new biodegradable polymer"; Ann. Thorac. Surg. 68, 2298-2304; Dec. 1999.

**228.** Asahara, T *et* al.; "Isolation of Putative Progenitor Endothelial Cells for Angiogenesis"; Science 275, 964-967; Feb. 14, 1997.

**229.** Shi, Q *et al.*; "Evidence for Circulating Bone Marrow-Derived Endothelial Cells"; Blood 92, 362-367; July 15, 1998.

### I. FAT STEM CELLS

**230.** Zuk, PA *et al.*; "Multilineage cells from human adipose tissue: Implications for cell-based therapies"; Tissue Engineering 7, 211-228; 2001 (reporting that human adult fat stem cells could be expanded and maintained in culture for extended periods, and could be differentiated into fat, cartilage, muscle, and bone).

**231.** Norton, A; "Stem cells from body fat—limitless supply"; Reuters Health; Oct. 18, 2000 (press report discussing recent findings that fat stem cells can transform into bone).

### J. LUNG STEM CELLS

**232.** Emura, M; "Stem cells of the respiratory epithelium and their in vitro cultivation"; In Vitro Cell Dev. Biol. Anim. 33, 3; Jan. 1997.

### K. DENTAL STEM CELLS

**233.** Gronthos, S *et al.*; "Postnatal human dental pulp stem cells (DPSCs) *in vitro* and *in vivo*"; Proc Natl Acad Sci USA 97, 13625-13630; Dec. 5, 2000 (identification and isolation of stem cells from human dental pulp that could be induced to differentiate into tooth structures).

## L. MAMMARY GLAND

**234.** Kim, ND *et al.*; "Stem cell characteristics of transplanted rat mammary clonogens"; Exp. Cell Res. 260, 146-159; Oct. 10, 2000.

## M. SPERMATOGONIAL STEM CELLS

**235.** Izadyar, F *et al.*; "Spermatogonial stem cell transplantation"; Mol Cell Endocrinol 169, 21-26; Nov. 27, 2000.

**236.** Johnston, DS *et al.*; "Advances in spermatogonial stem cell transplantation"; Rev. Reprod. 5, 183-188; Sept.. 2000 (review).

## N. GASTROINTESTINAL STEM CELLS

**237.** Booth, C, Potten, CS; "Gut instincts: thoughts on intestinal epithelial stem cells"; Journal of Clinical Investigation 105, 1493-1499; June 2000

**238.** Pageot LP *et al.*; "Human cell models to study small intestinal functions: recapitulation of the crypt-villus axis"; Microsc Res Tech 49, 394-406; May 15, 2000
(The intestinal epithelium is continuously and rapidly renewed by a process involving cell generation, migration, and differentiation, from the stem cell population located at the bottom of the crypt. Important advances have been achieved over recent years in the generation of normal human intestinal cell models.)

**239.** Wright NA; "Epithelial stem cell repertoire in the gut: clues to the origin of cell lineages, proliferative units and cancer"; Int J Exp Pathol;81, 117-143; April 2000
(Gastrointestinal stem cells are shown to be pluripotential and to give rise to all cell lineages in the epithelium.)

**240.** Bach SP *et al.*; "Stem cells: the intestinal stem cell as a paradigm"; Carcinogenesis 121, 469-476; 2000

**241.** Wong, WM, Wright NA; "Cell proliferation in gastrointestinal mucosa"; J. Clin. Pathol. 52, 321-333; 1999

**242.** Booth C *et al.*; "Maintenance of Functional Stem Cells in Isolated and Cultured Adult Intestinal Epithelium"; Experimental Cell Research 249, 359–366; 1999

## O. STEM CELLS FROM PLACENTA

**243.** Anthrogen, in a press release, reports that they can isolate stem cells from placenta after delivery, and that these stem cells so far have been induced to form bone, nerve, cartilage, bone marrow, muscle, tendon, and blood vessel. This press release is available

at <http://www.mcpf.org/AnthroGen%20Discovery.htm>. AnthroGen has also posted articles based on that press release at <http://www.anthrogenesis.com/page411559.htm>.

## P. OTHER SIGNIFICANT RESEARCH INVOLVING ADULT STEM CELLS

**244.** Asahara, T *et al.*; "Stem cell therapy and gene transfer for regeneration"; Gene Ther. 7; 451-457; March 2000.

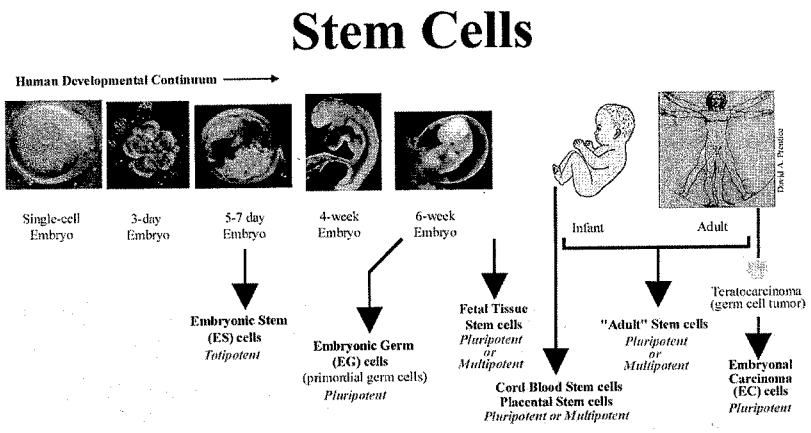
**245.** Wei, G *et al.*; "Stem cell plasticity in mammals and transdetermination in Drosophila: Common themes?"; Stem Cells 18, 409-414; Nov. 2000.

## Q. STEM CELLS FROM UMBILICAL CORDS

**246.** Researchers at the University of South Florida have reported at the meeting of the American Association for the Advancement of Science (Jan. 2001) and the American Academy of Neurology meeting (May 2001) that human cord blood stem cells can be induced to form neurons. When injected into the bloodstream of rats which had suffered stroke, the adult stem cells found their way to the brain and repaired much of the damage. Rats which were previously paralyzed showed 80% recovery. (From Meetings press releases).

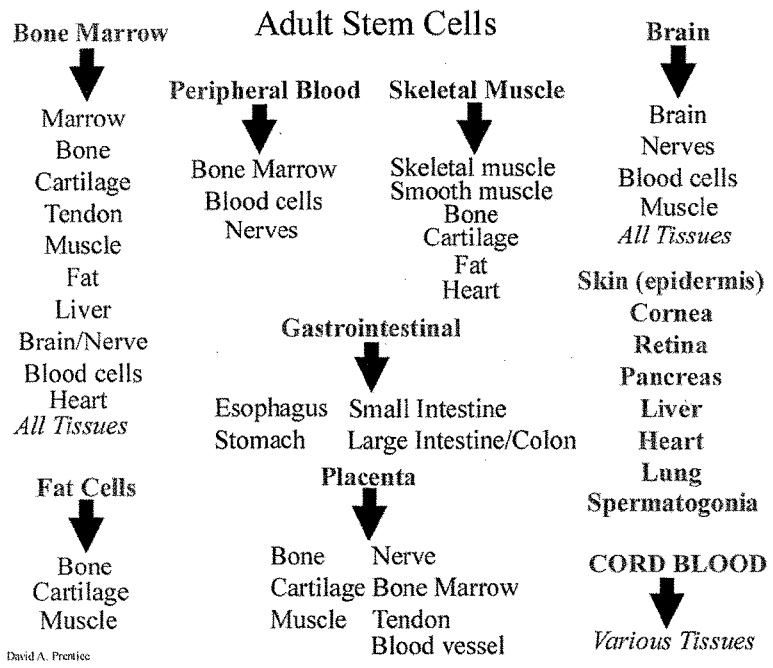
## Appendix B

Sources of Stem Cells and their Potentials



**Appendix C**

Post-Natal (non-embryonic) Stem Cells and their Known or Possible Derivatives
(not an all-inclusive list)
(as suggested by the peer-reviewed scientific literature; for placenta by company press releases)



## Appendix D

Sampling of the Peer-Reviewed Scientific and Medical Journals in which Adult Stem Cell Research Achievements have been Published (not an all-inclusive list)

Annals of Thoracic Surgery

Biochemical and Biophysical Research Communications

Blood

Bone Marrow Transplant

British Journal of Haematology

British Medical Journal

Cancer

Cell

Diabetes

Experimental Cell Research

Hepatology

Journal of Biological Chemistry

Journal of Cell Biology

Journal of Clinical Investigation

Journal of Clinical Oncology

Journal of Neuroscience

Journal of Neuroscience Research

Journal of Thoracic and Cardiovascular Surgery

The Lancet

Nature

Nature Biotechnology

Nature Immunology

Nature Medicine

Nature Neuroscience

Neurology

Neurosurgery

New England Journal of Medicine

Proceedings of the National Academy of Sciences USA

Science

Tissue Engineering

Mr. WELDON. Thank you, Dr. Prentice. We will now hear from Joan Samuelson.

Ms. SAMUELSON. Thank you. I think my job today is, using the same phrase that was used earlier, to put one of the human faces on this side of the debate, as you guys will. A lot of what I was going to talk about has been talked about at great length by many other witnesses and questioners. So I am going to try not to repeat things that have been said, but I think it's vitally important that this committee, as best it can, tries to stand, if only briefly, in our shoes. Many of you probably already do, having loved ones with the many disorders that could be helped by stem cell research, and I recognize that, but I think it's important that I share both my thoughts and my feelings.

Frankly, when I came in at the beginning of the hearing I had lots of thoughts going through my head, but at this point I've really come full circle and what I want to share most is the feelings. Because listening to this discussion, I'm sad and I'm scared.

Why am I sad? This has been a rough month at the Parkinson's Action Network because almost all of the people who work with us and our board of directors struggle with this disease and live the consequences, and this is a particularly bad month. Our Education Advocacy Director is here, John Rogers, and John buried his dad last week. John believes, as do I, that if this research had been aggressively funded from years ago when it was identified as having promise, his dad might be alive today.

In the room, at the end of the front row, is Milly Kondracke, my good friend and wife of Morton Kondracke, Washington columnist, who has just recently written this book, "Saving Milly." It's about Milly. It's about his love for her. It's about Milly's struggle with Parkinson's, and the last chapter is called, "Losing Milly."

Milly has not been able to swallow whole food for the last 2 weeks, and she's going on a feeding tube tomorrow. I pray that Milly is going to be around when this cure is ready, and I believe that it will be failure not of science if she's not. If we've lost her, it will not be the fault of science and the brilliant researchers in our country. It will be a failure of politics and a lack of a Federal investment in this disease.

The scientists tell us this isn't an incurable disorder anymore; it's a curable one, but the investment is not being made. And why? Is it really for any good reason? That's what torments me.

The scare part comes because I think the reason I was asked to testify is I'm really on that cusp. I've had Parkinson's for almost 15 years, diagnosed 14 years ago, and I, as was Milly—we were diagnosed at almost exactly the same time. For whatever reason—and we don't understand it—Milly has progressed a lot faster than I.

I still respond to that other medical miracle called L-dopa, the pill that we pop that replaces this missing dopamine that's lacking from the brain cells that have deteriorated. When I woke up this morning, like every morning, I was almost frozen stiff from my Parkinson's symptoms, and I was able only to reach over to the bedside and take a pill and put it in my mouth with a little water, and, hallelujah, like other mornings, within 45 minutes I was able to move.

I know without brain repair, without this research, the day will come that, however many of those pills I take, I will not be able to move. Like Milly, I will be in a wheelchair. Like Milly, I will not be able to speak, and like Milly, I will be having great difficulty swallowing, and at some point that is the likely thing that will cause my death.

The scientists tell us this research is crucial to our rescue, and they tell us, as Dr. Fischbach did and as the brilliant scientists that I quote—and I've got two letters attached to my testimony—that embryonic stem cell research is, indeed, vital to our rescue, that adult stem cells are not going to do the job by themselves.

So I simply have to implore you to stand in our shoes and ask these questions: What if not every embryo out there in the freezer can be adopted? I completely agree that we should draft regulations today that enthusiastically encourage every donor couple to consider adoption of those embryos. I think that's one of these wonderful modern-day miracles. But what if some of them are going to be discarded? And the reality is embryos were discarded today; they were discarded yesterday; they're going to be discarded tomorrow. And they're not helping rescue us.

How can we live with that? What if adult stem cells aren't enough? What if we just go down that path and 5 years from now it proved they weren't enough and that we needed the embryonic stem cell research? I don't know that I can hang on that long? I pray Milly can. I pray for the other million of Americans with Parkinson's and the people with all the other diseases—juvenile diabetes and Alzheimer's and spinal cord injury and the rest—that could be close to a cure.

Please think about that. I implore the President to think about that and stand in our shoes as he contemplates this decision and to make a decision soon, and I implore all of you and the rest of Congress to do the same. Thank you.

[The prepared statement of Ms. Samuelson follows:]

**TESTIMONY OF**

**JOAN SAMUELSON, PRESIDENT**

**PARKINSON'S ACTION NETWORK**

**BEFORE THE HOUSE GOVERNMENT REFORM**

**SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY**

**AND HUMAN RESOURCES**

**JULY 17, 2001**

Mr. Chairman and members of the Subcommittee, thank you for this opportunity to testify at this very important hearing on embryonic stem cells. As one of more than a million Americans who suffer from Parkinson's disease, this issue has deep personal significance. I am honored to join Senator Hatch and Dr. Gerald Fishbach on this panel.

The Parkinson's Action Network was created in 1991 to give voice to a community that had been largely invisible, and as a consequence has not received the federal research investment equal to its great potential. PAN's mission is to educate the country and its leaders about the need to speed research, deliver breakthroughs and cure this dreadful disease. Almost every member of our staff, Board of Directors and volunteer force is deeply, personally affected by Parkinson's. Our Executive Director, Elisabeth Bresee, lost her father to Parkinson's in 1980. Our Advocacy Director, John Rogers, lost his father just seven days ago. Our sincere sympathy is with John and his family.

I have struggled with Parkinson's since my diagnosis 14 years ago. Our board member, Morton Kondracke, has just written a moving book chronicling his wife Milly's struggle with Parkinson's. Milly, who is confined to a wheelchair, dependent on others for care and has almost no capacity to speak, is in great danger of being lost to us very soon. Time is not neutral.

Parkinson's is a devastating progressive neurological disorder that makes it difficult to walk, causes uncontrollable tremors, and in its final states robs individuals of the ability to speak or move. Parkinson's is caused by the degeneration of brain cells that produce dopamine, a neurochemical controlling motor function. There is great reason for hope, however. In the last several years, scientists have made tremendous progress in the search for a Parkinson's cure.

At this point, they have a roadmap only. What they desperately need is the federal investment to enable them to move their scientific vision to reality – that is, to a therapeutic option that will repair the brain's system controlling motor function. One of the most promising lines that requires that funding involves using human embryonic stem cells.

Stem cells are the building blocks of the body, with the ability to divide indefinitely and differentiate into virtually any type of cell in the human body. Scientific experts testifying before Congress in December of 1998 named Parkinson's as the first disorder that they expected to benefit from stem cells, and predicted it could be done within a

decade -- and as soon as five years -- if the funds needed to tackle this problem were available. But, Parkinson's sufferers are not the only ones who stand to benefit from embryonic stem cells – the millions of people suffering from other devastating diseases such as diabetes, Alzheimer's, amyotrophic lateral sclerosis (Lou Gehrig's disease) and Huntington's – as well as stroke, burn and spinal cord injury victims -- could also be rescued.

Embryonic stem cells are made available by leftover embryos created by and for couples undergoing the scientific miracle of in vitro fertilization. These embryos are destined to be destroyed or frozen indefinitely. I think it is wonderful that the Staege family, who is here with us today, was able to adopt a baby produced through in vitro fertilization. While no one would argue against allowing the adoption of embryos, no one can credibly argue that more than a small fraction of those presently in storage would ever be adopted. The reality is that most of these embryos will be discarded.

Many at today's hearing will argue that "adult" stem cells may be just as effective in treating or curing diseases and will say that embryonic stem cell research is no longer necessary. This is simply untrue.

The potential value of "adult" stem cells is much less certain and experts in this field of research agree that it will take years of further study to determine their therapeutic potential. Dr. Irving Weissman, Professor of Pathology and Developmental Biology at Stanford University, was quoted in a July 9 Newsweek article as saying, "No paper

shows definitively any adult stem cell in humans turning into anything else." I am submitting for the record a letter from Dr. Weissman -- and another from Dr. Ole Isacson, Director of the Morris K. Udall Parkinson's Disease Research Center of Excellence at McLean Hospital/Harvard Medical School -- that provide further detail about adult vs. embryonic stem cells. In addition, 80 Nobel Laureates wrote President Bush in support of embryonic stem cell research earlier this year.

The Parkinson's Action Network agrees that "adult" stem cells may hold promise, albeit more remote, and believes that more research should certainly move forward on this front. However, we strongly caution that this research not come at the expense of embryonic stem cell research which we know has enormous potential to save the lives of untold millions of Americans. To shut down one avenue of medical research that could speed the pace of a cure would be unthinkable – more lives would be lost. With appropriate ethical safeguards and federal oversight, we must aggressively pursue all forms of stem cell research in order to realize its potential as soon as humanly possible. It would be shortsighted and naive to focus solely on "adult" stem cells.

Unfortunately -- cruelly -- precious time is being wasted. In the three years since scientists at the University of Wisconsin and Johns Hopkins University first isolated embryonic stem cells and debate has ensued, lives have been lost. Perhaps Elisabeth Bresee's father could not have been helped in the 80's by a more aggressive research investment. But we cannot avoid the fact that John Rogers' father's death may have been unnecessary: he might be alive today had the research moved ahead aggressively.

Mr. Chairman and members of the Subcommittee, I am not a scientist, but I am someone who struggles through each day with a chronic, degenerative, presently incurable illness. I speak for the larger Parkinson's community for whom time is not neutral. Each day that the government upholds the ban on federal funding for embryonic stem cell research a choice is made to ignore the millions of Americans suffering from debilitating diseases. We need a medical rescue and we need it now. Scientists agree it is possible this decade.

The Parkinson's Action Network urges you to open your minds and your hearts and look beyond politics. This debate is about giving life and giving hope, not taking life. It is about saving real, living people who are suffering each and every day, watching as their lives are being lost to often-fatal diseases. These leftover embryos, that may provide a medical miracle, have no chance of becoming life. Why then should we sit back and watch as they are discarded when they could be used instead to save lives?

Again, I thank the Subcommittee for the opportunity to testify.

**Harvard Medical School**
*Department of Neurology and Program in Neuroscience*

ASSOCIATE PROFESSOR
OF NEUROLOGY (NEUROSCIENCE)

OLE ISACSON, M.D. (DR. MED. SC.)

**McLean Hospital**
*An Affiliate of the Massachusetts General Hospital*

DIRECTOR OF
NEUROREGENERATION LABORATORY

July 16, 2001

Ms. Joan Samuelson
President
Parkinson's Action Network
300 North Lee St.
Alexandria, VA 22314

Via fax: (703) 518-0673

Dear Ms. Samuelson:

I am confirming to you in writing what we discussed on the phone regarding embryonic stem cells. As you know, stem cells are a new field of biomedical study and one with exceptional promise. We have obtained dopaminergic neurons of the same kind that die in Parkinson's disease through the use of embryonic mouse stem cells. Such cells have not yet been obtained by use of adult stem cells. The cells that were obtained from embryonic stem cells were transplanted to mouse and rat brains, where they reconnected the circuitry typically damaged in Parkinson's disease. These cells were also shown to be functional and were able to carry out the functions that normally are handled by the dopamine cells that die in Parkinson's disease. We and others are very encouraged by the results of using embryonic stem cells, both from learning how to deal with cell degeneration seen in Parkinson's disease and as potential new therapies. Any infringement on the freedom to study such cells in research laboratories will surely reduce the speed by which such medical discoveries can be made. This is basic research that elucidates how things work at the biological level and it does not necessarily imply the need to use embryonic stem cells in the actual medical therapy. Therefore, it is absolutely necessary that federally funded and free research can continue to help understand the neurobiology underlying Parkinson's disease and neurodegenerative disorders and provide needed treatments for patients with these diseases.

Sincerely yours,

Dr. Ole Isacson
Director, NINDS Morris K. Udall Parkinson's Disease Research Center of Excellence
and Director, Center for Neuroregeneration Research
McLean Hospital/Harvard Medical School

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July 13, 2001

Joan Samuelson
Parkinson's Disease Action Network

Dear Joan:

My name is Irv Weissman. I have an M.D. from Stanford (M.D., '65) and have spent my life in research. I am the Karel and Avice Beekhuis Professor of Cancer Biology in the Departments of Pathology, Developmental Biology, and Biology at Stanford University and its Medical School. I am an elected member of the National Academy of Sciences, American Academy of Arts and Sciences, American Association for the Advancement of Science, California Academy of Sciences, and others. My research has been over the past 15 years mainly on adult stem cells. My laboratory was the first to isolate any stem cell (the mouse blood-forming stem cell), and two companies I have co-founded have isolated human adult stem cells (SyStemix for blood-forming stem cells, and StemCells, Inc. for human brain stem cells). I do not do human embryonic stem (ES) cell research, and neither do the companies with which I am involved. In fact the company doing human ES research is a competitor to my companies that do adult human stem cell research. Yet I strongly support federal funding for human ES cell research.

You wished a brief summary of the relative merits of adult vs. ES cell research, especially as it might impact the eventual treatment of Parkinson's Disease.

To begin, the common property of all stem cells, adult or embryonic, is that they are cells which can make more of themselves (we call this self-renewal) as well as give rise to daughter cells that are more differentiated. Adult blood-forming stem cells make more adult blood-forming stem cells as well as all blood cells; adult brain stem cells make more adult brain stem cells as well as the various neuron types (dopaminergic included), and glial cells (oligodendrocytes and astrocytes). In rare cases highly purified mouse adult stem cells of one variety (say blood-forming stem cells) can give rise to mature cells of another type (say liver). But all of these experiments have been done in mice only and only a few of these experiments were done with purified stem cells. In the other experiments whole tissues like bone marrow, which contains at least 3 different kinds of stem cells, could give rise to blood as well as some other tissues. Therefore, even in the best of the mouse experiments as of today, there are only a few experiments that show adult stem cells of one type giving rise to tissues of another type.

ES cells are really cell lines established from the inner cell population of blastocysts. Human development begins with a fertilized egg, and the period between fertilization of the egg and the appearance of the blastocyst, containing ~200 cells, is called the preimplantation phase of development. Many embryologists call this the first stage of embryonic development. When the blastocyst implants in the uterus, an event that occurs some, but not all of the time in the body, the real stages of embryonic development begin. The undifferentiated cells start to become the main tissue layers, but they do not yet form identifiable tissues or organs; for example, a recognizable and functioning brain does not yet exist, and therefore the properties of the brain and mind are not yet present. The phase of development when the embryo begins to form recognizable organs and tissues is called the fetal developmental period, and this lasts until birth. The cells that can be cultured to give rise to ES cells are only found to date in the preimplantation blastocyst. ES cell lines in culture can be manipulated so that groups of ES cells can turn into cells found in many tissues of the body, including some brain cells, some heart cells, some blood cells, etc. ES cells cannot turn into human beings and cannot even make organs on their own. But the pluripotency of ES cells lets us know that these cells contain and can activte the genetic plans to develop most of the cell types in the body.

The most important reason that we need to study human ES cells in research laboratories is that these cells will allow us to unlock the mysteries of the decisions that undifferentiated cells make when they become the important differentiated functional cells of the body. Today no adult stem cells have this pluripotency. While it is likely that both adult type brain stem cells and brain cells derived from ES cells will play a role in regenerating degenerated parts of the brain in human conditions such as Parkinson's Disease, Alzheimer's Disease, Lysosomal Storage

Diseases, and perhaps strokes, much intensive research by the best and the brightest needs to be carried out to know the relative potential of ES cells versus adult brain stem cells in that regard.

What happens if human ES cell research cannot be carried out under federal funding at the major institutions of the United States? We will have given up the possibility to learn first and in human cells what are the genetic pathways to form not only brain cells but also every other cell type of the body. We will cede that research to a small number of privately funded companies, for whom profit must be their predominant motive, and at which the best and brightest surely will not come in the numbers necessary to solve these major human developmental problems. Furthermore, the research will be carried out in those countries which have already indicated that it is important enough to them to fund and to expand this research for scientific and medical reasons. It should be pointed out that although there are many sides to the philosophical debate as to when human life begins - in the preimplantation stage, in the embryonic stage, or sometime during fetal development - there is no doubt that banning ES cell research will cost human lives of humans who are already born, already thinking, and already engaged in this world. Imagine if we had banned recombinant DNA research in the 1970's: We would not have erythropoietin, which has saved the lives of so many kidney failure and chemotherapy treated patients; we would not have the new drug GLEEVEC, which seems to be able to bring almost every patient with chronic myelogenous leukemia into long-term remissions, etc. That is to say, those who would ban this research are responsible for the loss of lives or prevention of morbidity that will surely come from some avenue of ES research, although no one can predict today which of those avenues will be the most productive.

I hope this helps you in your discussions.

Yours sincerely,

Irving Weissman /gs

Irving L. Weissman, M.D.
Professor of Pathology and
Developmental Biology

Mr. WELDON. Thank you, Ms. Samuelson. We will now hear from Mollie and Jackie Singer.

Ms. MOLLIE SINGER. I want to thank you for giving us the opportunity to speak today. My name is Mollie Singer and this is my twin sister, Jackie. Eight years ago, I was diagnosed with juvenile diabetes, and ever since then, I worry that my sister will get this terrible disease. So far, I have had 21,000 shots and 28,000 finger pokes. At age 5, I had open-heart surgery which was made harder because of my diabetes. Because of all these problems I've had, I worry about my future and I don't want Jackie or anyone to go through what I've been through. We need to do something to stop it. Please support the NIH Guidelines for Embryonic Stem Cell Research.

Now my sister, Jackie, would like to say a few words.

Ms. JACKIE SINGER. Since Mollie was 4 years old, I've watched her struggle with her diabetes. It's so hard. For more than half our lives, we have visited our Representatives in Washington, DC, to ask them to support diabetes research. We have helped raise over $75,000 for research. We have written letters to President Bush. We have visited the National Institutes of Health to see research laboratories and speak with Dr. Spiegel and Dr. Harlan. We have done all this to help cure diabetes, but it still isn't cured.

Mollie may look normal, but her disease is very hard on her body. All Mollie wants is to live a normal, healthy life, and embryonic stem cell research is our best hope.

Ms. MOLLIE SINGER. Last week we wrote a letter to President Bush to tell him our thoughts about embryonic stem cell research. I'd like to read this letter to you now.

Dear President Bush,

We hadn't planned on writing you so soon, but this morning we were watching the news and we heard about the people in Virginia who made embryonic stem cells in the laboratory. We were so upset, we couldn't believe that they made cells just so they could be destroyed. We must be very naive because we never thought someone would do something like this. So we asked mom how this could happen and she explained that right now it is legal, but that she is completely against this type of research and so is the Juvenile Diabetes Research Foundation.

We feel so bad, because for a long time we have asked you to help us and to support embryonic stem cell research, but we never meant like this. Our family is Catholic and we have prayed and asked God to help us know what is right and what is wrong about embryonic stem cell research. We always thought it was wrong to make embryos, especially when they did it for no other reason than to destroy them.

But we also believe it is just as bad to treat the embryos that already exist as though they are worthless. Because embryos are so special, embryonic stem cells should be allowed to have meaning. We should respect them and value them, and we shouldn't be wasting such a special gift. If these cells will never be able to become a human life, then maybe the most moral thing to do is find out if these cells can save lives rather than simply throw them out. Whenever we have difficult decisions to make, we usually ask WWJD, "what would Jesus do," and we don't believe that Jesus would ever waste a gift from God.

We never talked to you or anyone about how much we know about stem cell research, so most people think that because we are only 12 that we couldn't possibly understand the moral and medical issues that are involved, but we do understand. We are devout Catholics and have had many conversations with our family and parish priest about this subject. Also, for the past few years we have visited research laboratories, including NIH, and have talked for hours with quite a few well-known researchers. We have listened to many knowledgeable and respected people on this subject and, above all, we have prayed for guidance.

President Bush, we don't want you to see our picture or think of us and somehow associate the support we asked for with the researchers who created their own embryos. Yes, we want you to remember us when you make your decision. But, when

that time comes, we want you to know that we, along with all the other people who desperately want to cure their diseases, are talking about the embryos that already exist, not the embryos created by scientists.

At the beginning of this year and as a result of what we have learned, we finally made the decision to support embryonic stem cell research, but only the ones that are in existence and that will be destroyed after a few years. We can only imagine how difficult this decision is for you, but it helps us to know that someone as wise as you are was chosen to make this decision. At least we can be sure that you will do what you honestly believe is for the greater good and in the best interest of all the people.

As always, we will keep you and your family in our prayers.

And we signed our letter, "Love, Mollie and Jackie."

Ms. JACKIE SINGER. Please help us. I don't want Mollie to go blind. I don't want Mollie to have kidney failure. I don't want Mollie to have a heart attack or stroke. I want Mollie to live. Please support embryonic stem cell research and give the researchers the opportunity to cure diabetes. Thank you for listening to us.

[The prepared statement of Ms. Jackie Singer and Ms. Mollie Singer follows:]

**Testimony**

**By**

**Mollie Singer**
**Jackie Singer**

**On Behalf of**

**Juvenile Diabetes Research Foundation International**

**Regarding Embryonic Stem Cell Research**

**Before the**

**Criminal Justice, Drug Policy and Human Resources Subcommittee**

**2154 Rayburn Building**

**July 17, 2001**
**2:00 PM**

**Mollie Singer**

My name is Mollie Singer and this is my twin sister, Jackie. Eight years ago, I was diagnosed with juvenile diabetes, and ever since then, I worry that my sister will get this terrible disease. So far, I have had 21,000 shots and 28,000 finger pokes. At age 5, I had open-heart surgery which was made harder because of my diabetes. Because of all the problems I've had, I worry about my future and I don't want Jackie or anyone to go through what I've been through. We need to do something to stop it. Please support the NIH Guidelines for Embryonic Stem Cell Research. Now my sister, Jackie, would like to say a few words:

**Jackie Singer**

Since Mollie was four years old, I've watched her struggle with her diabetes – it's so hard! For more than half our lives, we have visited our Representatives to support diabetes research. We have helped raise over $75,000 for research. We have written letters to President Bush. We have visited the National Institutes of Health (NIH) to see research laboratories and speak with Dr. Allen Spiegel and Dr. David Harlan. We have done all this to help cure diabetes. Mollie may look normal, but her disease is very hard on her body. All Mollie wants is to live a normal, healthy life, and embryonic stem cell research is our best hope!

**Mollie Singer**

Last week, we wrote a letter to President Bush to tell him our thoughts about embryonic stem cell research. I'd like to read this letter to you now.

Dear President Bush,

We hadn't planned on writing you so soon, but his morning we were watching the news and we heard about the people in Virginia who made Embryonic Stem Cells in the laboratory. We were so upset, we couldn't believe that they *made* cells just so they could be destroyed. We must be very naïve because we never thought someone would do something like this! So, we asked mom how this could happen and she explained that right now it is legal, but that she is completely against this type of research and so is the Juvenile Diabetes Research Foundation.

We feel so bad, because for a long time we have asked you to help us and to support Embryonic Stem Cell research, but we NEVER meant like this! Our family is Catholic and we have prayed and asked God to help us know what is right and what is wrong about Embryonic Stem Cell research. We always thought it was wrong to make embryos, especially when they did it for no other reason then

to destroy them. But, we also believe it is just as bad to treat the embryos that already exist, as though they are worthless. Because embryos are so special, Embryonic Stem Cells should be allowed to have meaning. We should respect them and value them, and we shouldn't be wasting such a precious gift? If these cells will never be able to become a human life, then maybe the most moral thing to do is find out if these cells can save lives rather then simply throw them out! Whenever we have difficult decisions to make, we usually ask WWJD, what would Jesus do, and we don't believe that Jesus would ever waste a gift from God.

We never talked to you or anyone about how much we know about stem cell research so most people think that because we are only twelve that we couldn't possibly understand the moral and medical issues that are involved, but we do understand. We are devout Catholics, and have had many conversations with our family and Parish Priest about this subject. Also, for the past few years we have visited research laboratories, including NIH, and have talked for hours with quite a few well-known researchers. We have listened to many knowledgeable and respected people on this subject and above all, we have prayed for guidance.

President Bush, we don't want you to see our picture or think of us and some how associate the support we asked for with the researchers who created

their own embryos. Yes, we want you to remember us when you make your decision. But, when that time comes we want you to know that we, along with all the other people who desperately want to cure their diseases, are talking about the embryos that already exist. Not the embryos created by scientists.

At the beginning of this year and as a result of what we have learned, we finally made the decision to support embryonic stem cell research, but only the ones that are in existence and that will be destroyed after two years. We can only imagine how difficult this decision is for you, but it helps us to know that someone as wise as you are, was chosen to make this decision. At least we can be sure that you will do what you honestly believe is for the greater good and in the best interest of all the people.

As always, we will keep you and your family in our prayers

Love,

Mollie and Jackie Singer

**Jackie Singer**

I don't want Mollie to go blind! I don't want Mollie to have kidney failure! I don't want Mollie to have a heart attack or stroke! I want Mollie to live! Please

support embryonic stem cell research and give researchers the opportunity to cure diabetes. Thank you for listening to us!

Mr. WELDON. Thank you, girls.

We will now hear from Dr. Carl Hook. You are recognized for 5 minutes, Doctor.

Dr. HOOK. Thank you, Mr. Chairman. I'd like to start my comments by first stating that I'm speaking as a private citizen and not as a formal representative of the Mayo Foundation.

Mr. Chairman and members of the subcommittee, thank you very much for this opportunity to participate in this hearing today concerning one of the most important issues facing this government and country today. The issue of embryonic stem cell research places before us critical choices that will determine the nature and soul of our Republic for years to come.

There are four questions before us, and they are these: No. 1, as a society, are we willing to devalue and commodify members of our human family?

No. 2, are we willing to violate principles of human subjects research that have arisen from the ashes of atrocities committed here and abroad under circumstances when other members of the human community have been devalued and commodified for utilitarian logic, precisely as is occurring now in the stem cell debate?

No. 3, are we willing to transform our concept of proxy informed consent for medical care into a license to kill by allowing genetic parents to effectively abandon the offspring they deliberately conceived to fatal medical experimentation under a pretense of informed consent.

No. 4, are we willing to set the precedent that the promise, not proof, of future medical treatments for third party patients is sufficient to endorse the destruction of living human beings now?

Human subject research none of us would argue is an evil thing. It has provided many wonderful treatments to patients over the past 200 years. However, the history of human research is checkered with horrible abuses, including in our own country the Tuskegee syphilis trials, the Willowbrook hepatitis experiments, and across the ocean during the Second World War experiments performed at Dachau.

During the Nuremberg war crime trials, conducted at the conclusion of World War II, the German researchers tried for their crimes defended themselves by forwarding this argument: First, there allegedly existed a great need for research in order to save the lives of soldiers and sailors. Two, the subjects of the experiments were already targeted to die. Someone else had made the decision that they were to die; we didn't. And, therefore, three, we should not let this valuable commodity, this chance to learn in ways we otherwise could not, go to waste.

This argument, resoundingly rejected by the Nuremberg tribunal, is precisely the same argument that is being put forward today to justify using government funds and authorizations for research on human embryos. The only difference is that we have substituted human embryos as the group of devalued, commodified human beings who are to be sacrificed on the altar of scientific progress.

One of the products of the Nuremberg trials was the Nuremberg Code of Research Ethics, created with the hope that the mistakes in Germany would never be repeated by the research community again. The document has served as the foundation of all subse-

quent statements governing human subjects research. Section 5 of that document reads, "No experiment should be conducted when there is an a priori"—that is, a prospective—"reason to believe that death or disabling injury will occur, except perhaps in those experiments where the experimental physicians are to serve as subjects."

It is ironic, indeed, that as that great generation which protected us from expansion of such reductionistic, utilitarian dehumanization of our fellow human beings and bequeathed to us the wisdom and legacy of the Nuremberg Code, as that generation is passing away, we are abandoning the principles for which it fought and the lessons it painfully learned.

A subsequent international document governing human subject research is the Declaration of Helsinki of the World Medical Association. Under the section on basic principles it states, "Concern for the interests of the subject must always prevail over the interests of science and society."

Later, addressing non-therapeutic biomedical research, the statement reads, "In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out."

There is no question that embryonic stem cell research is non-therapeutic research when the small human being is dissected to its death. It comes down to this fundamental question: Is the human embryo a human being whose research protocols ought to be governed by these rules? Yes, she is. She is a human being who is in an early phase of her maturation. She is a human being at a developmental stage that you and I once inhabited. She is not some other species. She is not just tissue. Tissue cannot continue to develop into a full adult human being unless acted upon by extreme laboratory manipulations, which are as yet still uncertain in feasibility.

Dehumanization of the embryo is a form of ageism, or age-based discrimination. All of the attempts to use some developmental milestone beyond fertilization as the magical point at which a human being is finally recognized as being human have been arbitrary, subjective, and have been proposed by those who want to do something to or with the individual in question.

I am concerned that we have heard expression of this logic from the distinguished Senator in his testimony earlier today, but, even worse than trying to use a developmental milestone, we have reduced our definition of humanity to geography rather than biology.

This fact that our arbitrary definitions of humanity have been proposed usually to justify doing something to others should disqualify them, and we should not use such self-serving arguments to define away each genetically unique human being's humanity. Once a genetically unique individual exists at fertilization, she is human. She is a being. She is a human being, and she is covered by the rules of human subjects research.

Even if one wishes to say that as a society we are not sure about the nature of the human embryo, the so-called agnostic stance, then we are still compelled to provide the same protections as apply to other human beings because there is still the significant possibility that the embryo is a human being. To choose otherwise

is to say we don't have to be sure we're not destroying human beings, and therefore, it is permissible to destroy humans for utilitarian purposes.

I make one final point. Recently, there were hearings here in Washington that revealed that in other countries individuals condemned by the death penalty have been having their organs harvested at the time of their death or were killed in the process of having their organs harvested, and this was decried, as all civilized nations would do. And yet the perpetrators of these crimes against humanity were only employing the exact same "stewardship logic" as the proponents of destructive embryonic stem cell research. How can we, with any sense of good faith, decry such opportunism based upon the demeaning and commodification of our fellow human beings, turn around and target another group of human beings, human embryos, for the exact same type of behavior?

We dehumanize the immature members of our human family at great risk. If we can define away others' humanity, then in the end none of us is truly protected by our supposed codes of protection. That sort of thing may take place elsewhere, but it should never happen in the United States of America.

Thank you.

[The prepared statement of Dr. Hook follows:]

**Testimony of C. Christopher Hook, M.D.**
**before the**
**United States House of Representatives Committee on Governmental Reform**
**Subcommittee on Criminal Justice, Drug Policy and Human Resources**
July 17, 2001

[Dr. Hook's comments are his own and do not necessarily reflect the views of the Mayo Foundation. He is presenting in his roles as a Senior Fellow of the Center for Bioethics and Human Dignity, a member of the Christian Medical Association's Ethics Commission, a co-founding member of Do No Harm: The Coalition of American's for Research Ethics and as a private citizen.]

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to participate in this hearing concerning one of the most important questions facing this government and country today. The issue of embryonic stem cell research places before us critical choices that will decide the nature and soul of our Republic for years to come. The questions before us are these: As a society, are we willing to devalue and commodify members of our human family? Are we willing to violate principles of human subject research that have arisen out of the ashes of atrocities committed here and abroad under circumstances where other members of the human community have been devalued and commodified using utilitarian logic, precisely as is occurring again in the debate on living human embryo research? Are we willing to transform our concept of proxy for medical care into a license to kill by allowing genetic parents to abandon their living human embryos to fatal medical experimentation under the pretense of giving their "informed consent"? Are we willing to set the precedent that the promise, not proof, of future medical treatments for third party patients is sufficient to justify the destruction of living human beings?

Human subject research has provided many wonderful treatments to patients over the past 200 years. However, the history of human research is checkered with horrible abuses, including the Tuskegee syphilis trial and the Willowbrook hepatitis experiments here in the United States, and the experiments performed at Dachau during the Second World War. During the Nuremberg war crime trials, conducted at the conclusion of World War II, German researchers on trial defended themselves on the following grounds: (1) a great need allegedly existed for the research to save the lives of soldiers and sailors; (2) the subjects of the experiments were purportedly already targeted to die (*i.e.*, German researchers alleged that someone else made the decision to kill them); therefore, (3) we should not let this valuable commodity, this chance to learn in ways we otherwise could not, be wasted. This argument, resoundingly rejected by the tribunal, is precisely the same argument put forward today to justify using government funds to conduct research on human embryos. The only difference is that we have substituted human embryos as the group of devalued, commodified human beings who are to be sacrificed on the altar of research and supposed progress.

One of the products of the Nuremberg trials was the Nuremberg Code of Research Ethics. The Code was created with the hope that the research community would not repeat the mistakes in Germany. Indeed, it is interesting that Germany, the country with the most horrific experience with fatal human subject experimentation, today bars not only the destruction of living human embryos for research purposes, but also the freezing of human embryos because of the high associated death rate (11-50% death rate at thawing). The Nuremberg Code of Research Ethics has served as the foundation of all subsequent statements governing human subject research. Section 5 of the Code states, "No experiment should be conducted where there is an *a priori* reason [*i.e.*, prospective reason] to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as subjects."

In 1949, Dr. Leo Alexander, one of the participants in the Nuremberg trials, recorded his observations and the lessons he hoped we would learn from the Dachau tragedy in the *New England Journal of Medicine* [Volume 241: 39-47, July 14, 1949]. One of his comments is particularly pertinent to this discussion:

> The case, therefore, that I should like to make is that American medicine must realize where it stands in its fundamental premises. There can be no doubt that in a subtle way the Hegelian premise of "what is useful is right" has infected society, including the medical profession. Physicians must return to the older premises, which were the emotional foundation and driving force of an amazingly successful quest to increase powers of healing and which are bound to carry them still further if they are not held down to earth by the pernicious attitudes of an overdone practical realism.

It is ironic that as the generation that protected us from the expansion of reductionistic, utilitarian arguments leading to the dehumanization of fellow human beings passes away, we are abandoning the principles for which it fought and the lessons it painfully learned.

A subsequent international document governing human subject research is the Declaration of Helsinki of the World Medical Association. It states in the section on Basic Principles, "Concern for the interests of the subject must always prevail over the interests of science and society." Concerning non-therapeutic biomedical research, the Declaration adds, "In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out." The even more contemporary European Union Convention on Human Rights and Dignity of the Human Being (1997) states, "The interests and welfare of the human being shall prevail over the sole interest of society and science."

The bottom line of all of these statements is that to prevent abuses and protect all human beings, strict limits must be placed on medical research. There are certain lines that must never be crossed. Research that directly and explicitly will lead to the death of the subject is, and should be, completely forbidden. The protection of the individual human subject must outweigh any interests society asserts in performing experimentation on her.

It comes down to this fundamental question: Is the human embryo a human being whose research protocols ought to be governed by ordinary medical ethical rules? She is. The human embryo is a person in an early phase of maturation through which everyone of us passed. She is not some other species. She is not merely tissue. Tissue cannot continue to develop into a full adult human being, unless acted upon by extreme laboratory manipulations which are still of uncertain feasibility.

Dehumanizing the embryo is a form of agism, or age-based discrimination. All of the many attempts to use some developmental milestone beyond fertilization as *the point* at which a human being is finally recognized as a human being have been arbitrary, subjective and proposed by those who want to do something to or with the individual in question. That last fact, alone, should disqualify these subjective and self-serving attempts to define away each genetically unique human being's humanity. Once a genetically unique individual exists at fertilization, she is human and she is a being; she is a human being and protected by the rules of human subject research. Even if one wishes to say that we, as a society, are not certain about the nature of the human embryo -- a supposed "agnostic" stance -- then we are still compelled to provide the same protections to her that we apply to other human beings, because there is still the significant possibility that the embryo is a human being. To choose otherwise is to say that we do not have to be sure that we are not destroying human beings or, in essence, that it is permissible to destroy human beings for utilitarian purposes.

Because living human embryos are human beings whose participation in research should be governed by traditional codes of human subject research ethics, the current proposal to destroy them raises additional concerns. Among these is the issue of informed consent. The Nuremberg Code, the Declaration of Helsinki, the Belmont Commission Report and the U.S. Code of Federal Regulations mandate that prospective subjects of biomedical research provide informed consent prior to participation in research. The post-Nuremberg codes allow that, in cases where the prospective subject cannot provide informed consent, a proxy may provide it. However, they require that the research have therapeutic value to the subject, or, if not of therapeutic value, the information cannot possibly be obtained via other means. In all cases, direct harm or death to the individual is forbidden, or the harms incurred must be significantly less than the potential benefits to the subject.

Clearly, the proposed research that leads to the death of the individual embryonic human being is not therapeutic and violates the prohibition against disproportionate harm. Most importantly, no proxy can authorize the death of a ward through participation in research. Proxies must always act in the best interests of the ward. Any proxy that would authorize the deliberate killing of a ward is in breach of his or her responsibility and has relinquished any right to serve in the capacity of a proxy. Any system, such as the NIH Guidelines, that would allow a proxy to consent to the deliberate killing of the ward is in violation of all codes of human subject research. Parents who would choose death for the children they deliberately conceive, rather than pursue the available and responsible option of giving the children to others via adoption, have violated their parental

responsibility. Our government should not participate in this tragedy at all and particularly not by capitalizing or permitting others to capitalize from such gross irresponsibility.

Another classic principle of human subject research is that we should pursue knowledge using the least dangerous or damaging approach feasible. The ostensible therapeutic goals of human embryonic stem cell research can be pursued via methods that do not lead to the destruction of human life. It is ethically mandatory that adult stem cell research be pursued to its conclusion before research threatening the life of a human being is considered. In addition, human subject research should always be preceded by sufficient animal model research to justify the research on humans. Research on animals using stem cells has just begun. Therefore, it is far too early to know what embryonic stem cells can or cannot do, both for good and harm. We have no business destroying human beings for research when our animal studies are still in their embryonic phases.

As a final matter, hearings in Washington recently revealed that other countries harvest the organs of individuals condemned by the death penalty. All civilized nations find this practice repugnant. Yet the perpetrators of these crimes against humanity employ the same "stewardship" logic used by proponents of destructive embryonic stem cell research. We cannot with any sense of good faith decry the commodification by other countries of human beings, yet turn around and engage in precisely the same behavior against another target group of humans: embryos.

We dehumanize the immature members of the human family at great risk. If we can define away others' humanity, in the end, none of us is safe. This sort of thing may take place elsewhere, but it should never happen in the United States of America.

Mr. WELDON. Thank you, Doctor.

The Chair will now recognize himself for 5 minutes for questioning.

Ms. Samuelson, I want to thank you for your testimony. It was very compelling. Not only did I take care of many Parkinson's patients when I practiced medicine, but I had an uncle I was very close to who ultimately did die of the disease. Certainly I salute you and all Parkinson's sufferers who deal with this on a daily basis.

You testified before the Commerce Committee about a year ago in support of fetal research to develop possible treatments for Parkinson's disease. As I am sure you are probably aware, the research that you were advocating for at that time, about a little over a year ago, had to be cut short because of some pretty severe adverse clinical outcomes. Some of the patients had uncontrollable tremors, and the research protocol was ended.

In your study of this issue, I assume you look at the research. Have you seen any research studies to suggest that these stem cell research protocols, specifically embryonic stem cell protocols, hold any particular promise, and, in particular, over the use of adult stem cells or other treatment modalities that are out there?

Ms. SAMUELSON. Thank you. Obviously, I'm not a scientist. I care about it deeply and I study it as best I can as a layperson. So——

Mr. WELDON. Well, I am going to ask the two people sitting to your right to respond to my questions because I expect them to be able to handle it better. I wanted to give you the first crack at the question.

Ms. SAMUELSON. Well, I appreciate that.

Mr. WELDON. Parkinson's is a common disease. It is one of the more frequent diseases that are cited by people to argue in favor of embryonic stem cell research. I just haven't seen a good study to suggest that it has any potential application, and I was wondering if you have anything you want to share with the committee.

Ms. SAMUELSON. Sure. Sure, there are two thoughts. I spend a lot of time talking to the scientists to understand it as well as I can and to separate out hope from reality. Because, of course, we feed ourselves on hope because sometimes that's the only thing we have to go on.

But one of the two letters that are attached to my testimony is from Dr. Ole Isacson, who is the director of the Morris K. Udall Center for Research at Harvard. Let me just briefly read a couple of sentences.

He says, "We have obtained dopaminergic neurons," which you know are the brain cells that are slowly degenerating in Parkinson's. "We have obtained dopaminergic neurons of the same kind that die in Parkinson's disease through the use of embryonic mouse stem cells. Such cells have not yet been obtained by use of adult stem cells. The cells that were obtained from embryonic stem cells were transplanted to mouse and rat brains where they reconnected the circuitry typically damaged in Parkinson's disease. These cells were also shown to be functional and were able to carry out the functions that normally are handled by the dopamine cells that die in Parkinson's disease."

He would dearly love to take that research and carry it forward into human clinical trials.

Mr. WELDON. Did he publish that research that he's citing to you in the letter format?

Ms. SAMUELSON. I don't know. I don't know, and I commend you to talk to him and we can certainly put him in touch with you. I think he would probably welcome the chance to come here and speak about his research.

Mr. WELDON. I want to give Dr. Prentice an opportunity to respond to this——

Ms. SAMUELSON. OK.

Mr. WELDON [continuing]. In the time I have left, I've only got about a minute left—or Dr. Fischbach.

Dr. PRENTICE. Thank you, Mr. Chairman. I believe I have seen a reference for the study in which Dr. Ole Isacson in the culture dish was able to achieve the transformation of the embryonic stem cells into the dopaminergic cells. I don't believe this study has been published in terms of transplant into animal models with Parkinson's, although Dr. Fischbach might have that information.

And that is correct that in the culture dish the adult stem cells have not been transformed, at this point at least, into dopaminergic neurons. There is a published study using adult stem cells, adult brain stem cells, in which the cells were not removed from the animal, which was a model of Parkinson's, but instead a growth factor was given directly into the brains of the animals of this Parkinson's model, and they did achieve some therapeutic benefit. So the indications are that this could possibly be done as well in terms of patients, although, obviously, we still need to do the animal model studies to see whether this would work.

Dr. FISCHBACH. Can I comment on that study? The study you referred to is an interesting one, funded by the Neurology Institute. Although it did show modest improvement in one measurement of movement, reducing the rigidity, not the tremor or the axial signs, it did exhibit terrible side effects in 15 percent of the patients.

Mr. WELDON. You are talking about the New England Journal study, correct?

Dr. FISCHBACH. Yes. I wrote an editorial that accompanied that study. To my mind, as I said in that editorial, this was the perfect example of the need for stem cell research; that what was transplanted in that study were whole clumps of tissue, that they were not purified cells; that they were regions of the brain, the mesencephalon from embryos implanted in the tissue. It took four embryos per patient, that with the advent of stem cell lines which might grow up to billions of cells from one, and the purity of the stem cell lines and the ability to control the cells much better than you could with a mixed heterogeneous bit of tissue, that this was a real call for research on stem cells.

Now the difficulty with that study is the difficulty with all clinical research: Gains are hard-won and adverse side effects occur. We must learn from them and promote additional research.

I don't think the Ole Isacson study is yet published, but an earlier one by Ronald McKhie of the NIH is, using rat embryonic stem cells to restore dopamine-containing neurons in the mid-brain of mice who were made a very good model of Parkinson's disease. It

restored the neurons. It restored the dopamine, and it reversed the abnormal movements. And this was with embryonic rat stem cells.

I think you're quite right that we're not there yet in human trials with human embryonic stem cells, but we are at the stage where all of the animal research has pointed to this as the very next step. So I think that's the region we're poised at. There's good animal experimentation in the areas I know about in cases of stroke, multiple sclerosis, spinal cord injury, Parkinson's disease, and Alzheimer's disease, leading to, pointing to the next step of clinical trials in humans.

Mr. WELDON. My time has expired. I would love to get into this in more detail. I need to now recognize Ms. Davis, a member of the subcommittee.

Mrs. JO ANN DAVIS OF VIRGINIA. Mr. Chairman, I am going to yield to Congressman Smith if you can come back to me.

Mr. WELDON. Without objection.

Mr. SMITH OF NEW JERSEY. Thank you very much, Ms. Davis, and thank you, Mr. Chairman, for yielding. I just have a couple of questions I would like to ask our distinguished panel, and thank them for their testimony today.

Dr. Hook, in his statement—and this is to you, Dr. Fischbach—says, "One of the products of the Nuremberg tribunals was the Nuremberg Code of Research Ethics. The code was created with the hope that the research community would not repeat the mistakes in Germany. Indeed, it is interesting that Germany, the country with the most horrific experience with fatal human subject experimentation, today bars the destruction of living human embryos for research purposes."

Would you support a law that barred the creation of human embryos for research purposes?

Dr. FISCHBACH. I would support that law. I think that is a step beyond what is necessary now. Although that has scientific, as mentioned before, advantages, I would support that law.

Mr. SMITH OF NEW JERSEY. You would support banning the creation of human embryos for research, just so I am clear?

Dr. FISCHBACH. Specifically for research, yes.

Mr. SMITH OF NEW JERSEY. Would the other panelists want to respond to that as well?

Dr. PRENTICE. I would definitely support the banning of creation of human embryos for research.

Ms. SAMUELSON. I'm offended at it, by it. I have been careful at every step to study both sides of the issues because I am a moral and ethical person as well as a desperate patient. I think it's important that we do that, and it's not the choice that's before us right now.

Mr. SMITH OF NEW JERSEY. But my question is, because it has been suggested that somehow if the President were to OK the funding of embryonic stem cell research, that may have a chilling effect on private research on embryos, but there is a larger question here as to whether or not it ought to be legal. We are talking today primarily about funding, but the very issues that are raised at this hearing go far beyond that. That's why the question.

Ms. SAMUELSON. And that's why we need Federal regulations in this arena.

Mr. SMITH OF NEW JERSEY. So you would not support it, just to be clear? Or you would support it? I mean it's very clear-cut. Some countries ban it, like Germany——

Ms. SAMUELSON. I'm not a theologian or a scientist. I know this particular field and have studied it carefully to make a moral, ethical decision about that, and that's the choice that's before us right now.

Mr. SMITH OF NEW JERSEY. But, as lawmakers, we are faced with what could be an explosion of human experimentation that may or may not be covered by our current statute. So if it is found to be infirm and does not reach to a Jones Clinic, for example, that may require, or at least an attempt, to try to legislate on the issue, and that's why the question.

Ms. SAMUELSON. And Federal funding shouldn't be used for that. It should have the same rigorous scientific and ethical scrutiny that stem cells have had, that this use of existing embryonic stem cell research has had.

Mr. SMITH OF NEW JERSEY. So you would be, in terms of—you would say that, whether there is Federal funding or not, the NIH guidelines should apply, so you would not be for banning it? Just so we're clear. I am just trying to elicit an honest response.

Ms. SAMUELSON. You're asking me to give you an answer about something I haven't studied, and the easy thing to do would be to do that. I have not done this in this work, and I just don't feel I can.

Mr. SMITH OF NEW JERSEY. Any of the other panelists?

Dr. HOOK. Clearly, it should be forbidden, not just not funded, but completely outlawed.

Mr. SMITH OF NEW JERSEY. I appreciate that. Thank you.

Let me just ask perhaps, Dr. Prentice, if you would respond to this and, Dr. Fischbach, if you would like as well: Have adult stem cells or embryonic stem cells been more successful in clinical trials and which has shown greater success in treating diabetes, adult stem cells or embryonic stem cells?

Dr. PRENTICE. Well, Congressman, in terms of clinical trials, there have been no clinical trials with embryonic stem cells. There are currently no reports of embryonic stem cells being used whatsoever in patients, whereas there are numerous reports of adult stem cells or cord blood stem cells successfully being used. We have Nathan sitting here because of the success of adult and cord blood stem cells, and the cells are being used, the adult stem cells, successfully for numerous treatments in terms of cancer therapies along with chemotherapy or radiation, in terms of treatments for multiple sclerosis and lupus and a number of other conditions, even to grow new corneas to restore sight to legally blind patients and the first report recently of using a patient's own adult muscle stem cells to take care of damage due to a heart attack.

Mr. WELDON. The gentleman's time has expired. The Chair now recognizes Ms. Schakowsky, a member of the subcommittee, for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. First of all, Mr. Hook, I want to tell you that comparing the Nuremberg laws to stem cell research is offensive to me as a Jew, and I feel that you are denigrating the annihilation and the planned murder of 6 mil-

lion living, breathing individuals by comparing that to the combination of a sperm and an egg in a test tube, and I just want to state that very clearly for the record, and I have a question for you.

Would it be your position, then, as someone who believes that discarding embryos is murder, that a couple who may offer those embryos should be forced to put all 23, for example, remaining genetically similar embryos up for adoption?

Dr. HOOK. First, I'd like to say no offense was intended, Ma'am. I was referring not to the entire Holocaust, but to the experimentation which was what the Nuremberg doctors' trials were in part about. I would submit back to you that the logic is, indeed, identical, and that's very disturbing.

Ms. SCHAKOWSKY. No, I want to disagree with that because then you are saying that my support of stem cell research is equivalent to the logic that led to the annihilation of the Jews and others, and I reject that wholeheartedly, emphatically.

Dr. HOOK. Your logic is the utilitarian argument that was used to do inhumane destructive research——

Ms. SCHAKOWSKY. Well, let's follow this question then. Are you saying, then, that those 23 remaining embryos, that they should be forced to be put up for adoption? And, further, should they be frozen forever, for example, against the wishes of the couple? Because then carrying your logic to its extreme, that is what would happen.

Dr. HOOK. Well, we do have laws that prohibit abandonment of other children, and we do have laws that prohibit the abuse of other children. Proxies who use their proxy authority to make a decision leading to the death of the child they conceived certainly could be considered abusive. I think this is a very large question that we as a society must confront, and this stem cell debate has brought to the focus not only issues of stem cell research, but it has brought up questions about the entire assisted reproductive process that we use.

Ms. SCHAKOWSKY. So it is well known in this process that many embryos don't survive. This is known from the start, the dethawing and implantation process. So if, as you believe, an embryo is morally equivalent to a human being, then is it not immoral to dethaw and implant, even for the purposes of adoption, knowing that many of these will not survive?

Dr. HOOK. That is problematic, yes. There are those who would advocate that IVF may be done with fresh cycles, limiting the number of conceived embryos, and not cryo-preserving them. Others assume or accept that the loss in the cryo-preservation process is akin to the loss that may occur naturally. Certainly, the intent is not there for the destruction of the embryo. That is morally different than our making choices that specifically destroy the embryo rather than taking a chance.

Ms. SCHAKOWSKY. I would think that the parents of this diabetic child who testified so eloquently would disagree with that.

Let me ask you, Dr. Fischbach, a question that was asked also to Dr. Hook—no, not Dr. Hook. Anyway, the question being the issue of adult stem cell research, and if you could compare for us the efficacy of stem cell and embryonic stem cells?

Dr. FISCHBACH. Let me say at the beginning—and then I'll tell you why, but in the beginning I want to say that I disagree with

my colleague in that I know of no adult stem cell which has been used to treat a central nervous system disorder in a human, and I don't know that in either published or unpublished records.

And I want to be clear that I am very much in favor of adult stem cell research because I think the promise here is great, but we should be absolutely precise about the definition of the word "stem cell." There are mixtures of cells which contain a few cells that can take on the identity of a missing cell, but to truly be a stem cell and truly to be useful for therapy, this cell must be purified, isolated, and it must be able to proliferate. We must understand whether these cells not only are effective, but whether they are safe. For that reason, I don't know of any adult stem cell that has been identified, purified, and grown up to large quantities to the point where we can do safety studies, where the FDA would treat this as a new medicine. Embryonic stem cells have that promise, and that's already happened.

Ms. SCHAKOWSKY. Thank you. Thank you, Mr. Chairman.

Mr. WELDON. The gentlelady's time has expired. The Chair now recognizes the gentleman from California, Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I would thank the panel. I am sorry I wasn't here for all of your presentation, but I got a report on what you all had to say.

Dr. Fischbach, you are the former Director of NIH's Institute for Neurological Disorders and Stroke and the current dean of the school of medicine at Columbia University. In your opinion, why is it so essential for medical progress for scientists to be able to do research with embryonic stem cells?

Dr. FISCHBACH. Because I think the embryonic cell, by most criteria, is not identical to the adult stem cell. In fact, everything that we've seen in animal embryonic cells indicates that they have a greater diversity of offspring, and this is going to be essential in complex tissues, where these cells must respond to a myriad of signals, and also that they have the ability to proliferate essentially eternally, so that they can produce a line of cells which will be the same this year and next year and the year after, where one can test the safety as well as the efficacy of this cell. It will be easier to characterize.

Now it may well be that we will learn more in short order about adult stem cells, but I don't think we can predict breakthroughs or when they will occur. So I think that research ought to go on in both areas, but I would be strongly opposed to seeing research stop in one area that is so promising.

Mr. WAXMAN. If research were allowed to proceed, when would you expect that patients would start to see benefits?

Dr. FISCHBACH. To see benefit? Well, the clinical trial mentioned earlier is an important lesson. I think we have to make this jump from advanced animal experimentation to human trials, but unless we are allowed to do research on all sorts of stem cells, we will not be able to answer that question at all. My own prediction is I think I'm hoping within the next 5 to 10 years we will see real advances in trophic factor and stem cell research in humans.

Mr. WAXMAN. A number of my colleagues made the point, so if the government funds aren't used for this kind of research, the private sector would step in to provide adequate funding, and the re-

search benefits would still be there, but we wouldn't use taxpayers' dollars, especially the taxpayers who are offended by this research. How do you respond to that?

Dr. FISCHBACH. Well, my worry, Congressman Waxman, is that research behind closed doors is behind closed doors and that we will not have the scrutiny of peer review and public criticism of that research. Indeed, even today, with two or three companies conducting stem cell research, there are worries about accessibility to these stem cell lines because of patent infringements. They are just not going to be available as if these were open to the public. And I think that the quality of the research, if I can be chauvinistic, will not be as great as if publicly supported scientists are involved.

Mr. WAXMAN. What would be the situation at universities? How difficult would it be for them to accept private funding for this research, if we had a Federal ban on funding research?

Dr. FISCHBACH. I'm sorry, how would——

Mr. WAXMAN. How difficult would it be for universities to accept private funds if there is a Federal ban?

Dr. FISCHBACH. Well, I think there are many, many individuals who feel passionately about this who would contribute, but the rules and regulations would make it difficult because people would essentially have to run two types of laboratories, where they had their government-funded research and their private research.

Mr. WAXMAN. And let me ask Mollie Singer a question, if I could, and maybe pull the mic over. How old were you when you were diagnosed with diabetes?

Ms. MOLLIE SINGER. I was 4½ years old.

Mr. WAXMAN. And can you tell us about your daily routine, checking your blood sugar levels and giving yourself insulin, and the like?

Ms. MOLLIE SINGER. Well, I test my blood sugar 10 to 16 times a day, and this is an insulin pump, and I bolus instead of taking shots and it has insulin right here. It's connected to me, so that delivers insulin.

Mr. WAXMAN. What would a cure mean for you? It would mean you wouldn't have to do all those things anymore, huh?

Ms. MOLLIE SINGER. I wouldn't have tests. I wouldn't have to take shots or have an insulin pump. I could just be a normal kid and have sleepovers and just have a real life.

Mr. WAXMAN. Thank you very much for being here.

Mr. WELDON. The gentleman's time has expired. The Chair now recognizes the gentlelady from New York, Mrs. Maloney.

Mrs. MALONEY. Thank you. I particularly want to thank the Singer young ladies and Nathan for being here because they are really here on their spring vacation, their holiday—or summer vacation.

I would like to ask you, how is your life different from your sister, the fact you don't have juvenile diabetes?

Ms. JACKIE SINGER. Well, I don't have to test and I don't have to wear an insulin pump. Even though I'm her sister and I don't have diabetes, it still affects me greatly. I think that if this disease is cured, it would really mean a lot to both of us and all of our family.

Mrs. MALONEY. Thank you so much.

Joan Samuelson, how many people have Parkinson's and what are the cures that are available now?

Ms. SAMUELSON. It's around a million Americans. At the moment, in the sense of an effective therapy that will last for a person's normal lifespan, there is no cure. The scientists say there could be. But really the options now are essentially the medicine L-dopa that I talked about in my testimony, which eventually just doesn't work, and a couple of surgical options, something called deep brain stimulation that sometimes works for a while but isn't really regarded as something that's repairing the system and it continues to deteriorate.

Mrs. MALONEY. As a woman with Parkinson's, what do you fear the most about your illness?

Ms. SAMUELSON. Losing the things that Milly has lost: my independence, my freedom, my dignity. I so admire her courage, and I guess God gives you what you need when you need it, and my suffering is daily, but it's nothing like what she goes through every day, having someone else feed her and dress her, and so on. Mort's book talks at length about that. I fear—I'm beginning to fear death as well because I'm starting to think that the cure won't be in time.

Mrs. MALONEY. Do you believe that Federal funding will improve or reduce oversight and accountability of research using embryonic stem cells?

Ms. SAMUELSON. Well, I guess there's no question that it would increase it. It's so the engine that drives biomedical breakthroughs, and so there's this vacuum right now where it's just not going on in a concerted, careful way, and it should be.

Mrs. MALONEY. Mr. Chairman, I would like permission to place in the record a memo from Harriet Rabb to the former Director of NIH which states that the current NIH guidelines are legal and gives a legal explanation.

Mr. WELDON. Without objection.

Mrs. MALONEY. I would also like to place in the record the National Bioethics Advisory Commission's Executive Summary.

Mr. WELDON. Without objection.

Mrs. MALONEY. Dr. Fischbach, would you give us a sense of the review process used by the NIH that led to the establishment of the stem cell guidelines that were issued in August 2000, and was it comprehensive? Can you give us an oversight?

Dr. FISCHBACH. Well, this was a long and I think very thorough process. It occupied more than a year of time. A working group was formed by the then-Director of the National Institutes of Health, Harold Varmus, that consisted of scientists, patients, patient advocates, lawyers, ethicists, and other members of the public. They worked for a year and drafted guidelines, and they were advised and criticized constructively by the National Bioethics Commission. They published their results in the Federal Registry, received numerous inputs, modified the guidelines, and then finally published them. So I think it was an extremely thorough, unusually thorough, series of deliberations and got very wide airing among the scientists and advocate and legal community.

Mrs. MALONEY. Do you support the guidelines?

Dr. FISCHBACH. I do support the guidelines.

Mrs. MALONEY. And are you familiar with the recommendations regarding stem cell research by the National Bioethics Advisory Commission which was established by the prior President? Was it fair? Was it balanced? Do you support their recommendations? Could you give us an oversight?

Dr. FISCHBACH. Well, the NBAC, as it's called, was established by the President, and they in many ways went beyond—or the guidelines are more conservative than the NBAC recommendations. So I don't want to—I want to stay with the NIH guidelines, which I believe in a real sense are a compromise between what NBAC recommended and no stem cell research, human embryonic stem cell research at all.

Mr. WELDON. The gentlelady's time has expired. The Chair now recognizes the gentlelady from Virginia, Ms. Davis.

Mrs. JO ANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

Ms. Samuelson, you said a little bit ago that you fully supported Federal regulations?

Dr. FISCHBACH. I'm sorry, is that——

Mrs. JO ANN DAVIS OF VIRGINIA. No, Ms. Samuelson. I guess I am going to go back to Congressman Smith's comment because I am not sure I understood your answer. Would you support a ban on embryos that were created just for the purpose of research?

Ms. SAMUELSON. I don't think Federal funding should be supporting that research now, if that's your question.

Mrs. MALONEY. Will the gentlelady yield for a clarification——

Mrs. JO ANN DAVIS OF VIRGINIA. Not at the moment.

Mrs. MALONEY [continuing]. Of information?

Mrs. JO ANN DAVIS OF VIRGINIA. Not at the moment. After I have finished, I will.

Mrs. MALONEY. OK.

Ms. SAMUELSON. There's no ban in the same sense as the ban on Federal funding, a de facto ban now, on embryonic stem cell——

Mrs. JO ANN DAVIS OF VIRGINIA. No, I mean, would you support a Federal regulation that says embryos cannot be created strictly for the purpose of research?

Ms. SAMUELSON. I think I would if I studied it. Maybe it's my legal training. I haven't studied that one. As I said to Mr. Smith, it offended me when I read about it.

Mrs. JO ANN DAVIS OF VIRGINIA. Right. Well, we have that company in Virginia down not too far from where I am from. That is why I am asking the question.

Ms. SAMUELSON. I don't understand—as I understand it, it's not necessary, and I do find it personally offensive.

Mrs. JO ANN DAVIS OF VIRGINIA. Let me followup on that. It has been suggested that only embryos from fertility clinics would be destroyed for research. Yet, the biotech industry testified before Congress just last month that embryo cloning would be necessary to prevent transplant rejection. Do any of you here support research that involves the cloning of the human embryos?

Dr. FISCHBACH. I think that's a hypothesis. That's getting back to the immune rejection theory. The notion is that, if you make your own stem cell line from your own nucleus and your own egg, that it will not be subject to these immunological constraints because it's identical with yourself. I think there's good reason to be-

lieve that embryonic stem cells derived from other embryos will be less immunogenic with time as they're carried in culture. So I've heard that argument, but I don't think that's a decisive argument for cloning for research.

Mrs. JO ANN DAVIS OF VIRGINIA. Let me just state, Ms. Samuelson, you know, for us to put ourselves in your shoes, well, certainly I don't have Parkinson's and don't have cancer and diabetes, but I will tell you that my husband's father had Parkinson's, my very best, dearest friend who is my husband's sister has diabetes, just went through kidney transplant. So this is a hard issue for me because I want the research; I support the research, especially a cure for diabetes. I just cannot support taking human embryos to do that. But I will tell you I give my support wholeheartedly to the research for adult stem cell research and any other cure, but I can't justify the taking of what I perceive to be one life to save another life.

Thank you, Mr. Chairman.

Ms. SAMUELSON. I just wish we could do it all and aggressively. The column yesterday by William Safire, I didn't—I would have attached it to my testimony, if I had the time. These are complicated issues, and I thought it was a real thoughtful analysis of a whole series of issues. So I commend that to the committee.

Mr. WELDON. Well, we can add that to the record.

Ms. SAMUELSON. Thank you.

Mr. WELDON. We've got unanimous consent.

And I would also like to add to the record, under unanimous consent, the legal memorandum on the illegality of the Federal funding on embryo stem cell research by Samuel Casey, along with his comments to NIH.

I want to thank all of our witnesses——

Mrs. MALONEY. Mr. Chairman?

Mr. WELDON [continuing]. For your testimony. The gentlelady from New York is recognized.

Mrs. MALONEY. Just as a point of information and clarification, a number of questions have been asked about the support for the creation of embryos for the removal of stem cells, and I would like to clarify that current NIH guidelines would not allow Federal funding for the creation of embryos for that purpose. So that is clearly the law now.

Mr. WELDON. I thank the gentlelady for her comments.

Mrs. MALONEY. Thank you.

Mr. WELDON. And I want to thank, again, all of the witnesses, particularly our two young ladies who did a very excellent job of appearing before the committee——

Mrs. MALONEY. And Nathan. Don't forget the young man.

Mr. WELDON [continuing]. And Nathan. You were all, all the young people were excellent. Additionally, I want to thank our physician and doctor witnesses.

The meeting is now adjourned.

[Whereupon, at 4:55 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

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*Friday, September 28, 2001*

SPOTLIGHT

## Actions Speak Louder

As week 3 since the attacks winds down, the worry is not necessarily how well the U.S. can keep its int'l coalition together, but how long can the **Bush** WH go before domestic pressures for visible retaliation become too great. (#2)
-- *WSJ*'s **King** and **Cummins** note that Bush aides "worry that their patient approach runs the risk of seeming sluggish or even timid." **One admin. official** believes it could only be days before public criticism for lack of action starts: "We're OK today, but I'm not sure what my answer will be a little further down the road." The aide admitted Bush could face "some real anxiety if something doesn't happen in a week or two." The report also notes the "delays in visible action could erode the wide political support" Bush has "enjoyed so far -- a risk that may be most acute" within **Bush's own party**.
-- Could it be the worry over this lack of public patience that led someone(s) in the admin. to leak to *USA Today* this am that U.S. commandos have been in Afghanistan for two weeks?

QUOTE OF THE DAY

"It doesn't matter who initiated this, but that both of us are interested in talking."

-- ***Jesse Jackson**, on his contact with the Taliban, mult., 9/28.*

TOP NEWS

■ **A Public Appearance?**
Somebody knows bin Laden's whereabouts; Taliban delivers message; bin Laden brags about his secured finances. (#1)

■ **bin Laden As Country?**
Int'l report sees Osama takover of Taliban (#3); analyst believes Osama's eyeing Iraq takeover. (#1)

■ **Global Politics**
U.S. embassy vacates non-essentials in Indonesia...Italy PM roundly criticized...Peru proclaims country bin Laden-free. (#2)

■ **Deal Or Threat?**
Ferrer only holdout on Rudy term-extension; mayor may run for full 3rd term. (#17)

■ **His First Test?**
Gore's IA speech 9/29 could be something interesting to dissect. (#13)

■ **A Milton-Bradley Game?**
No. But naming the "operation" might be just as fun. See reader suggestions. (#49)

**Richard E. Cohen**
**Michael Barone** **Charlie Cook**

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## Media Monitor

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**??? OVERLOOKED ???**

**HISTORY IN THE MAKING?**
**Should Rep. Henry Bonilla (R) face off against Dallas Mayor Ron Kirk (D) for TX SEN, the race will be unique for its lack of a non-Hispanic white candidate. While being unique, will it be the first ever Senate race not to feature a white major party nominee? Email responses to hotmail@njdc.com.**

## ▶ OPERATION ENDURING FREEDOM

### 1 AFGHANISTAN: Pakistani Delegation Will Meet With Omar Today

A Pakistani delegation "making a last-ditch bid to persuade" the Taliban "to comply" with U.S. demands in surrendering **Osama bin Laden** "arrived" in Afghanistan today. The delegation is scheduled to met with Taliban supreme leader Mullah **Mohammad Omar** in Kandahar (*AFP*, 9/28).

Pakistani officials said the delegation's mission "would be to discuss ways in which the Taliban can be saved" from a U.S. attack, "namely by agreeing" to hand over bin Laden. The delegation said they "were going to tell" Omar that "continuing to harbor" bin Laden "would injure the cause of Islam everywhere" (**Jones**, *Dallas Morning News*, 9/28).

Taliban Information Minister Mullah **Qudrutullah Jamal** said that an earlier decision by Taliban leaders asking bin Laden to voluntarily leave Afghanistan "had been delivered" to bin Laden. Jamal said the "edict had to be delivered by a messenger" because bin Laden lacks modern facilities (**Burns**, *New York Times*, 9/28). But Pakistani government officials said it was "extremely unlikely" that bin Laden "would comply" with the request (**Luce/Nicoll/Fidler**, *Financial Times*, 9/27).

ABC's **Woodruff**: "Today Taliban leaders indirectly admitted they know where Osama bin Laden is" ("World News," ABC, 9/27).

The delegation's mission is a "measure of how desperately Pakistan wants to avoid being drawn into backing" a U.S. attack against Afghanistan (**Jones**, *Dallas Morning News*, 9/28).

The Pakistani mission "is a measure of how desperately the military government ... want to avoid drawing this country ... into backing" an American attack on Afghanistan (**Burns**, *New York Times*, 9/28).

#### Taliban Targeted For Criticism

*Washington Post*'s **Krauthammer** writes, "Yes, we need to get Osama bin Laden. Yes, we need to bring down the terrorist networks. But the overriding aim of the war on terrorism is changing the regimes. And it starts with the Taliban. ... A logical stage two is Syria. It harbors a myriad of terrorist groups, but the regime is as rational as it is cynical. ... Stage three is Iraq and Iran, obviously the most difficult and dangerous. Which is why it would be foolish to take them on right away. Changing regimes in Kabul and changing policy in Damascus, however, would already have

radically changed the regional dynamic by demonstrating American power in a region where power, above all, commands respect" (9/28).

### Northern Alliance Spots bin Laden

CBS News reports Northern Alliance officials say they have "spotted" bin Laden in the "central Afghan province of Uruzgan, and his closest advisers were seen in the city of Jallalabad near the Pakistani border" (9/28).

CBS' **Palmer**: "The Foreign Minister of the Northern Alliance ... says that he's sure Osama bin Laden is inside the country. He said bin Laden has been sighted in the past few days in the central providence" ("Evening News," CBS, 9/27).

### Don't Bank On Totally Freezing bin Laden's Assets

bin Laden said U.S. attempts to freeze his bank accounts "will not make any difference" because "al Qaeda has more than three different alternative financial networks." bin Laden: "It is being run around the world by well-educated youth. We do not have a few hundred or a few thousand but hundreds and thousands of highly educated youth, who were well aware of all these things and know the alternatives" (*AFP*, 9/28).

### bin Laden Seeks To Undermine Arab States With U.S. Support?

*Rolling Stone*'s **Alexander** asked ex-State Dept. official **Michael Vlahos**, "What is the terrorists strategy in attacking the U.S.?"

Vlahos: "They want to see the U.S. force weak Arab states into supporting America, which will further undermine those governments' authority. The key here is too purify Saudi Arabia. And once saudi Arabia becomes a truly Islamic state, then you will have this source for the renewal of Islam.

More Vlahos: "I think bin Laden wants to overthrow (Iraqi Pres.) **Saddam Hussein** as well. Iraq is a successor colonial kingdom. It's like the British colony is still there. Saddam Hussein appears in a British uniform, as do (Egyptian) President **Hosni Mubarak** and King **Abdullah** of Jordan. These are colonial successor kings. So it's not a question of just Saudi Arabia and the U.S. - it's really about the whole of Arab Islam. And if you look at the power of Islamicist movements in Egypt, Algeria and Turkey, there's a real powder keg here" (10/25 issue).

### Oh So Sticky

CBS' **Pizzy**: "CBS News has come into possession of an interesting document. It's a memo sent to the United Nations Security Council in March by the Russian federation this story has come out but when you read the memo it is quite interesting. It lists what it claims are 55 bases, camps and headquarters used by Osama bin Laden inside Pakistan. It also lists a bunch of Pakistani officers it claims have helped the Taliban and it says more than a dozen nationalities are represented in bin Laden's al Queda terrorist network" ("Early Show," 9/27).

### Post-er Children

CNN's **Hemmer**: "Afghan soldiers leaving their posts, young men avoiding military recruitment. Some of the reports and some of the information coming from CNN sources that could be signaling a possible decay within the Taliban regime" (CNN, 9/28).

CNN's **Robertson**: "Some within the Taliban ranks, monitoring posts, checkpoints along the road not being manned, the indication being that some low-level and mid-level Taliban soldiers are not turning up for duty. Also, reports, as you say, that people are trying to escape, desertion: refugees from Kabul here in Quetta report leaving Afghanistan because they were trying to avoid being called up for the army. Also, United Nations officials reporting that on the border with Iran, that some fighting-age Afghans trying to flee to Iran are being turned back by Taliban officials. But very hard to get accurate confirmation of all these reports at this time, but certainly talking to Taliban officials today, they said that they couldn't confirm or deny these reports. They did say that around their stronghold of Kandahar they felt that they still had substantial support at this time. But they said their government, the Taliban government is concerned about these reports" (CNN, 9/28).

### Militants Derail Pro-Government Rally In Pakistan

The Pakistani government held a "national solidarity day" 9/27 "to try to rally public opinion behind its decision to support probable" U.S. military action against Afghanistan (**Luce/Beattle**, *Financial Times*, 9/27). But it was a "sobering debacle suggesting that public support" for the government's decision to support the U.S. "is thin, unenthusiastic and controversial." In Quetta, pro-government speakers trooped into the park appearing tense and grim-faced but still managing to generate a smattering of applause. ... After about four speakers issued statements that the nation stood in solidarity" with Gen. **Pervez Musharraf**, "a local mullah came to the microphone and stunned organizers by denouncing both the U.S. and the Pakistani's government's decision to support" Pres. **Bush** (**Marshall**, *Los Angeles Times*, 9/28).

"No one missed the underlying pro-American message, even though the only flags waved were green-and-white Pakistani ensigns bearing the crescent moon of Islam" (**Nickerson**, *Boston Globe*, 9/28).

### Northern Alliance

The U.S. military "has begun discreetly helping" the Northern Alliance "in the form of advice and a discussion of the group's needs on the ground as it conducts an offensive" in northern Afghanistan. Proponents contend that "aiding" the Alliance "would put more added pressure" on the Taliban "to offer up" bin Laden. But others worry that Pakistan "may cease to provide assistance" if the U.S. "overtly helps" the Alliance. But the Alliance's DC rep **Haron Amin** said the Alliance "urgently needs military aid now, especially in the form of air cover as Taliban fighter-bombers strike" at Alliance troops (**Scarborough**, *Washington Times*, 9/28).

### This Is Only A Test...

Residents of Kabul scurried for cover today believing an American air attack was under way. But it was only Taliban troops testing anti-aircraft guns (*AFP*, 9/28).

### ...This Is Not

U.S. and British warplanes "struck air defense targets" in Iraq's southern "no-fly" zone "for the second time in a week today." A U.S. military spokesperson said, "The strikes were in response to recent hostile threats by the Iraqis" (Reuters, 9/28).

### Iran Remaining Neutral?

NBC's **Maceda**, in Iran: "No one hates the Taliban more than Iranians. ... So why doesn't Iran make a bold move ... and pledge cooperation with the U.S.-led coalition? Because .... it just cannot. Iran's religious leadership is split between moderates ... and conservative leaders. ... The bottom line is that ... Iran is likely to remain neutral" ("Nightly News," NBC, 9/27).

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## 2 GLOBAL ALLIANCE: While Patience May Be Popular Overseas...

"America's allies have greeted Washington's slow and deliberate build-up to its war on terrorism with relief. Yet the decision by the U.S. not to lash out with a rapid military response has also been accompanied by some confusion about what Washington intends to do. The is partly because, although the plan is already under way, it is also still evolving. In phase one, the U.S. is seeking to destroy the suspected mastermind" of the 9/11 attacks, **Osama bin Laden**, and al Qaeda. "That means a military and intelligence effort focused mainly on Afghanistan, though not exclusively since associated organizations are said to operate in other parts of the world, such as Chechnya and Bosnia." Even in Afghanistan, "it appears the U.S. ... does not intend to rush to overt military action. There are several possible reasons." First, polls "have not detected any domestic clamor for rapid retribution. Second, time is needed both to put" together the int'l coalition and to allow intel to "develop about the whereabouts" of bin Laden and al Qaeda. "Moreover, it is clear

that U.S. military planners are also taking account of an intensifying humanitarian crisis in and around Afghanistan" (**Fidler**, *Financial Times*, 9/28).

And under the header "Patience Is A Component Of This Military Strategy," *Wall Street Journal*'s **King** and **Cummins** write, **Bush** admin. aides "say they are continuing to hone ideas for a military response, ... even as they worry that their patient approach runs the risk of seeming sluggish or even timid. Hoping to maintain the strong public support they have enjoyed so far," Pres. Bush and his top aides "stressed" 9/27 "that the antiterror campaign will be slow to unfold, multifaceted and possibly even unsatisfying to the American people." A military strike against bin Laden and his network, "could still be a week or more away as the U.S. seeks to identify the proper targets and determine how to best strike them." One senior admin. official, "however, acknowledged that political pressure for a military response could grow in coming days": "I think we're OK today, but I'm not sure what my answer will be a little further down the road." He added that the admin. could face "some real anxiety if something doesn't happen in a week or two." Some U.S. authorities have hinted that the main obstacle is "insufficient intelligence" on where bin Laden and his allies are. But intel officials "dispute that any delay is being caused by a shortage of knowledge." One senior intel official: "The problem is not a lack of Xs on a map," but the need to work out the details on a much wider strategy "of what do we attack and how." It also is "possible, of course, that covert actions that can't be publicized already are under way, or that the talk of patience could be a cover for imminent action of some kind" (9/28).

Speaking of "actions," *USA Today*'s **Kelley** reports, "Elite troops from U.S. special operations forces have been inside Afghanistan the past" two weeks looking for bin Laden, "but they're having difficulty locating him and are asking other nations for additional intelligence help, senior U.S. and Pakistani officials have confirmed privately." The presence of these U.S. teams inside Afghanistan "has not been officially acknowledged by either Pakistan" or the U.S. "But their arrival here 2 weeks ago and subsequent movement into Afghanistan have been reported by English- and Urdu-language newspapers here, and would not come as a surprise to bin Laden" or the Taliban (9/28).

Still, for the WH, the problem "is that delays in visible action could erode the wide political support" Bush has "enjoyed so far -- a risk that may be most acute within the president's own party. While there is little sign of public impatience, some hawkish voices within" the GOP "have complained that the administration in general," and Sec/State **Colin Powell** "in particular, have plotted an overly cautious approach that leaned too heavily on building" coalitions. "The danger for Mr. Bush is that those voices might rise in coming days" (**KingCummins**, *Wall Street Journal*, 9/28).

### Tangible Signs Of Progress Needed?

Sen. **Max Cleland** (D-GA), on classified info: "It's the nature of, in many ways, guerilla warfare. But there's also an adage about guerilla warfare that if the guerilla doesn't lose, he wins. So we've got to do some winning here." Cleland: "I think absolutely, ultimately you've got to kill or capture the people who came after us and shed American blood on American soil September 11. That's what the end game is" ("Hardball," MSNBC, 9/27).

Sen. **Hillary Clinton** (D-NY), on if she knows about any military action: "No. And I hope we don't know. ... I believe we are getting into position and taking action to prepare us. ... I know in the last eight years ... there were many things that were prevented that people didn't know about." More HRC: "It's started. I'm confident of that ... but I don't think anyone can put a time table on it" ("Late Show," CBS, 9/27).

NBC's **Brokaw**: "We think that probably special operations forces from the United States could be in Afghanistan. Certainly they are in the region" ("Today," NBC, 9/28).

*New York Times*' **Friedman** writes, "The big question is how we fight this war to deliver to Americans what they want -- which is not revenge, but justice and security. It requires a new attitude toward the battle and new strategy on the battlefield. What attitude? We need to be really focused, really serious, and just a little bit crazy. I don't mean we should indiscriminately kill

people, especially innocent Afghans. I mean that the terrorists and their supporters need to know that from here forward we will do whatever it takes to defend our way of life -- and then some. From here forward, it's the bad guys who need to be afraid every waking moment. The more frightened our enemies are today, the fewer we will have to fight tomorrow" (9/28).

From a *St. Louis Post-Dispatch* editorial: "Despite some confusion over goals, Mr. Bush deserves credit for realizing that quick military action alone cannot achieve American objectives. Diplomatic, financial and law enforcement efforts may ultimately be more important, if less emotionally satisfying. Americans are willing to follow their president to victory. But he needs to further articulate where it lies" (9/28).

### Timeline Watch

FNC's **Baier**, on the timeline: "As U.S. military build-up continues, there are increasing signs from the administration that a military strike may not be imminent. ... General Shelton says the U.S. retaliation to terrorists will be multidimensional, using all possible tools, not just military and not just actions able to be seen on television or described in the newspaper" ("Special Report," FNC, 9/27).

CBS' **Rather**: "More than two weeks after the terror attacks on the United States, President Bush is still moving U.S. forces into position for a possible strike back in Afghanistan. ... President Bush is adopting what appears to be a 'go slow' strategy in response to the terror attacks" ("Evening News," CBS, 9/27).

### The Coalition -- Condemning Italy's PM Nearly Unanimous

"Muslims around the world" 9/27 "demanded an apology" from Italian PM **Silvio Berlusconi** after he "asserted that Western civilization was superior to Islam" (see *Hotline* QoD, 9/27). Words such as "barbaric," "unacceptable," "silly," and "racist" "rained down on Berlusconi," who made the controversial comments" 9/26. Belgium, which holds the rotating presidency of the European Union, "struck out at Berlusconi, who took office in June amid concerns abroad about his business background and far-right political partners." Belgian PM **Guy Verhofstadt**: "I can hardly believe Mr. Berlusconi made such remarks, because the European Union is based on values such as multiculturalism and the meeting of different civilizations. Such statements could be dangerous because they can lead to a feeling of humiliation" (**Balmer**, Reuters, 9/28).

In Turkey, the "traditionally anti-Western Islamist newspaper *Akit* called Berlusconi 'a new Mussolini.'" But Berlusconi's spokesperson "defended Berlusconi, saying the leader could not be accused of insulting Islam after having 'fought for the participation of modern Arab countries in the alliance against terrorism' and called for a solution to the crisis in the Middle East." Berlusconi's "gaffe illustrated how difficult it has become to maintain cohesion in a coalition that includes moderate Muslim countries as well as Saudi Arabia, Russia, China and Western countries." Berlusconi "is notorious for his ham-handed remarks and for accepting Italy's neo-facists as partners" in gov't (**Schmetzer**, *Chicago Tribune*, 9/28).

Berlusconi's comments were also "quickly condemned by other Italian politicians." **Amr Musa**, Sec.-Gen. of the 22-nation Arab League added: "We don't believe there is a superior civilization and if he said so he's utterly mistaken" (AP, 9/28).

### The Coalition -- Trouble In Indonesia?

"Concerned by mounting threats against Americans" in this country, the U.S. Embassy on 9/27 said that it will begin withdrawing "nonemergency employees and family members who wish to leave the country." In recent days, "several Islamic fundamentalist groups have threatened to kill Americans" if the U.S. "retaliates against Afghanistan." One "radical newspaper published a death threat" this week against U.S. Amb. **Robert Gelbard**, who "criticized Indonesian authorities for not taking action against extremists who have threatened to harm Americans." Gelbard: "They have not been prepared to act, to warn or to arrest people who break the law when there are threats against the lives of Americans" (**Paddock**, *Los Angeles Times*, 9/28).

Under the header, "Indonesia's President Backs U.S. Does Her Country?" *Christian Science*

to Pakistan. "The resolutions call for the defense force to transport ammunition and weapons for other nations and, more controversially, to use weapons to protect refugees and defense agencies of other countries." Japan's '46 "pacifist Constitution prohibits the agency from using force to settle" int'l disputes and "limits armed self-defense to Japanese territory" (**Hernandez**, *Boston Globe*, 9/28).

### The Coalition -- Latin American Support

"The presence of suspected followers" of bin Laden in Lima, Peru, "is a thing of the past," Peruvian First VP **Raul Diez Canseco** said. Diez Canseco said the issue was "from the time of Mr. **Vladimiro Montesinos**," the imprisoned ex-spy chief "who revealed in a video that bin Laden used Lima as a rest stop for his group." Montesinos said in a taped statement then: "The center of gravity for Bin Laden in Latin America is here in Lima," a city he called "a rest stop, not to initiate actions in Peru but to act against the United States, Argentina, Brazil, Chile and the rest of the American continent." Diez Canseco said the gov't was "very active" in efforts to prevent terrorists from entering the country. Diez Canseco: "Currently, no privileges exist in Peru for these types of people, there are very strict controls at the airport, intelligence services are working hard and we are sure that if we do things properly we will have no problem" (Latino News Service, 9/28).

Meanwhile, the Chilean gov't "announced it will speed up ratification" of two int'l agreements to fight terrorism adopted by the OAS after the 9/11 attacks. The Chilean legis. "will receive by next week the OAS anti-terrorism agreements, as well as an accord drafted" by the U.N. "to prevent the financing of terrorist activities," Chilean Foreign Minister **Soledad Alvear** said. "Both agreements have already been signed by the Chilean government, but must be ratified by the legislature for them to take effect" (Latino News Service, 9/28).

### Understand Anti-Americanism

Baltimore *Sun*'s **Englund** writes, "Dislike, resentment, anger and hatred toward America arise in many forms and in many places. An anti-American could be a student in South Korea, a rightist in Japan, a soccer fan in Greece, a priest in Russia, an imam in Ghana, a protester in Pakistan, or a hijacker" in the U.S. "Anti-Americanism isn't always very logical, or consistent. It is, fortunately, only rarely violent. In some cases it has more to do with local politics than with actual American actions. But it is a potent force in a world dominated by a single economic and political superpower. ... It is in the Middle East that anti-Americanism has found its most virulent voice." And among those "drawn" to bin Laden, "neither Israel nor Iraq is the motivating issue. Rather, it is U.S. support for the governments of Saudi Arabia and Egypt. Both regimes are seen to be repressive, corrupt and wholly dependent on American backing."

Throughout "most of the world, America is inescapable. It is a beacon for millions. But for millions of others, it's more like a lightning rod for pent up resentment and frustration. High on the list of visible American institutions abroad is the military. In Japan, for instance, there's an ever-present level of unhappiness over the U.S. occupation of Okinawa. In China, the collision of an American spy plane with a Chinese jet fighter caused fierce anger. Even in South Korea, which was saved from conquest by the U.S. Army, activists blame the American military for countenancing a massacre of university students" in '80. Greeks "blame" the U.S. for supporting a "military dictatorship" there from '67-74. "Russians, smarting from the loss of empire and power and worrying about the integrity of their own country, were aghast" at the '99 air war in Kosovo, "which they saw as an inexcusable American intervention in the affairs of Serbia" (9/28).

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## 3 INTERNATIONAL COVERAGE: Will bin Laden Take Over Afghan Militia?

PTI/Bombay *Afternoon Despatch & Courier*: "Experts here do not rule out" that Osama bin Laden, who "is married to the Taliban supremo Mullah **Mohammad Omar**'s daughter, will

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**Congress of the United States**
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DAVE WELDON
15TH DISTRICT, FLORIDA

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August 2, 2001

Chairman Mark Souder
Subcommittee Criminal Justice…
Government Reform Committee
B-373 Rayburn Office Building
Washington, D.C. 20515

Dear Chairman Souder: Mark

I am writing you about the testimony of Gerald Fischbach, M.D. at the Government Reform Criminal Justice subcommittee hearing on stem cells, July 17. During the hearing, Dr. Fischback testified in regard to a paper by Dr. McKay which he claimed demonstrated that mouse embryo stem cells were converted into neural cells. He also claimed that the neural cells were transplanted into the mice and successfully treated their Parkinson's disease. At the hearing, I questioned his statement and requested that he submit the citation to this study.

I have attached my request and his recent response. He admits that the study he mentioned did not use cells "from the inner cell mass of an early blastula", verifying that his testimony was misleading. He does refer to another study that supposedly demonstrates the "promise of such cells in future work." However, this study refers not to the treatment of Parkinson's which the discussion concerned but with spinal cord injury in rats.

The committee may wish to contact Dr. Fischbach for a more complete explanation. Let me know if you have additional questions concerning Dr. Fiscbach's testimony.

Sincerely,

Dave

Dave Weldon, M.D.
Member of Congress

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July 20, 2001

Gerald D. Fischbach, M.D.
Vice President for Health
& Biological Medical Sciences
Columbia University Health Sciences Division
630 West 168 Street
New York, NY 10032

Dear Dr. Fischbach:

I enjoyed hearing your testimony at the hearing earlier in the week and, in particular, I was quite intrigued by your comments regarding a study evidently showing that embryonic stem cells had been successfully used in a rat model of Parkinson's disease. I did find a publication from a Dr. McKay from Nature Neuroscience, August 1998, entitled "Transplantation of expanded mesencephalic precursor leads to recovery of Parkinsonian Rats"; however, that study seems to have used fetal brain tissue and not embronic stem cells.

I am looking forward to hearing back from you on this matter. I have maintained the position that advocates for embryonic stem cell research have not yet demonstrated its usefulnes in an animal model and that claims of its potential human clinical usefulness are highly exagerated. But, if I'm incorrect in that assertion, I would like to know as soon as possible.

Sincerely,

DAVE WELDON, M.D.
Member of Congress

DW:br

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COLUMBIA UNIVERSITY
HEALTH SCIENCES DIVISION

OFFICE OF THE VICE PRESIDENT
FOR HEALTH AND BIOMEDICAL SCIENCES
AND DEAN OF THE FACULTY OF MEDICINE

July 26, 2001

Congressman Dave Weldon
332 Cannon House Office Building
Washington, DC 20616

Dear Congressman Weldon:

You are absolutely right about the McKay paper. The authors used cells isolated from the neural tube of twelve day old embryos. The cells survived, they produced dopamine when implanted into a rat model of Parkinson's Disease and they functioned well enough to reverse many of the motor disabilities. It is difficult to draw a distinction between embryo and fetus in a mouse whose gestation period is only twenty one days. However, the cells isolated by McKay's group were not from the inner cell mass of an early blastula. They are probably closer to the blastula cells then to adult stem cells, but this is speculation. I am not familiar with the unpublished studies of O. Isaccson, using blastula stem cells for treating an animal model of Parkinson's Disease that was mentioned by Joan Samuelson during the testimony.

In addition to the embryonic stem cell reversal of a multiple sclerosis model that I forwarded to your office last week, I refer you to a paper by McDonald et al, 1999 (Transplanted embryonic stem cells - survive, differentiate, and promote recovery in injured rat spinal cord., Nature Medicine 12 (Dec. 5) 1410-1412) that reversed paralysis of rodents in a spinal cord injury model. This is an unusually well documented study of embryonic stem cells that I think illustrates the promise of such cells in future work. That promise was emphasized by the recent report (unpublished), from Hopkins using embryonic stem cells to reverse spinal cord injury caused by a toxic virus.

I hope this information is helpful. Please call on me anytime if you think I can add to your own investigations. I am greatly impressed with your dedication and the breadth of your knowledge and want to help. I am also grateful for the opportunity to testify on such an important matter.

Sincerely,

Gerald D. Fischbach, M.D.
Vice President for health and Biomedical Sciences

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Reuters Medical News for the Professional

# Adult Stem Cell Found That Can Transform into Nearly Any Organ Cell Type

WESTPORT, CT (Reuters Health) May 03 - Researchers have identified a cell, derived from adult bone marrow, that appears capable of becoming virtually any cell in the body, according to the results of an animal study published in the May 4th issue of *Cell*.

Dr. Diane Krause, from the Dept. of Laboratory Medicine at the Yale University School of Medicine in New Haven, Connecticut, and colleagues transplanted a bone marrow cell from adult male mice into irradiated female mice, and then tested for the presence of a Y chromosome in various tissue specimens from the female mice.

The researchers found evidence of the cell's progeny not only in blood and bone marrow specimens, but also in tissue from the skin, liver, large and small intestine, stomach, esophagus, and lung.

"Other researchers have found that bone marrow cells can become skeletal muscle and brain, but they haven't found that they can become lung, gastrointestinal tract, and skin," Dr. Krause told Reuters Health. "Our findings are significant not only because of the three additional tissue possibilities, but also because we identified one cell that has the capacity to differentiate into all of these organs."

Dr. Krause notes that a "similar cell probably exists in humans, but we haven't tested that yet." However, "we did show previously that there are bone marrow cells in humans that can differentiate into mature hepatocytes," she said. "There is no reason to assume that a cell similar to the one identified in the current study doesn't exist in humans."

Currently, Dr. Krause's group is "looking at the role these cells play in wound and tissue injury repair [and] investigating the use of these cells in autologous gene therapy for patients with a single-gene defect."

*Cell* 2001;105:369-377.

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EXPAND STORY

## Study finds amazingly versatile adult stem cells

By Will Dunham

WASHINGTON, Aug 13 (Reuters) - Stem cells located in the skin of adult mice can transform into nerve, fat and muscle cells, and cells in the human scalp appear to possess similar qualities, researchers said on Monday in a finding that points to the potential of using one's own cells to treat disease.

These adult stem cells -- master cells that can turn into other cell types -- showed impressive versatility, highlighting the promise for therapeutic applications involving stem cells, aside from those harvested from live human embryos.

In a study appearing in the journal Nature Cell Biology, scientists led by Freda Miller at McGill University in Montreal took skin samples from the backs and abdomens of adult and juvenile mice and isolated stem cells. In a laboratory, the scientists then prompted the mouse stem cells to turn into neurons, several types of glial cells (cells that support the nerve cells), smooth muscle cells and fat cells.

The researchers then decided to see if similarly flexible stem cells existed in human skin. They found stem cells in skin from adult human scalps. Using the same prompting methods they used with the mouse cells, they guided the human stem cells into transforming into cells very much like nerve cells.

``Some adult stem cells might not be as restricted as we had thought," Miller said in an interview.

The skin cells in Miller's research were not from the outer layer of skin, but rather from an underneath layer.

Scientists hope to harness the transformational abilities of stem cells to craft treatments for various human diseases. The idea would be to use stem cells to regenerate healthy tissue to replace tissue damaged by disease or injury.

The neural cells created in the study are like those that potentially could help patients recover from a spinal cord injury or a brain disorder like Parkinson's disease.

Embryonic stem cells have displayed a wondrous ability to transform into virtually any cell type in the body, suggesting that they might be the most useful in tackling disease.

It had been thought that stem cells taken adult tissue is less versatile, but Miller's work and other recent studies suggest that might not be the case.

HOW VERSATILE ARE ADULT STEM CELLS?

The new study, she said, places adult stem cells ``somewhere on the continuum between embryonic stem cells, which make everything easily, and most adult stem cells, which would prefer to be one thing but can, if pushed, perhaps do something else, maybe. The key question for us as scientists is how much can they become?"

The study shows that highly versatile adult stem cells may be easy to access. ``You could potentially take a small biopsy of skin and harvest the patient's own stem cells, expand them (in a process that allows them to proliferate in a laboratory dish) and then use them to treat that patient," Miller said.

Using cells from a patient's own body would eliminate the possibility of transplant rejection that could occur with a treatment involving embryonic stem cells that the body's immune system could interpret as a foreign invader.

Unlike many other adult stem cells that have been studied, the ones Miller worked with proliferated impressively in the laboratory. Being able to generate large numbers of stem cells would be vital to allow for any future transplantation of them into damaged tissue with the aim of regeneration.

``Most adult stem cells are very tissue-biased in the sense that they really would like to become cells of their tissue of origin," she said. For example, stem cells from skin generally want to turn into skin cells rather than brain cells.

Embryonic stem cells are the building blocks of the developing baby, explaining why they can turn into so many cell types. Adult stem cells serve more as spare parts for limited repairs, explaining why they may not be as versatile.

But in Miller's study, the only broad grouping of cells that the mouse skin stem cells did not become was cells from organs such as the liver. ``And we're working very hard now to ask if they can become those things as well," she said.

McGill University licensed the patents on the technology used in the study to Aegera Therapeutics Inc., a privately held Montreal-based biotech firm that has formed a partnership with Cambridge, Massachusetts-based Curis Inc. (CRIS.O).

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Reuters Medical News for the Professional

# Adult Stem Cells Hold Hope for Autoimmune Disease Patients

CHICAGO (Reuters Health) Aug 13 - A strategy in which adult stem cells were extracted from the blood of two Crohn's disease patients and used to correct the defect in their immune system has shown preliminary success, researchers reported late last week.

Physicians at Northwestern Memorial Hospital in Chicago said on Thursday that a 22-year-old female Crohn's disease patient was doing "phenomenally well" 2.5 months after undergoing the procedure. They were so pleased with her progress that they performed the procedure on a second Crohn's disease patient, a 16-year-old boy, last week.

Immunologist Dr. Richard Burt, who performed the procedures, said early results in both patients were very encouraging.

The female Crohn's disease patient "had bloody, watery diarrhea about 10 times a day for 9 years, with a lot of abdominal pain," Dr. Burt said. "Since the procedure, she has had no diarrhea, is eating and is in no pain. But we have to be very careful. This is experimental — one patient never means anything," he cautioned. "We can't say we've cured anybody. Only time will tell. But this is obviously the best thing we could have wished for," he added.

The technique is also being tested at several other US hospitals. Multiple sclerosis patients who underwent a similar procedure at another hospital to rebuild their immune systems with their own stem cells have also shown progress, Dr. Burt said. Though the therapy did not repair existing damage to their nervous systems, it halted the development of new lesions, he explained. However, stem cell therapy on lupus patients elsewhere did repair the damage to their organs, he noted.

Dr. Robert Craig, a gastroenterologist at Northwestern working with Dr. Burt on Crohn's disease, said it took 3 years to find suitable patients for this experimental therapy. "They need to be very sick. They have to have failed on other therapies. There aren't that many people who are ill enough to warrant this type of therapy, because the therapy itself is life threatening," he said.

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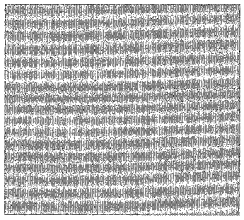
Today's News

Federal funding of embryonic stem cell research has been a recent topic of debate. President Bush announced on Thursday his decision to support funding of only those cell lines that have already been derived from embryos. However, Dr. Burt believes that "If you're able to use your own stem cells," the embryonic stem cell issue is "not just ethically moot, it's practically moot."



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# Seeds of possibility

## The debate over using stem cells harvested from embryos has been complicated by the discovery that adult stem cells are found throughout the human body

Carl T. Hall, Chronicle Science Writer
Monday, July 23, 2001
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URL: -

Some of the most spectacular discoveries about stem cells lately have come from the dawning realization that embryos are not the only source of these biological miracle workers.

Just about everywhere scientists look in the adult body - the bone marrow, the brain, even the unwanted fat drawn from patients undergoing liposuction - stem cells show up.

Stem cells are immature cells that have not yet developed into a specialized form. In the embryo, they are the seeds from which all the 200- plus cell types of the human body are formed, whether they are destined to be shaped into bone or blood, muscle or teeth.

This remarkable transformative power suggests stem cells could also be used as a source of transplant material - building blocks of a new era of regenerative medicine.

"You can expand embryonic stem cells ad nauseam and theoretically get unlimited numbers of whatever cell types you want," said Dr. Jon Odorico, a surgeon at the University of Wisconsin who works in separate labs on adult and embryonic cells.

Abortion opponents oppose the very idea of carrying out any research that involves the destruction of human embryos. From their standpoint, the research amounts to the taking of a human life - wrong regardless of medical value.

"It's a question of ethics and morality," said C. Ben Mitchell, senior fellow at the Center for Bioethics and Human Dignity, based in Deerfield, Ill. "The arguments being made are like saying a person on death row is going to die anyway so let's go ahead and harvest his organs, or let's just kill every fourth person on the sidewalk."

Others maintain just as vigorously that the embryos from which the cells are taken would otherwise be discarded, typically as surplus material from in- vitro fertilization clinics.

Efforts are under way to find some middle ground in that moral debate. But now there's a new aspect to consider: The adult body harbors stem cells, too, and so the diseased body may carry the seeds of its own repair.

Cadavers' cells live on

In perhaps the most remarkable example of this latent regenerative power, it was discovered two years ago that neuronal stem cells, identified in the brains of cadavers, can live on after a person has died.

Cells that have taken on a particular specialty in adult tissues may be capable of switching identities.

A recent study by Helen Blau, professor and chair of molecular pharmacology at Stanford University School of Medicine, revealed bone marrow cells going to the brain and assuming the traits of neurons and supporting glial cells.

Whether the cells actually take on normal function has yet to be proven. But at a minimum, findings so far suggest an innate capacity for self-repair at a low level throughout life.

That capacity is "truly amazing," Blau said. "We are in the very early days of this, but it's an incredibly promising area. If we understand the cues and the mechanisms, we could enlist them to treat disease."

The hope is to identify the signals that induce stem cells to change into a particular form. In that scenario, still a long way off, the body's own cells could be recruited for repairs. Or a few cells taken from a patient with a degenerative condition like Parkinson's disease could be transformed into fresh new material for a brain-cell transplant. The problem of tissue rejection would be avoided, because the transplanted cells would carry the patient's own genetic imprint.

Already, long before the medical implications become clear, the findings are reshaping the ethical and political debate under way in Washington, D.C., over taxpayer-financed stem cell research.

Beyond the moral issues, opponents of embryonic stem cell research argue there is no pressing need to destroy human embryos to get stem cells. They also claim that adult-derived cells may even be somewhat easier to control in certain respects.

That view is not shared by the majority of researchers, however, who point out that very little would be known about the adult-derived stem cells without the benefit of research on the stem cells in embryos.

"We have to learn a lot more about these cells," said Lana Skirboll, director of the Office of Science Policy at the National Institutes of Health, releasing a long-awaited scientific update on stem cells last week.

Adult stem cells different

After reviewing a vast body of research, scientists at the NIH concluded that adult and embryonic stem cells are quite different, both in their fundamental biological traits and how they might be used in the laboratory or clinic.

"We have a lot to learn about each one from the other," Skirboll said.

Some researchers argue that particular varieties of stem cells from adults may be better suited

to treating a particular disease than embryonic cells. In some ways, the astonishing proliferative power of the embryonic cells may turn out to be too much of a good thing, perhaps posing a risk of runaway growth if not carefully controlled.

Dr. Marc Hedrick of the University of California at Los Angeles compared the embryo-derived stem cells to Ferraris and the adult varieties to Fords. "Both may get you to the same place, but maybe the risks might be greater one way versus the other," he said.

Hedrick, who described himself as "pro-life" and who does no research on embryonic cells, led a research team that reported in April that stem cells residing in human fat, taken from liposuction procedures, could be turned into muscle, bone and cartilage.

But the idea that adult stem cells offer an easy way out of the current policy morass is dismissed by nearly all of those who work in the field.

It's proving to be an enormous challenge just to find the blood-forming stem cells of the bone marrow, let alone finding ways of getting more rare types to behave in a laboratory dish.

In one of the most recent studies, Dr. Diane Krause at the Yale University School of Medicine showed how bone-marrow stem cells in adult mice could transform into several different tissue types. But to make that clear it took an elaborate, convoluted series of steps, tracking fluorescent-labeled stem cells through multiple generations of mice.

"There are probably a million factors involved in this that we don't know yet," said Krause, a staunch advocate of embryonic stem cell research who testified to that effect last week before a Senate subcommittee.

Curative powers speculative

"The fact is we know very, very little about adult stem cells," she said.

At the same time, the curative powers of embryonic cells are also still speculative - a point sometimes obscured in the current political battle.

"I've been dismayed at the alacrity with which we've moved to the idea that we are going to take these embryonic stem cells and within two weeks we'll have cures for all the major killers of mankind," said Barbara Koenig, executive director of the Center for Biomedical Ethics at Stanford University.

Many scientists argue that the real value of embryonic stem cell research is what it can reveal about how a human body develops, and how remnants of that process appear to linger throughout life. And where that ultimately leads is anybody's guess.

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A difficult recipe for adult stem cells

Multi-purpose stem cells have been found in adults as well as embryos, but in exely limited numbers. Scientists have yet to find a way to purify the adult stem cells from humans, but are making some progress in animal studies. 1. Cells are removed from the bone marrow of a laboratory mouse. Only about 1 cell in 100,000 is the sought-after stem cell. 2. The stem cells tend to be smaller and lack certain biological markers compared with more mature, specialized

cells. So researchers narrow the hunt by sorting for cells with the right characteristics. 3. The sorted cells are labeled with fluorescent dye and injected into the bloodstream of another mouse. Two days later, the stem cells have somehow found their way to the bone marrow of the recipient. 4. The labeled cells are removed one by one from the bone marrow, and each is injected into another mouse. Scientists then trace the cells for weeks or months as they mature and migrate to various organs. By now, about one cell in every six turns out to be a stem cell. Source: The journal Cell Chronicle Graphic

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EXPAND STORY **Scientists Seek Methods to Create Stem Cells Without Using Embryos**

---- By Gautam Naik and Antonio Regalado Staff Reporters of The Wall Street Journal

DJ via Dow Jones

Early last year, Michael Bishop, president of Infigen Inc., an animal-cloning company in Madison, Wis., went to his board with a plan for getting into research on human embryonic stem cells. It is these primitive, undifferentiated cells that develop into the body's mature, tissue-specific cells, and many scientists believe they hold the key to great advances in treating a wide range of diseases.

The board, however, was troubled. "There were certain board members to whom stem-cell research was personally an issue," says Dennis McCormick, co-president of the New York-based leveraged-buyout fund Ardsheild Inc. and chairman of Infigen's board. When Dr. Bishop explained that competitors were planning to create human embryos using cloning technology -- as a means of creating stem cells matched to any individual -- the board drew a firm line.

"To create human embryos -- that was outside the ethical and moral view of the entire board," Mr. McCormick says. "That was discussed very briefly and rejected. It was like, `No way.'"

But Dr. Bishop, whose closely held concern had already produced cloned cows and pigs, had a way around the ethical quagmires of embryo research. His scientific team had hit on a possibly revolutionary way to turn any adult cell into a stem cell, without using embryos.

The concept is known as "cellular reprogramming": Adult cells are taken from a patient and brought back to their embryo-like state. Those cells would then be turned into specialized cells -- say, heart muscle. These heart cells would be transplanted into the very patient they were derived from. Since there is a perfect genetic match, the patient's immune system ideally wouldn't reject the transplantation.

The board was swayed and the new approach has become Infigen's core research focus.

In the midst of the intense political and ethical debates over embryo research as a source for stem cells in the U.S., companies like Infigen and academic scientists are racing to come up with new -- and noncontroversial -- ways to generate the cells. In fact, some of the companies fighting hardest to encourage the government to fund embryo-related research and even to allow research on human cloning, are also betting that discoveries emerging from their labs could render the current controversy moot.

As more companies jump into the fray and scramble for patents, some executives characterize the atmosphere as akin to the Wild West. At a congressional hearing on Wednesday, Advanced Cell Technology Inc. of Worcester, Mass., declared that it had filed a patent on reprogramming cells. PPL Therapeutics PLC, the British concern that helped clone Dolly the sheep four years ago, is also reporting initial success conducting similar experiments. And an Irish biotech start-up, TriStemGroup, says it turned cells from a human blood sample into their embryonic counterparts in six hours. So far, scientific journals have refused to publish the findings, the Dublin company says.

PPL executives say they have already pulled off the biological equivalent of turning back time simply by injecting the liquidy contents of a cow egg into an adult cow cell. "We intend to do this with human cells," says Alan Colman, chief scientist at the company, based in Edinburgh, Scotland. "It would help us to avoid the destruction of human embryos" for medical research, he adds.

PPL may have made the most progress. Last October, the U.S. government gave the British company's

Virginia lab nearly $2 million to pursue a cell-reprogramming project. In February, PPL boasted in a press release that it had transmuted a cow's adult skin cell into a beating heart cell but declined to reveal the method used.

PPL still won't describe the entire process -- to avoid tipping off rivals, it says -- but is willing to shed a little more light on the technique. According to Dr. Colman, the company extracted the cytoplasm out of a cow egg, or oocyte, and inserted it into skin cells. This turned the skin cells into something that closely resembled undifferentiated stem cells, like those found in early-stage embryos. By adding various chemicals, PPL turned the embryo-like cells into heart cells which began to beat even while sitting in a petri dish.

It wasn't easy. Cytoplasm is a viscous material and getting it inside tiny adult cells proved quite a challenge. Dr. Colman says that the experiment doesn't work every time and concedes the company's press release may have been premature.

In the current frenzied environment, Dr. Colman says, scientists "are tending to defer systematic investigation for a later day." He adds that many stem-cell "announcements" are "mainly about publicity and ego." Still, the company plans similar experiments with human cells in its British labs.

For now, scientists are captivated by the astonishing ability of human and animal eggs to "rewind" mature cells to their original, primitive state. Though little understood, this property has already been tapped to clone animals like Dolly. Now scientists are trying to identify and harness the magical factors in the egg responsible for the rejuvenating trick. So far they have found that if the material inside an egg is simply injected into -- or dribbled onto -- an adult cell, that cell can sometimes revert to its embryonic state.

At Infigen, Dr. Bishop says there may be a number of ways to use the cytoplasm of eggs or other methods to reprogram cells. Funded by the U.S. Department of Commerce's Advanced Technology Program and the U.S. National Institutes of Health, the company is exploring the cell-rewinding process in cattle and pigs.

"We are looking at all the ways to make a cell become what we want it to become," Dr. Bishop says, noting that the company is trying to raise a total of $10 million to $15 million to support the effort.

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# Clone Study Casts Doubt on Stem Cells

Variations in Mice Raise Human Research Issues

By Rick Weiss
Washington Post Staff Writer
Friday, July 6, 2001; Page A01

Mice cloned from embryonic stem cells may look identical, but many of them actually differ from one another by harboring unique genetic abnormalities, scientists have learned.

The presence of these subtle and previously undetected genetic glitches could help explain why so many clones do not survive to birth. It also adds credence to scientists' fears that even apparently healthy clones are not as normal as they seem – a consideration relevant to the debate over the safety and morality of human cloning.

The work also shows for the first time that embryonic stem cells – which are at the center of an escalating political and ethical debate as President Bush decides whether federal funds should be spent to study them – are surprisingly genetically unstable, at least in mice.

If the same is true for human embryonic stem cells, researchers said, then scientists may face unexpected challenges as they try to turn the controversial cells into treatments for various degenerative conditions.

In an unusual move reflecting the politically sensitive nature of the research, the scientists who conducted the study deleted at the last minute part of a sentence in their published report that had alluded to this potential ramification, and added a sentence emphasizing the cells' therapeutic promise. It is true that genetic instability in human embryonic stem cells may complicate efforts to turn the cells into cures, the lead researcher said yesterday. But he said he was afraid that any mention of that potential problem in the article might be exaggerated by political factions that oppose the research on religious and ethical grounds.

"A non-scientist could really misinterpret the words," said Rudolf Jaenisch of the Whitehead Institute for Biomedical Research in Cambridge, Mass., who led the research with Ryuzo Yanagimachi of the University of Hawaii. "It does need to be checked to see if human [embryonic stem] cells are also so unstable. But even if they are, we don't think it will be a problem."

The new work, published in today's issue of the journal Science, focused on cloned mice, each created from a single cell. But rather than making the clones from a single adult skin cell, as is common in the field, scientists made these from single embryonic stem cells, a special kind of cell of interest to cloners because they produce live clones at 10 times the efficiency of other kinds of cells.

Surprisingly, tests indicated that although every cloned mouse had exactly the same genes as every other – a hallmark of cloning – they varied considerably from one to the next in terms of which of their genes were active and which were dormant, a result of aberrant gene regulation.

The apparently random variation in the way genes were regulated in the clones suggests that the cloning process itself can sometimes scramble the molecular "switches" inside cells that tell various genes when to turn on and when to turn off. Considering what a delicately orchestrated process fetal development is, such regulatory mayhem in a developing clone could help explain why the vast majority of cloned animals die long before they are born, and why live-born clones often suffer from serious malformations.

Moreover, none of the abnormally regulated genes was predictive by itself of whether a clone was healthy. That means it won't be easy to come up with a genetic test to determine which developing clones will be

healthy – a strike against some advocates of human cloning who have claimed they could avoid creating genetically aberrant human clones by testing developing fetuses and aborting those whose genes seem abnormal.

To see if the genetic variation found in the mouse clones was entirely a result of the cloning process or was in part "inherited" from the originating stem cells, the team did molecular tests on individual mouse embryonic stem cells. They found that even stem cells that should have been identical displayed very different patterns of gene activation, an indication that gene switches are inherently unstable in this class of cells.

Such varying patterns could have big effects on how cells behave, scientists said. Imagine that a score for a piece of music is photocopied many times, but the notation saying which instruments should actually play their parts is different from one copy to the next – the equivalent to some genes being on and others off. The sequence of notes would be identical in each copy – the scores would be clones – but each would sound very different when played.

If human embryonic stem cells prove to be as variable in this way as their mouse counterparts apparently are, then a political compromise floated by the Bush administration in the stem cell debate may not be as practical as some had hoped. That possible compromise would limit the number of embryonic stem cell lines, or colonies, that scientists could work on, thus limiting the number of embryos destroyed. But if seemingly identical cell lines are subtly different from each other, then some may have particular promise for certain uses – such as to make new brain cells for Parkinson's patients – and others may excel at other tasks, such as becoming cardiac tissue for heart attack patients.

"You may have to establish hundreds of lines to get the few you'd want to have," said John Gearhart, a stem cell researcher at Johns Hopkins University.

Gearhart said he agreed with Jaenisch that the newly discovered genetic instability in embryonic stem cells will probably not interfere with scientists' goal of turning the cells into therapies. Proper "on-off" patterns of gene activity in stem cells are crucial for the coordinated development of an entire fetus, he said, but are less crucial if all that is wanted is to make the cells grow into pure tissues, such as cardiac muscle.

In the original draft of their paper, the authors called for research to see if genetic instability in stem cells might "limit their use in clinical applications." A spokesman for Science said editors there allowed Jaenisch to eliminate that language just days before publication because the change did not involve scientific data, only the authors' interpretation of their data.

Jaenisch said no one knows yet if so-called adult stem cells, which are retrieved from adults instead of from embryos, are more genetically stable than embryonic stem cells. Some opponents of embryo research have advocated focusing solely on adult stem cells.

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Tuesday, April 10, 2001 **Fat May Be the Answer for Many Illnesses**

By THOMAS H. MAUGH II, Times Medical Writer

Fat, the great American obsession, may provide a new source of replacement cells for a variety of medical treatments and eliminate the need for the controversial use of embryonic stem cells.

A team of researchers from UCLA and the University of Pittsburgh has isolated stem cells--primitive cells with the potential to become virtually any type of tissue--from fat collected by liposuction and converted them into bone, cartilage and muscle.

The researchers believe the cells could have many applications, from damaged knees to brain implants for Parkinson's disease and strokes.

At a time when the Bush administration appears inclined to ban the use of embryonic stem cells from aborted tissues, the new research reported in today's edition of Tissue Engineering offers an alternative source that could be much more plentiful and much less controversial.

"This could take the air right out of the debate about embryonic stem cells," said Dr. Mark Hedrick of UCLA, the lead author. The newly identified cells have so many different potential applications, he added, that "it makes it hard to argue that we should use embryonic cells."

"This is extremely significant in terms of its potential," said Dr. Michael T. Longaker of Stanford University. "Unfortunately, fat is a substantial natural resource in the USA. This is a great way to do something with it."

Another team at Duke University has produced similar results, turning stem cells from fat into cartilage. "It's very important for different groups to reach the same conclusion with a study with this much potential impact," said Dr. Farshid Guilak, who led the Duke study.

Both groups are performing tissue experiments in animals, and both suggested that it would be about five years before the first clinical trials could be conducted in humans.

Among the first applications might be cartilage implants for repairing knees and other joints, as well as noses and ears. Cartilage cells grown in the laboratory are already being used to repair damaged knees, but the use of stem cells would dramatically increase the supply of tissue available.

The repair of broken and defective bones that resist healing is also high on the agenda.

Further in the future, the cells might be used for a much broader variety of

applications, including brain implants for Parkinson's disease and strokes and in the repair of heart tissues.

"We don't yet know the limits for stem cells found in fat," said Dr. Adam J. Katz of the University of Pittsburgh, a co-author. "So far, we have seen promising results with all of the tissue types we have examined."

Most cells in the adult human body are somatic cells. They have adopted an identity--skin, heart, muscle, whatever--from which there is no going back. Skin cells cannot be converted into brain tissue, or vice versa.

Embryos, in contrast, have a large percentage of cells that have not yet adopted a genetic program and that have the potential to become any kind of cell in the body. These stem cells--so-called because all other cells stem from them--are a prize for researchers and clinicians, but their use is highly controversial because the only way to obtain them is through an abortion.

Research that involves using any tissue obtained from abortion has been a hot-button political issue in recent years, pitting the scientific research community against anti-abortion forces.

Former President Ronald Reagan banned federal funding of research using fetal tissue, which involves the transplantation of more developed cells. That ban was continued by President Bush's father, but reversed by former President Bill Clinton.

Federally funded fetal tissue research continues--researchers have already transplanted dopamine-producing fetal brain cells into Parkinson's disease patients--but the fate of stem cell research is uncertain under the new Bush administration.

In 1993, Congress prohibited the executive branch from stopping fetal tissue transplantation research. But the Bush White House is reviewing the law involving stem cell research, and is believed to be leaning toward forbidding such research if the cells are obtained from embryos.

Any research that bolsters obtaining stem cells from adults is expected to solidify Bush's position that it is unnecessary to use embryos to obtain stem cells.

Over the past decade, researchers have found that adults also have stem cells in a variety of locations, ranging from bone marrow to the brain. But they are present in small numbers, and recovering them can be difficult and painful.

They can be converted into specific tissues by exposing them to a complex mixture of growth hormones and other chemicals, which requires a different formula for each desired tissue. The trick is discovering what needs to be included in each cocktail.

The best source of such cells now is bone marrow, but recovering the cells requires drilling a hole directly into the bone, which remains painful for weeks after the procedure, Guilak said. And the yield is small, typically a few milliliters.

Liposuction, in contrast, is performed through an incision in the skin that is about 1 inch long and is relatively painless. Moreover, the procedure produces a thousand times as many stem cells as can be obtained from bone marrow.

In older adults, the percentage of stem cells is even higher in fat cells than in marrow, Guilak said.

And because each person would theoretically serve as his or her own fat donor, there would be no problem with rejection of implanted cells.

"This is extremely significant in terms of its potential," said Longaker of Stanford.

You don't even have to be fat to be a donor. "Even in skinny people, there is ample fat tissue in the buttocks and elsewhere," said Hedrick of UCLA.

Both groups of researchers have grown human cartilage samples the size of a

quarter to a half-dollar and implanted them in mice with no immune system, so that they are not rejected. So far, the implants have been very stable, with no signs of deleterious changes.

But they want to study them for much longer periods of time. "We wouldn't want cartilage in the knee to turn into fat," Guilak said. Guilak, for one, is optimistic, but he wants to make sure.

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EXPAND STORY

## Embryos Created for Stem Cell Research

Medicine: Scientists' experiment, which used no federal funds, comes at politically sensitive moment on larger issue.

LAT via Dow Jones

Publication Date: Wednesday July 11, 2001 Page A-1 Los Angeles Times (Home Edition) Copyright 2001 / The Times Mirror Company By AARON ZITNER TIMES STAFF WRITER

WASHINGTON -- Inflaming the already heated debate over stem cell research, a team of Virginia fertility researchers report today that it created human embryos for the specific purpose of disassembling them to obtain the valuable stem cells inside.

The experiment, which was legal and used no federal funds, throws a spotlight on one of the murkiest areas of medical research--the creation of human embryos for laboratory experiments--at an unusually sensitive moment. Within weeks, President Bush is expected to announce whether the federal government will fund medical research using embryo stem cells, capping three years of contentious debate.

Several experts said the report, from researchers at the Jones Institute for Reproductive Medicine in Norfolk, Va., appeared to be the first published account of scientists producing embryos only to harvest their stem cells.

They said different teams had probably created embryos for other research purposes, but the practice is not widely discussed because of possible public backlash. The report appears in the July issue of the journal Fertility & Sterility.

Embryonic stem cells can grow into any type of cell in the body, and scientists hope to guide the cells to become replacement tissue for patients--new pancreas cells for diabetics, heart muscle for cardiac patients and brain cells for Parkinson's patients. But anti-abortion groups say the research is equivalent to murder because human embryos are destroyed in the process of obtaining stem cells.

To date, scientists have obtained stem cells from embryos donated by fertility patients. These patients often create more embryos than needed in the course of trying to have a child.

The government is also eyeing these "spare" fertility clinic embryos as a source of stem cells should Bush approve a funding plan. In lobbying the Bush administration, many scientists and research advocates have argued that it is more ethical to use these embryos in research than to have them discarded or frozen indefinitely, as patients usually do. They have noted that under National Institutes of Health rules, no embryos would be created for the federally funded research.

"Is it more ethical for a woman to donate unused embryos [for research] . . . or to let them be tossed away as so much garbage when they could help save thousands of lives?" asked Christopher Reeve, the actor and a research supporter, in testimony before the Senate last year.

Now, the Jones Institute researchers are adding a new wrinkle to the ethical calculation behind embryo cell research.

In their report, the scientists say they solicited eggs and sperm from paid donors and used them to create 110 fertilized eggs. Forty matured to the stage where stem cells usually develop, though the scientists

successfully isolated and cultured cells from only three of them.

Explaining why the research was conducted, the institute's ethics advisors said, "It was our duty to provide humankind with the best understanding of early human development." But the work was criticized by people on both sides of the stem cell debate.

"This is really ghoulish, a ghoulish exercise they've engaged in," said Douglas Johnson, legislative director of the National Right to Life Committee, an anti-abortion group.

If Bush approves federal funding for research with "spare" embryos, Johnson said, then scientists in time will demand funding to create embryos for research. "Once the federal government abandons the principle that it will not collaborate in embryo destruction, it has no principled basis for refusing to support these further outrages."

Richard Doerflinger, an official with the United States Conference of Catholic Bishops, said the experiment "shows the slippery slope in action. Once clinics get used to the idea of research on spare embryos, they will become desensitized enough to consider creating embryos solely to be destroyed."

Some supporters of embryo cell research criticized the report as well, saying that it was clear from work with fertility clinic embryos that stem cells could be obtained from embryos created for research purposes.

"It seems an unnecessary step, and it certainly raises the ante politically," said Alexander Capron, a USC professor of law and medicine. "It suggests that the scientists themselves don't see a reason to abstain from something that seems of marginal medical utility, and which is much more problematic ethically, and is therefore certain to inflame people" who oppose embryo cell research.

Timing of Research's Disclosure Is Cited

"This is not good timing," said Dr. Robert Lanza of Advanced Cell Technology Inc., a Massachusetts company working with stem cells and related materials. "They're throwing gasoline on the fire."

Others said the new report showed that Bush should support federal funding because it would bring much embryo research under federal ethics and public disclosure rules.

Unless he proposes a change in federal law, Bush's decision would not bar researchers from repeating the Jones Institute experiment. Even if he prohibits federal funding for the work, research in the private sector would remain untouched. No federal law bars the creation of embryos for research purposes, though some states have sought to regulate the practice.

Dr. William Gibbons, chairman of the department of obstetrics and gynecology at Eastern Virginia Medical School, which houses the Jones Institute, said research findings from the project were announced at a professional meeting last fall, and the paper was submitted in November. He called it an accident of timing that it is being published just as stem cell research has taken a high profile in Washington.

Gibbons said the research was approved by three internal ethics panels, and that the researchers' method allowed them to select egg and sperm donors who they thought were most likely to produce the healthiest embryos. On average, the 12 women in the experiment were under age 30, compared with ages 34 to 36 for the average fertility patient at the institute.

Moreover, the egg and sperm donors knew from the start that they were contributing to a research project,

Gibbons said. By contrast, fertility patients are usually focused solely on their goal of producing a child, and research concerns come as an afterthought.

Finally, Gibbons said, donors in the program were screened for their psychological fitness to participate in the research, whereas fertility patients are usually not screened for that purpose.

"We felt that this was the most straightforward, purest form of informed consent for donors, in that everyone understood the nature of this from the start," he said.

Research Involving Embryos Highlighted

The release of the report brought attention to the use of human embryos in research that does not involve stem cells. Many bioethicists believe that scientists at private companies and fertility clinics create embryos as part of research into fertility techniques and contraception, but the practice is not widely discussed.

Robert Edwards and Patrick Steptoe, who developed the technique of in vitro fertilization, "created a number of embryos for research purposes only, before they implanted an embryo into a woman," said Ronald Green, an ethics professor at Dartmouth College. They conducted the research over the course of a decade.

Federal panels have taken different views of the creation of embryos for federally funded research. The practice was endorsed by an advisory panel to the Department of Health and Human Services after the 1978 birth of the world's first "test tube baby," Green said. But President Reagan and Bush's father, George Bush, never put the policy into practice.

In 1994, a special panel of the NIH also endorsed the creation of embryos in limited circumstances for federally funded research, but President Clinton rejected the idea. More recently, the National Bioethics Advisory Commission, created by President Clinton, considered the idea but did not endorse it.

When the NIH last year issued guidelines for the first-ever federal grants for embryo cell research, it said the cells could come only from embryos donated by fertility patients.

The Bush administration put the NIH funding plan on hold this year, pending a review. Bush has said he will announce a decision soon on whether to start or withdraw the funding plan, but he has not announced a timetable.

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The Public i
An Investigative Report of the Center for Public Integrity


Life for Sale?

# Embryo Research: Profit vs Ethics?

**Corporations team up with patients' rights groups to overpower opposition to research that destroys embryos, but could save lives**

By Shaun Taylor-Corbett

(Washington, August 24) Biotechnology companies specializing in stem cell research stand to reap huge financial windfalls from successful therapies developed via this science. To ensure that their research can continue and perhaps accelerate, some of the companies have teamed up with patients' rights groups against certain religious and pro-life groups in the fight over federal regulation of this controversial field. As a result, what was once a debate between science and religion has become, in part, a clash between profits and ethics. New guidelines from the National Institutes of Health, released yesterday, mark the first hard-fought victory for patients' rights groups and biotechnology companies interested in this issue. President Clinton took the occasion to voice his support for the guidelines, noting the "potentially staggering benefits" of this technology.

Geron Corporation and Advanced Cell Technology (ACT) are the two companies most interested in NIH funding for research involving stem cells derived from human embryos. Stem cells are undifferentiated, and can develop into brain, heart, or any number of more specific cells. They form within the first eight days of an embryo's life, and develop into almost all of the human body's various tissues and organs.

Since Geron's successful isolation of these types of cells in 1998, scientists and patients' rights groups have jubilantly theorized about the extraordinary possibilities in developing treatments for a whole range of diseases and ailments. For example, depending on the future success of stem cell research, scientists might be able to grow stem cells into the neuron cells of the brain, which could provide treatments to those suffering from Parkinson's and Alzheimer's disease, or heart cells for those suffering from cardiac ailments.

Yet as exciting as these potential medical advancements are, embryonic stem cell research presents plenty of tough ethical dilemmas. The most accessible supply of human stem cells is found in human embryos, which both pro-life advocates and many religious groups consider to be human life. Scientists must harvest the stem cells from the inner cell mass of the blastocyst, the embryonic phase that begins after eight days of development; in so doing, they destroy the embryo itself. According to the new NIH guidelines, scientists will be able to use federal funds for research on embryonic stem cells, but not for the derivation, or harvesting, of those stem cells from the embryos. Even after the first grants are awarded under the new guidelines, they will still have to pay for the stem cell derivation with their own money.

### Corporate Funding

The companies that stand to benefit from federal funding for embryonic stem cell research are not sitting idly by as the battle rages between patients' rights groups and the religious/pro-life community. One of the patients' rights groups most active in the legislative debate on federal oversight of stem cell research is the Alliance for Aging Research, which bills itself as "the nation's leading citizen advocacy organization for improving the health and independence of older Americans through public and private research," according to their mission statement.

The Alliance also happens to receive funding from private sector biotechnology companies that have a financial stake in the outcome of the stem cell debate, including Geron, which gave the organization $25,000 in 1998, according to Alliance tax returns. (When contacted for this article, the Alliance had not

completed its 1999 tax returns.) Ronald Eastman, the former CEO of Geron, also sits on the Alliance's board.

Some of the world's biggest biotech and pharmaceutical companies are also counted as some of the Alliance's top funders. Among them are Pfizer, which contributed approximately $200,000 to Alliance in 1998, Eli Lilly and Company ($130,000), GlaxoWellcome ($43,781), Merck & Co. ($49,154), Warner-Lambert ($41,000), SmithKline Beecham ($35,000), Bristol-Myers Squibb ($35,000), Johnson & Johnson ($35,000), Procter & Gamble ($25,000), Schering-Plough ($10,000), Amgen ($5,000), and Genentech ($5,000). In 1997, according to the organization's tax filings, Hoechst Marion Roussel, now part of Aventis Pharmaceuticals, gave the Alliance $465,000.

The Alliance also has a friend in Merrill Lynch & Co., Inc., whose executive vice president, John L. Steffens, chairs the Alliance's board of directors and personally contributed $25,000 of his own money to the organization in 1995. Merrill Lynch itself also gave $53,000 to the Alliance in 1998. A representative from the company's media relations department told The Public i that "Mr. Steffens has a keen personal interest in gerontology and all things related to aging. This is reflected in studies that Merrill Lynch has done for many years."

One of Steffen's fellow board members is Allan Fox, a former senior partner at Fox, Bennett, Turner, which split into two separate law firms in September of 1999. Mr. Fox is currently a senior partner at FoxKiser. According to Daniel Perry, executive director of the Alliance, Fox joined the Alliance's board after the breakup of Fox, Bennett, Turner and was not involved in lobbying for stem cell research. But, until last year, other members of the firm had been registered lobbyists for Geron, including Samuel D. Turner, a senior partner. Mr. Turner served previously as the deputy general counsel at the Department of Health and Human Services. At Fox, Bennett & Turner he worked primarily with patient advocacy groups and pharmaceutical and biotechnology companies, according to his official biography.

Fox, Bennett & Turner also funded the Alliance, chipping in $20,000 from 1997 to 1998. The firm declined to comment on the extent of its lobbying activities for Geron, though its federal lobbying reports list "stem cell issues" as a description of its lobbying work for the biotech company.

**'Embryos are not involved'**

A large part of the Alliance's attention has been focused on ensuring that federal funds can be used for embryonic stem cell research. In that regard, it created the Patients' Coalition for Urgent Research (Patients' CURe) in May of 1999. Perry, who is also chair of Patients' CURe, said in an interview that the Coalition was formed in part to support the controversial finding by NIH and the Department of Health and Human Services that federal funding for stem cell research did not violate a 1996 congressional ban, renewed every year since, on research harmful to embryos.

On January 15, 1999, Harold Varmus, director of NIH, received an official legal opinion that federal funds could be used for stem cell research. NIH's general counsel concluded that such use of federal funds did not violate the 1996 congressional ban on "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death" (section 128 of Public Law 104-99).

In a letter dated February 23, 1999, to members of Congress who oppose the NIH's determination, HHS Secretary Donna Shalala stated that "research on existing ... stem cell lines is both legal and appropriate," and that "there is nothing in the legislative history to suggest that the provision was intended to prohibit funding for research in which embryos – organisms – are not involved." In other words, because stem cells are technically not embryos, companies and NIH scientists should be able to use government funds for embryonic stem cell research as long as they derive the stem cells from the embryos at their own expense.

This is exactly what Geron and ACT are doing, but at a considerable cost, according to one official at the NIH familiar with the agency's policy on stem cell research. The official, who wished to remain anonymous, told *The Public i* that the fledgling stem cell industry would profit tremendously from federal funding that would cover embryonic stem cell research. In fact, complementary federal funding of private sector research has been shown to increase private sector pharmaceutical research productivity by as much as 40%, according to a study done by the National Bureau of Economic Research, a nonprofit research organization. Other studies have shown that public funding of biotech research also

leads to increased investment in private sector companies engaged in similar research.

"We knew that the research would be controversial and difficult for Congress to wrestle with," says Perry when explaining the reasons for creating Patients' CURe. The Coalition represents thirty-four major patients' rights groups, including the Alliance, and is, according to Perry, "a vehicle for bringing into contact media, politicians, and patients who are facing devastating diseases." Among the groups in the coalition are the American Parkinson Disease Association, the Christopher Reeve Paralysis Foundation, and the Juvenile Diabetes Foundation International.

HHS' findings did not go unnoticed. Many lawmakers, pro-life organizations, and religious groups felt the Department's determination was a sneaky attempt to circumvent the 1996 federal ban on research harmful to embryos. In a letter addressed to Secretary Shalala on February 11, 1999, seventy members of the House of Representatives, including Tom DeLay (R-Tex.), Jay Dickey (R-Ark.) Henry Hyde (R-Ill.), and Christopher Smith (R-N.J.), protested the HHS findings. "While the act of destroying or injuring an embryo would certainly be ineligible for Federal funding, the law has a broader application. It also bars the use of tax dollars to fund research which follows or depends upon the destruction of or injury to a human embryo," they wrote. The lawmakers who signed the letter believe that federal funding indirectly but inevitably influences how many embryos are killed based on the need for stem cells. Therefore, they believe, the NIH would be partly responsible for the death of embryos, and would be in violation of the 1996 ban.

Richard Doerflinger, associate director for policy development at the Secretariat for Pro-Life Activities of the National Conference of Catholic Bishops, believes that the NIH is eager to reverse the 1996 federal ban on embryonic stem cell research, and sees the HHS determination on stem cell research as a wedge to open up federal funding for other controversial research initiatives. He mentions genetic engineering and embryonic cloning as examples of such initiatives. In an article posted on the National Right to Life Committee's Web page, Doerflinger suggests that Geron and the NIH hope to use federal funds in the near future to clone embryos containing the same genetic material as the patient being treated, thereby decreasing the probability that the patient's body will reject the therapeutic embryonic stem cells. He states the following:

> "Geron and NBAC [the president's National Bioethics Advisory Commission] know that the much-touted use of 'spare' embryos may well fail to produce the promised results. But they also know that the 'unconscionable' step of using taxpayers' funds to create human embryos for destruction could doom the entire enterprise in the eyes of public opinion. So expect them to proceed with 'spare' embryos, perfecting the art of culturing stem cells and directing them to differentiate in the lab. And when they stand on the threshold of transplantation into humans, expect them to announce that they could save many lives, if only we will allow this one last step."

Thomas B. Okarma, president and CEO of Geron, responds that the company, as well as the scientists from NIH, would require only a limited "bank" of embryos from which to derive stem cells. "Once you have the bank of [stem] cells you need for the market you are entering, you are done," Okarma told *The Public i*. He explains that the regenerative qualities of embryonic stem cells make the acquisition of an endless supply of embryos unnecessary. When asked how many embryos Geron has used in its research, Okarma said he could not make a guess.

Interestingly enough, Geron recently purchased Roslin Bio-Med, Ltd., the Scottish company that cloned "Dolly" the sheep. Geron thereby acquired Roslin's cutting-edge cloning technologies, including a technique known as somatic cell nuclear transfer, one of Roslin's most important technologies. Both Roslin and ACT have been developing this technique, which can be used to create embryos (ACT officials did not make themselves available to be interviewed for this article). While creating human embryos is prohibited in the United States, the British government recently agreed to initiate legislation that would amend the ban on human cloning in that country.

**New Legislation**

While the new NIH guidelines clarify the right of companies to use federal funds for stem cell research in general, a new bill introduced in Congress, the Stem Cell Research Act of 2000 (S. 2015), would allow companies to use federal money to derive the stem cells from embryos, as well as use them in subsequent research. As noted by the NIH official, such a windfall of federal money would greatly benefit private companies like Geron.

S. 2015 was introduced in the Senate on January 31, 2000, by Senator Arlen Specter (R-Pa.), who chairs the Senate appropriations subcommittee on Labor, Health and Human Services, and Education. The bill goes a step further than funding embryonic stem cell research by proposing to federally fund the derivation of stem cells from human embryos as long as "the research involved shall not result in the creation of human embryos [or] the reproductive cloning of a human being."

A spokesperson from Specter's office said that the bill was introduced because "there is no oversight of the private sector regarding embryonic stem cell research." The spokesperson added that the bill would allow NIH researchers to draw from a controlled source of embryos and perform their research in an ethical manner. "The goal of the bill is not to urge couples to donate more eggs than necessary or create a bank of embryos," the spokesperson said, "but to allow federal researchers, who are the best in the land, to research embryonic stem cells."

However, those who are adamantly opposed to the bill, such as Senator Sam Brownback (R-Kans.), believe that the bill will have a much different effect. When Specter's Senate subcommittee held a hearing on stem cell research on April 26, 2000, Brownback, a member of the subcommittee, made his position regarding the research quite clear:

> "In brief, the Stem Cell Research Act of 2000 would allow federal funding for researchers to kill living human embryos. This research is problematic because it would use federal tax dollars to allow the government to procure, and therefore 'own,' a vast supply of living human embryos. The notion of 'ownership,' particularly by the Federal government, of other human beings is deeply disturbing. The bill defines a new class of human beings who, under the law, will simply not be allowed to live."

Biotech and pharmaceutical companies are not standing by while opposition to the research grows. Specter's second-largest campaign patron during the 2000 cycle is Amgen, whose employees have given the Senator at least $42,000. The bulk of that money was donated on August 10, 1999, by dozens of Amgen executives, according to the Center for Responsive Politics. During the current election cycle, according to CRP, the "Health Professionals" and "Pharmaceuticals/Health Products" industries have contributed almost $800,000 to the senator. The "Health Professionals" industry has contributed $31,500 to congresswoman Carolyn Maloney (D-N.Y.), who introduced a resolution in the House supporting HHS's decision to uphold federal funding for embryonic stem cell research.

Besides the companies themselves, the Biotechnology Industry Organization (BIO), which represents over eight hundred biotech and pharmaceutical companies (including Geron and Advanced Cell Technologies), is also actively engaged in trying to push federal funding for embryonic stem cell research through Congress. According to a letter written from BIO to Harold Shapiro, chairman of NBAC, BIO does not take an official position on "whether federal money should be used to fund research to derive…stem cells or to study these cells once they are derived." However, BIO "believes additional funding, including the use of public monies, will expedite progress in development of new stem cell treatments." Last year, O'Brien Callo, a major lobbying firm, raked in more than $100,000 for lobbying lawmakers on BIO's behalf. They focused their attention on "embryonic stem cell legislation" and other issues, including human cloning, according to federal lobbying records.

BIO's own lobbying records show that they spent a portion of their in-house lobbying expenses, which totaled $1,715,896, pushing their views regarding the "Stem Cell Report" that NBAC would issue to the President on September 7, 1999. NBAC was asked by President Clinton to examine ethical issues involved in stem cell research shortly after Geron's successful isolation of stem cells in 1998. According to Eric Meslin, executive director of NBAC, the Commission supports federal funding for embryonic stem cell research and "concluded that for purposes of public policy, there was no ethical distinction between the derivation of embryonic stem cells from embryos remaining after in vitro fertilization on the one hand, and the use of those stem cells." However, Meslin did mention that the Commission did not find the creation of embryos for the sole purpose of acquiring stem cells ethically acceptable.

The Alliance, the Coalition, and organizations within the Coalition have also been active in lobbying members of Congress to support federal funding for stem cell research. Some of their activities have included bringing patients facing serious illnesses to meet with congressional members involved in the stem cell debate, and arranging letters in support of stem cell research to be sent to the Hill.

Reacting to the activities of the major religious groups opposing the research, the Alliance sent a letter

addressing the controversial issue, signed by university professors of various faiths (Jewish, Muslim, Protestant, and Catholic), to House Speaker Dennis Hastert (R-Ill.). The letter gives support not only to federal funding for stem cell research, but also to funding for the derivation of stem cells from human embryos. They acknowledge that "all human life must be protected," but make a clear distinction between the level of protection that should be given to an embryo and to that of a fetus. "There is a significant difference between an embryo suspended in liquid nitrogen that will never be implanted inside a womb, and an unborn child who is already in the womb. We support embryonic stem cell research because it would use these frozen or otherwise discarded embryos to help ease the suffering of those with catastrophic disease."

According to the Alliance's Perry, the Juvenile Diabetes Foundation has also been an important player in lobbying Congress on the issue. The Foundation refused to confirm this. However, according to their 1999 annual report, the organization has been very influential in securing federal funding for NIH projects. The literature states that they "successfully advocat[ed] a fifteen percent increase in the NIH budget to $17.9 billion." It also mentions that Sen. Specter and Rep. John Porter (R-Ill.), who chairs the Labor, Health and Human Services, and Education appropriations subcommittee in the House, were "instrumental in working with JDF in advocating this large increase."

Patients' CURe also believes that the U.S. public supports its position on stem cell issues. To prove this point, the Coalition points to a survey, which it commissioned, in which seventy-four percent of the people polled favored federal funding for embryonic stem cell research. Perry says that the NIH funding decision "reflects the public's support for the research." However, the definition of "federal funding for stem cell research" used in the poll perhaps oversimplified the issue; it failed to alert the survey participants that a human embryo is killed in the process of deriving the stem cells, and that stem cells can also be derived from other parts of the body, though not as easily.

At the moment, S. 2015 remains in Senator Specter's subcommittee. According to Charles Robbins, Specter's press secretary, there is a possibility that the bill will go to the floor for debate this September.

**The Opposition**

"Embryos are a part of the human family. Because of that, we should not legislate in such a manner that it becomes common course to experiment or destroy a human embryo," says Laura Echevarria, director of media relations at the National Right to Life Committee. NRLC is one of the groups crusading against federal funding for both embryonic stem cell research and the derivation of stem cells from human embryos. Both the Christian Coalition and the National Right to Life Committee are spending hundreds of thousands of dollars lobbying Congress on these issues, and are coordinating their efforts with those of the National Conference of Catholic Bishops and the National Convention of Southern Baptists.

In 1999, NRLC spent a portion of its more than $340,000 of in-house lobbying expenses opposing Specter's legislation, which they say would "allow federal funding of embryo-destructive experimentation." They also lobbied for new legislation sponsored by Rep. Dickey that would "protect living human embryos."

Since 1997, the Christian Coalition has spent almost four million dollars in lobbying expenses on various issues, including opposition to "medical research on a human fetus or embryos." The Coalition has joined forces with NRLC in an attempt to cut off federal funding for stem cell research, including Specter's bill. In fact, Susan T. Muskett, director of legislative affairs for the Christian Coalition, was formerly a policy analyst for NRLC and lobbyied on stem cell research for that organization in 1999, according to NRLC's lobbying records.

The National Conference of Catholic Bishops, one of the two organizations comprising the American Catholic hierarchy, shares the same position as NRLC regarding stem cell research funding, and has been outspoken on the issue. Four of Richard Doerflinger's articles, all opposing federal funding for embryonic stem cell research, have appeared on NRLC's Web page, along with a letter issued by the National Conference of Catholic Bishops addressing the same issue.

While the National Conference of Catholic Bishops does not spend money on political campaigns or hire lobbyists, it has been influential in other ways. According to Doerflinger, his organization has sent letters, signed by various organizations opposing funding for embryonic stem cell research, to members of the Senate, and was partly responsible for encouraging approximately 50,000 people to send

Congress statements of opposition to funding for embryonic stem cell research. He also said that the NCCB focuses most of its lobbying on senators who are "on the fence" regarding stem cell research. On that list he included Sens. Joe Biden (D-Del.), Orrin Hatch (R-Utah), and Gordon Smith (R-Ore.). Senator Smith, a conservative Republican who normally votes to tighten abortion laws, has family members who have died or who are suffering from Parkinson's disease. According to his deputy press secretary, Rebecca Wilder, "he supports the concept of federal funding for stem cell research. However, he has not put his support behind a specific proposal."

Of all the members of the Senate, "Brownback has been our champion," says Doerflinger. Sen. Brownback has been the most outspoken opponent of Specter's bill, as well as of federal funding for any embryonic stem cell research. He has held public forums on the issue and is "looking at legislative options to make sure that the ban on embryonic stem cell research is not overturned," according to Eric Hotmire, Brownback's press secretary. According to Ben Mitchell, a consultant to the national Southern Baptist Convention, "Sam Brownback has been interested in providing a voice to those who have no voices."

Both Doerflinger and Mitchell criticize the government for taking the moral high ground in banning federal funding for embryo research, yet allowing funding for stem cell research that, they believe, encourages private companies to destroy embryos. "When someone does something really good, people want to be complicit. When something is morally problematic, complicity stops," says Mitchell. Conversely, Tom Okarma of Geron also finds the government's actions "a little bizarre from an ethical perspective."

**'Irresponsible Scientific Talk'**

"There is a lot of irresponsible scientific talk that this is the magic bullet that will solve all of these problems," says Doerflinger, referring to the diseases that many patients' rights groups and some biotechnology companies say will be cured by stem cell therapies. "Stem cells do promise certain benefits. However, it has to be underscored that they are theoretical," says Mitchell.

According to Annemarie Moseley, CEO of Osiris Therapeutics, a privately held biotechnology company that focuses on the development of cellular therapeutic products via adult stem cell research, embryonic stem cell technology is still in its early stages, and treatments for related diseases might not be available for another fifteen years. "While we support the continued research in the field, we do not think it would be fair for groups to believe that therapeutic strategies based on embryonic stem cells will be readily available in the near term. In that vein, we believe that the government should view embryonic stem cells as an early and potentially very beneficial developmental tool," she says.

This year's leading presidential candidates have generally avoided public discussion on stem cell research. The Gore campaign provided *The Public i* with this statement of the Vice President's position:

> "The medical benefits of using stem cells for research purposes are compelling and hold great promise for treatments of Parkinson's disease, heart disease, and other illnesses. However, because of sensitive ethical issues and social considerations raised by the derivation of human stem cells, he does not request any change [to] current law [to] permit federal funding for the derivation of stem cells from human embryos."

While Gore disclaims support for any a change in the ban on human embryo research, some skeptics say that the Administration has already endorsed a change in the law, without admitting it's a change. "The Clinton-Gore Administration and certain members of Congress have been looking for ways to fund human embryonic stem cell research without violating the letter of the congressional ban," states an article published on the NRLC web page. "To this end, administration officials offered several inventive readings of the statutory language."

Governor George W. Bush's campaign did not return repeated calls from The Public i, and his Web site makes no mention of the Republican candidate's position on stem cell research. Several media reports have indicated that Bush is opposed to stem cell research.

While it seems likely that biotech companies will soon cash in on the revised NIH guidelines, it is unlikely that Specter's bill will be signed into law and reverse the 1996 congressional ban on stem cell derivation, according to Doerflinger. Although the National Conference of Catholic Bishops is active on

Capitol Hill in their opposition to embryonic stem cell research, he acknowledges that the organization is facing very powerful opponents. When asked if the battle between the pro-life/religious coalition, and the biotech companies and patients' rights groups was one of money, he laughed. "If it were a question of money, they could buy and sell us if they wanted to."

Shaun Taylor-Corbett was a research associate at the Center for Public Integrity. He was assisted by Nathaniel Heller, James R. Soles Fellow.

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# Issues & Ideas

## Mixing Business With Stem Cells

MEDICINE

By Neil Munro

The fierce debate over federal funding for research on stem cells has focused on some profound questions, such as what are the moral tradeoffs in destroying human embryos. A less-lofty factor, however, is also shaping the debate: the pecuniary interests of the physicians and scientists performing the research.

Scientists engaged in the public debate over how best to use stem cells for the betterment of human lives are often prominent faculty members at prestigious universities and public research institutions. But often as not, they are also board members and shareholders of fledgling biotechnology companies, which stand to make hefty profits from the research the scientists are urging the government to fund. They are, in short, both disinterested scientists and very interested entrepreneurs.

This potential for conflict of interest also fuels disputes between competing groups of scientists, says Dr. Ammon Peck, a stem-cell researcher at the University of Florida (Gainesville). "There is more politics in science," he said, "than there is in business or in politics."

DPI-MAUSNETEF MILLER

**Stem Cells:** A researcher at the University of Wisconsin (Madison) looks through a microscope at culture trays containing stem cells from human embryos.

Some of the private-sector advocates for federal stem-cell research on human embryos are open about how it would benefit their interests. Thomas Okarma is the CEO of Geron Corp., which is based in Menlo Park, Calif., and is the market leader in this research. Okarma has testified repeatedly in favor of federal funding. Indeed, his company's market value is far below last July's $700 million. The company's stock value fell 50 percent, for example, after the Bush Administration began reviewing the Clinton Administration's policy that allowed federal funding for stem-cell research.

But the media coverage has often missed the financial interests of the scientists who have been prominent in supporting government funding for research into the use of stem cells from human embryos. Anti-abortion groups and some medical ethicists support research on stem cells taken from adults, but oppose embryo stem-cell research, because the embryo is destroyed to extract the stem cells.

One of the leading scientists who has spoken out in favor of research into embryo stem cells is Douglas Melton, who is typically identified in media reports as chairman of Harvard University's department of molecular and cellular biology. However, Melton is also a board member of Curis Inc., a Cambridge, Mass., company seeking to commercialize technologies based on stem cells drawn not from embryos, but from adult humans. Curis's market value is $190 million.

Similarly, Irving Weissman, a scientist at Stanford University who has spoken in favor of government funding for embryo research, is also the founder of two companies, SyStemix Inc. and StemCells Inc. At StemCells, Weissman serves on the board and owns shares. The company's stock price fell from last September's $8.00 per share to $6.55 in July. The stock's total market value is $135 million.

Within the National Institutes of Health, Ronald McKay is a prominent supporter of federal funding for embryo research, and has been quoted frequently in the media as an NIH scientist. But he also helped found—and still owns shares in—NeuralSTEM Biopharmaceuticals, a company in College Park, Md. NIH transferred a patent on fetal brain cells from McKay's NIH laboratory to NeuralSTEM, which is seeking a cure for Alzheimer's and Lou Gehrig's diseases.

Since January 1, these three researchers have been quoted 216 times in the national media, including *National Journal*, in support of federal funding for research on embryo stem cells, but in only 17 citations have they been linked to their companies. Weissman's private-sector ties were reported in 16 of 48 articles; McKay's relationship to NeuralSTEM was cited once out of 124 mentions; and Melton was not linked to Curis in any of the 44 articles for which he was interviewed.

McKay and Weissman, in interviews, said they try to keep their personal financial interests out of their public statements. "I work very hard when talking publicly to express an opinion which is predominantly technically based," said McKay. "I'm quite leery of expressing political opinion ... [and] I have no involvement in the day-to-day running of the company." Weissman said that when speaking at conferences, "I always disclose.... Everybody in this area should do that."

The problem of scientists' dual interests in commercial success and in scientific truth affects more than just stem-cell research, said Edward Benz, the new president of the Dana-Farber Cancer Institute at Harvard Medical School. "It is very, very difficult to keep them separate ... in every area of medical research," said Benz, who served with Melton and Weissman on an NIH planning board that helped formulate federal policy on stem cells. The best remedy, he said, is "full disclosure.... People should disclose anytime that they have something that might bias their remarks."

Although Benz is no longer a member of the NIH board, he served while he was chair of the department of medicine at the Johns Hopkins University School of Medicine. To illustrate the close ties between

university researchers and biotechnology companies, consider this: Johns Hopkins has a licensing deal with Geron that will give the school some of the company's profits from stem-cell commercialization, because a Hopkins scientist, John Gearhart, was a co-discoverer of stem-cell potential while working with Geron. The other co-discoverer, James Thomson of the University of Wisconsin (Madison), also has a licensing deal that may gain him and his patent-holder—the Wisconsin Alumni Research Foundation—a share of Geron's profits. Thomson and Gearhart, along with McKay and two other researchers, are listed as "special contributors" to an NIH report on stem cells released on July 18. Melton, Weissman, Okarma, and Peck are also cited as contributors to the report, which did not disclose any of the contributors' financial interests.

The commingling of scientific and business concerns is also illustrated by a key stem-cell planning group at NIH. The Stem Cells and Developmental Biology Planning Group is part of NIH's National Institute of Diabetes and Digestive and Kidney Diseases, whose budget is $1.1 billion. Of the planning group's 17 members, three are NIH officials, and the rest are university and private-sector researchers. In addition to Melton and Weissman, two of the group's other researchers are scientific consultants to Curis; one is a consultant for a New York-based company, ImClone Systems Inc. One of the Curis consultants is also working with Advanced Cell Technology Inc., based in Worcester, Mass., as it seeks to clone human embryos for experimental use.

Some of the group's members, including Benz and Dr. Leonard Zon, who works at the Children's Hospital of Boston, have no ties to the commercial sector. Zon said, however, that if his research is successful, it will likely lead to a partnership with a company—and so generate financial rewards for himself and his parent institution. Zon, who also serves on the Harvard faculty, has discovered possible methods of accelerating the reproduction of blood stem cells taken from human adults or embryos.

Indeed, most researchers get grants from NIH, and they have a potential conflict of interest in merely calling for more government funding, said former Sen. Connie Mack, R-Fla., who promotes federal funding for embryo stem-cell research. "I would think there are relatively few researchers who do not have some connection to federal funding, either directly or

**RONALD MCKAY:** A scientist at the National Institutes of Health, McKay also owns shares in a biotechnology company he helped found that does research on stem cells.

indirectly," said Mack, who himself sits on the board of two biotech companies based in Massachusetts, Exact Sciences Corp. and Genzyme Corp. Genzyme is working on stem cells. One test to measure possible financial influence on decision-making, Mack said, is whether a proponent held the same views before money came into the picture. "If I took a different position while I was in public life, it would be fair game to say, 'Why have you changed your position?' " said Mack, who has supported similar research since the early 1990s

Sometimes, however, the public statements of researchers seem completely at odds with their private business interests. For example, one of the key questions about stem cells is whether research on stem cells from adults is as promising as that done on stem cells from embryos. In media interviews, some academic scientists, including Weissman and Melton, play down the potential of adult cells, arguing that such cells are not true stem cells, or that embryo research is needed to fully understand adult stem cells. Yet much of the private research being done on stem cells, including that by Weissman's and Melton's companies, is focused on developing medical products in the near term from stem cells taken from adults, or from fetuses, but not from embryos. In Melton's case, his company, Curis, is trying to use its work on adult stem cells to develop cures for male pattern baldness as well as multiple sclerosis and other medical problems, and is also working with a Canadian company that has converted skin stem cells into working brain, bone, and cartilage cells.

Weissman's private affiliations also run toward adult stem-cell research. "I've placed my bets on adult stem-cell research," Weissman said. But he added that the federal government should fund embryo research to help develop knowledge and new therapies for the future, including therapies that help activate stem cells from adults. Transplants of embryo stem cells to treat diseases such as Alzheimer's are far distant, he said, but added: "I believe that human embryonic stem-cell [research] is vital to the health of science ... [to] academic medical science, [and] for the developing of the next round of biotech."

Financial interests also lie behind much of the internal politics among scientists, which can result in some promising science being downplayed, say researchers, including Peck and McKay. "Diabetes is one of the most political areas I've ever seen in science ... because there is so much potential financial gain, and almost everyone today in science has some connections to biotech or to pharmaceutical companies," said Peck. For example, Peck was not invited to attend an upcoming October NIH conference on diabetes and stem cells, nor to the June debate on stem cells hosted by the prestigious National Academy of Sciences, despite two relevant reports in the past six years by his research team. He and his team had used stem cells from adult mice to eliminate symptoms of diabetes in mice.

Part of the problem is his Florida location, Peck said. "We're not in the Northeast or West Coast 'in' groups in science," said Peck, who nevertheless is regarded well enough internationally to have been invited to Stockholm this week to chair the diabetes session at the International Congress of Immunology, held every three years. "We do have some very interesting results that would be shocking" to the attendees at the October NIH conference, he said, but he currently intends to publish the results at another forum. To commercialize his diabetes stem-cell technology, Peck's university transferred the patent to his company, Ixion Biotechnology Inc., in Alachua, Fla.

Generally, researchers see no cure for their potential conflicts of interest—except repeated disclosures and broad dissemination of scientific results. "It is an inherent conflict that the people best able to fund and the people best able to do the research will have relationships," said Benz. "If they didn't, the research won't get done." ■

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Oversight Hearing
"Fetal Tissue: Is It Being Bought and Sold in Violation of Federal Law?"
Subcommittee on Health & Environment
March 9, 2000
Prepared Statement of Ms. Joan I. Samuelson
President

Panel 1, Witness 6

The Parkinson's Action Network was created in 1991 to give voice to a community that has been largely invisible, and to increase funding for Parkinson's research in an effort to speed research, deliver breakthroughs and cure this dreadful disease.

I want to express my profound concern about the potential impact of today's hearing on medical research. Research using fetal tissue has produced lifesaving results. Medical science has used fetal tissue for decades, producing such breakthroughs as the polio vaccine. I am concerned that today's hearing will have a chilling effect that will slow, if not stop, vital medical research.

I worry that the real impact of today's hearing will be to deter medical research using fetal tissue -- research that can increase our understanding, improve treatments and help identify cures for diseases such as Parkinson's, Alzheimer's, cancer, HIV, diabetes, SIDS, and other life threatening and disabling diseases.

Why should I care? I care because research -- and in particular, research that uses tissue from elective abortions -- is my best hope for the future. I have Parkinson's disease and, at 15 years post-diagnosis, time is running out for me. When I wake up in the morning, I must wait an hour or more for my medication to work. Until it does -- if it does -- I am unable to get out of bed, get dressed, or do any of the myriad things required to allow me to be an active, productive, and independent citizen. Some days it takes hours. Some day -- perhaps very soon -- it will not work at all.

I know I've already given up so much already -- my law practice, running, hiking, and dreams too difficult to talk about. I know what waits for me if medical science doesn't find a cure -- the same slow death that robbed your colleague Mo Udall of his life.

Let me be clear. If laws are being violated, then the full weight of the law should be brought to bear on those individuals or companies. But the history suggests that effective safeguards are in place and working.

In lifting the ban on fetal tissue transplantation research in 1993, Congress adopted stringent safeguards to separate a woman's decision to have an abortion from the decision to donate the resulting tissue for medical research. This was done to protect against any potential inducement of women to have abortions. The law also established safeguards governing the sale of fetal tissue, and the solicitation or acceptance of fetal tissue for use in transplantation.

The NIH Revitalization Act of 1993 (42 U.S.C. §§289g-1 and 289g-2) (hereafter known as "the Act") states clearly that it is:

"*unlawful* for a person to "knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

The Act also prohibits a person from soliciting or accepting a donation of fetal tissue for transplantation under certain circumstances -- specifically, it is prohibited if a person who solicits or acquires the tissue pays "valuable consideration" for the costs associated with the abortion.

Violation of the Act is a *federal* crime, punishable by fines, imprisonment up to 10 years, or both. The law does permit reimbursement for "*reasonable* payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

As a way to ensure oversight, the Act also required the General Accounting Office (GAO) to carry out a review of the research on fetal tissue transplantation conducted or supported by NIH to "(1) determine compliance with informed consent and other documentation and (2) report on any violations occurring in the acquisition of human fetal tissue for use in transplantation."

In 1997, the GAO reported to this Committee that "the requirements of the act were being complied with." The GAO found that the ongoing fetal tissue transplantation research projects met the eight requirements in the Act, including informed consent of the donor, requiring statements from the attending physician and from the principal researcher, informed consent of the recipient, availability of statements for audit, compliance with state law, annual HHS review, and tissue purchase and donation restrictions.

With regard to the sale of human tissue, the report concluded unequivocally that "there have been *no reported violations* in the acquisition of human fetal tissue for use in transplantation,"

But I worry that the discussion of unproven allegations that have not been properly investigated will imperil one of my best hopes for a cure.

In the case of Parkinson's, fetal tissue transplantation research is beginning to show positive results and scientists are confident an effective treatment using transplanted cells will emerge.

I strongly support the safeguards in the Act that prohibit payments associated with the receipt of fetal tissue from elective abortion except for reasonable expenses occasioned by the transportation, implantation, processing, preservation, quality control, or storage of the tissue.

If the laws governing fetal tissue research are being violated, the individuals or companies involved *should and must* be properly investigated and charged.

Cell implantation is one of the most promising approaches to brain repair for people like me who have Parkinson's disease. Early results from trials of tissue transplantation have shown this to be a therapeutic strategy with great promise. Two NIH-funded, placebo-controlled, surgical trials on fetal tissue transplants in patients with advanced Parkinson's are now underway. One of these studies has completed its double-blind phase, and results will be submitted for publication soon. The other should be completed in a year. More research in this area, not less, needs to be done.

Congress has already debated and decided -- overwhelmingly -- to allow the use of fetal tissue for transplantation and medical research. Each time it has done so with a greater and greater majority of members --voting to lift the ban on fetal tissue transplantation research and establish clear safeguards for the use of fetal tissue for research in 1991, 1992, and in 1993 when the Congress finally adopted the provisions. In 1997, the Senate successfully defeated another effort to reimpose a ban on fetal tissue transplantation.

I think it is important to remember what the debate was really about. It was not a debate to settle the issue of abortion. What Congress had to decide was whether it was acceptable public policy to use tissue obtained from legal abortion that would otherwise be discarded to achieve significant medical goals. That is exactly what the 102nd and the 103rd Congress decided. Members like Majority Leader Bob Dole put it most memorably: supporting fetal tissue transplantation research was the "true 'pro-life' position."

It is the responsibility of this Subcommittee to carry out the will of Congress which has repeatedly demonstrated its support for fetal tissue research. The legislative history is clear on this point. Congress supports the collection of fetal tissue under strict guidelines for medical research.

I am here today to plead with you to be cautious about the use of inflammatory rhetoric that may confuse or distort the issues involved.

The consequences could be devastating to the million of Americans who suffer with Parkinson's. Please do not deprive us of our hope for a healthy future.

This hearing document was last edited by the Committee on Commerce on 03/10/2000 11:21:43 AM EST



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March 8, 2001

# Parkinson's Research Is Set Back by Failure of Fetal Cell Implants

By GINA KOLATA

A carefully controlled study that tried to treat Parkinson's disease by implanting cells from aborted fetuses into patients' brains not only failed to show an overall benefit but also revealed a disastrous side effect, scientists report.

In about 15 percent of patients, the cells apparently grew too well, churning out so much of a chemical that controls movement that the patients writhed and jerked uncontrollably.

The researchers say that while some patients have similar effects from taking too high a dose of their Parkinson's drug, in this case the drugs did not cause the symptoms and there is no way to remove or deactivate the transplanted cells.

On the researchers' advice, six patients who enrolled in the study but who had not yet had the implantation operation have decided to forgo it.

The results, reported today in The New England Journal of Medicine, are a severe blow to what has been considered a highly promising avenue of research for treating Parkinson's disease, Alzheimer's disease

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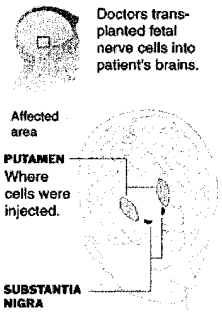
**Parkinson's Disease Study**

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and other neurological ailments. The study indicates that the simple solution of injecting fetal cells into a patient's brain may not be enough to treat complex diseases involving nerve cells and connections that are poorly understood. Some say it is time to go back to the laboratory and to animals before doing any more operations on humans.

The findings may also fuel the debate over whether it is appropriate to use tissue from aborted fetuses to treat diseases. Despite their disappointment, some researchers said they hoped that the results would not bring fetal cell research to an abrupt halt. The research has been controversial because the fetal cells were obtained from abortion clinics.

"This is still our one great hope for a cure," said Dr. J. William Langston, who is scientific director and chief executive officer at The Parkinson's Institute in Sunnyvale, Calif.

Parkinson's disease occurs when cells of the substantia nigra region in the base of the brain die, for unknown reasons. The hope was that fetal substantia nigra cells might take over for them. But, the study showed, in older patients the operation had no benefit and in some younger patients, the transplants brought on nightmarish side effects.

Although the paper depicts the patients with the side effects in impassive clinical terms, doctors who have seen them paint a very different picture.

Dr. Paul E. Greene, a neurologist at the Columbia University College of Physicians and Surgeons and a researcher in the study, said the uncontrollable movements some patients suffered were "absolutely devastating."

"They chew constantly, their fingers go up and down, their wrists flex and distend," Dr. Greene said. And the patients writhe and twist, jerk their heads, fling their arms about.

"It was tragic, catastrophic," he said. "It's a real nightmare. And we can't selectively turn it off."

One man was so badly affected that he could no longer eat and had to use a feeding tube, Dr. Greene said. In another, the condition came and went unpredictably throughout the day, and when it occurred, the man's speech was unintelligible.

For now, Dr. Greene said, his position is clear: 'No more fetal transplants. We are absolutely and adamantly convinced that this should be considered for research only. And whether it should be research in people is an open question."

Dr. Gerald D. Fischbach, who was director of the National Institute of Neurological Disorders and Stroke, which sponsored the study, said that while the operation had been promoted by some neurosurgeons as miraculous, this

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was the first time it was rigorously evaluated. It used sham surgery as a comparison, a controversial and rarely used strategy but one that researchers felt was necessary to understand the true effects of the operation.

Dr. Fischbach, who is now dean of the faculty of medicine at the Columbia University College of Physicians and Surgeons, was the director of the institute only at the end of the study.

"Ad hoc reports of spectacular results can always occur," Dr. Fischbach said. "But if you do these studies systematically, this is the result you get."

The surgery, he added, "is not the final solution that people would have hoped going into it."

In the study, researchers, led by Dr. Curt R. Freed of the University of Colorado Health Sciences Center in Denver and Dr. Stanley Fahn of the Columbia University College of Physicians and Surgeons, recruited 40 patients, ages 34 to 75, who had had Parkinson's disease for an average of 14 years. The patients were randomly assigned to have substantia nigra cells from four fetuses implanted in their brains or to have sham surgery, for comparison.

The surgery took place in Colorado and the patients were evaluated in New York. The fetal cell surgery involved drilling four small holes in the patient's forehead and then inserting long needles through the holes into the brain and injecting fetal cells. The sham surgery involved drilling the holes but not injecting needles into the brain. After a year, the patients were told whether they had the fetal cell surgery and, if not, they were offered it if they wanted it.

The study's primary measure of success was whether the patients themselves noticed that they were better, as determined by a survey that they mailed in a year later but before they knew whether they had had fetal cell implants or a sham operation. The study found no difference between the two groups — neither those who had had the fetal cell operation nor those who had had the sham surgery noticed an improvement in their symptoms.

Other tests, like neurologists' assessments of the patients while they were taking their medication and the patients' assessments of their condition in diaries they kept also showed no effect of the surgery. And there was no difference between the two groups in the doses of drugs needed to control the disease.

The one glimmer of hope came from assessments by neurologists before the patients had had their first dose of medication in the morning. By that measure, the 10 patients under age 60 who had had the fetal cell implants seemed better than those who had had sham surgery, with less rigidity, although their tremor was just as bad.

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**May** 1, 2001, Tuesday ,THIRD EDITION

**SECTION:** HEALTH SCIENCE; Pg. C1

**LENGTH:** 1314 words

**HEADLINE:** RESULTS OF NEW PARKINSON'S TREATMENT ARE UNCLEAR

**BYLINE:** By Richard Saltus, Globe Staff

**BODY:**
Lynda McKenzie could be a brave pioneer in medical science's quest to solve one of nature's cruelest diseases: Parkinson's, a degenerative brain condition that slowly robbed her of control over her body.

Or she may have been a victim of a rush by researchers to enroll desperate volunteers in a test of a controversial and little-understood treatment to implant nerve tissue from aborted fetuses into damaged areas of her brain.

That there's no easy answer is the unsatisfying bottom line for Parkinson's patients - about 1 million in the United States - who were pinning their hopes on the first scientifically sound trial of the novel Parkinson's treatment, the results of which were published last month and seemed to suggest dismal failure.

Or did they?

However one chooses to view McKenzie, there's no overlooking the holes drilled into her head on two different occasions - once in a "sham" placebo operation that gave her the holes but no implants, and once when she received the actual treatment.

Nor is there any doubt that she got no benefit from the exercise. The 48-year-old Toronto woman still has slowed movements, tremors, uncontrollable jerking and a shuffling walk.

"I feel like I'm back at square one," she said.

But she's not bitter. "Maybe [scientists] aren't barking up the wrong tree at all; maybe the answer's in the next forest over."

The Parkinson's study, conducted by researchers at the University of Colorado and published in the New England Journal of Medicine last month, concluded that the data showed a few glimmers of improvement in patients, but mostly a lack of effectiveness in subjects like McKenzie and 39 others who entered the trial.

But the report was met with decidedly different perspectives. A front-page story in The New York Times stated the experiments "failed to show an overall benefit but also revealed a disastrous side effect . . ." in "15 percent of patients" (six people). It said that six patients who had enrolled in the study but had not received the actual operation decided against it when showed the results.

A Los Angeles Times report on the same study under the headline, "Fetal cell implants improve Parkinson's patients," noted that the cells grew successfully in 85 percent of the patients (34 subjects) and that 14 patients who received the placebo treatment voluntarily subjected themselves to the operation after learning of the results.

(Globe wire services and other reports said the results showed little benefit, particularly for those over age 60).

So, should the research, already embroiled in ethical debates over the use of fetal cells in medical research, be continued or halted as a result of this first major test?

An editorial in the journal Nature Medicine published a week after the Parkinson's study said that, given how young the implant effort is, the small amount of benefit is "remarkable, and should encourage further research."

Some argued that such an ambiguous report shouldn't have been published at all, but bioethicist George Annas at Boston University said: "I think you had to publish the results because the trials got so much publicity."

To others - including three authors of an accompanying editorial in the journal - the dilemma reflects a "rush to randomized, controlled trials before" the experiment treatment is well understood. Still, many are praising the controlled trial - meaning there was a comparison group not treated - as having been shown vitally important as it demonstrated that some people believed they were improved by the fake surgery.

Some of the younger (age 60 or less) patients felt they could move a little more easily after the treatment, but so did some of the placebo, or control, group. Older patients saw no improvement. Studies did show that the implanted cells grew in the patient's brains and produced dopamine, the nerve messenger chemical that's deficient in Parkinson's patients.

But even these positive findings on some measures "didn't translate into meaningful improvement to patients," said Dr. Robert Hauser, a neurologist at the University of South Florida, a member of a team that's conducting a second federally funded trial of the implants.

To make matters worse, five patients developed dismaying, severe, uncontrollable movements two years after the implants. One neurologist called them "nightmarish." It's believed that the transplants were secreting too much dopamine into the brain, and there was no way to turn it down.

There were those who blamed the media. "The disappointing findings, aggravated by the negative tone of some of the news reports, will be upsetting to many in our constituency," warned the Parkinson's Disease Foundation in a message on its Web site.

As the dust settles, it seems likely that researchers will continue to test the implants, though more cautiously and after much thinking about what went wrong. Even though the results were not impressive, doctors have little else to offer patients who no longer respond to drugs.

"The honest truth is The New York Times piece was mostly right, [but] most of my colleagues are up in arms about it," said Dr. J. William Langston, president of the Parkinson's Institute in Sunnyvale, Calif.

But the Nature Medicine editorial saw it differently. "The press characterized the NIH-supported study as a major setback for Parkinson's research, but a more level-headed analysis shows that, in fact, this study offers much hope" for patients.

Langston and others say these results should send scientists back to the drawing board - or at least back to animal models until they better understand what's going on in the brain in people with Parkinson's.

"We had our hopes so much pinned on this. But when there's a horrible side effect, we've got to be honest about it," Langston said. "We shouldn't be working all this out in humans."

Over the past decade or so, scores of implants have been done in various countries with partial success, but the methods aren't standardized - how many cells to implant, exactly where to place them, where the holes are drilled, whether the health cells are fresh or have been kept in the laboratory for a while.

In the controversy following the latest report, Joan Samuelson, a Parkinson's patient who heads the Parkinson's Action Network, said: "This misleading fallout could confuse people about the potential" of future implant research. "If it does, it will create extra work for us on Capitol Hill to educate people and make sure it continues to be funded well."

Nobody believes that aborted human fetuses will be a routine source of tissue if the implants eventually succeed. Instead, it's hoped that embryonic cells grown in the laboratory can be coaxed to develop into brain cells. Another possible source is

within the patient's own brain - so-called "adult **stem cells**" that can become mature brain cells under the right conditions.

But getting from here to there is the current dilemma.

Some researchers noted specific methods used in the surgery, which varies from surgeon to surgeon, as possible explanations for poor results and that changing these parameters might work more effectively. That's the view of those who say the troubling results may contain the seeds of new paths to explore.

"I see this as one more signpost on the road to getting patients to improve on cell transplants," Hauser said.

Freed, the surgeon, had been upbeat about the trials prior to the new report. And, in its wake, he defended the work.

"It would have been naive to assume that all patients would have a uniform, excellent response to the transplant," said Freed in an e-mail interview. "That is, of course, our long-term goal."

There still is hope that a second federally funded study of implants for Parkinson's will show positive results, but data won't be reported for about a year.

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Biotechnology Newswatch

**March** 19, 2001

**SECTION:** Pg. 1

**LENGTH:** 619 words

**HEADLINE: Fetal** cell transplants flop in Parkinson's trial

**BYLINE:** By Mike Pezzella

**BODY:**
Hope that transplanted **fetal** brain cells would be a magic bullet to cure Parkinson's disease has faded after the first carefully controlled study of the procedure showed some patients developed horrible side effects.

In the 40-patient trial, conducted by teams from the University of Colorado and Columbia University, in New York City, 20 patients underwent a surgical procedure to implant the cells and 20 had a "sham" surgery in which holes were drilled in their skulls but no cells were transplanted.

Patients in the trial ranged in age from 34 to 75 and had suffered from the disease for an average of 14 years.

After a year patients under 60 who recieved the transplants showed significant improvement. But the benefits were seen only in the morning, before they received standard Parkinson's medication.

There was no real gain among the older patients.

A year after the initial surgery patients who underwent the sham or control procedure were also given the option of new surgery and implantation of **fetal** cells.

Trouble developed in the second year of the study when five patients who had recieved the **fetal** cells began to develop uncontrollable movements that caused

their heads to jerk about as arms were flung wildly in all directions.

In one patient, the effects were so severe that he could not eat and now uses a feeding tube.

One of the researchers, Dr. Paul E. Greene, of Columbia University College of Physicians and Surgeons, said the results were "absolutely devastating" to some of the patients.

While similar side effects can happen in Parkinson's patients on standard medication, the problem can be solved by regulating their doses. In the case of the **fetal** cells, they cannot be deactivated or removed.

**Fetal** cell implants have been used to treat Parkinson's since the late 1980s, but the Colorado-Columbia trial, led Dr. Curt R. Freed, of the University of Colorado, and reported in the New England Journal of Medicine, is the first real controlled study.

While the results produced a bumper crop of bad press Freed is not ready to give up the treatment. He cites the 10 patients under 60 who showed progress after the surgery.

"It was a clear-cut improvement," Freed said.

Freed also noted that the **fetal** cells survived in the brains of most patient, even though the apparently survived too well in some, producing too much of a chemical that controls movement.

Despite the disappointing results of the trial, Freed's group in Colorado is continuing to offer implants of **fetal** tissue. But they are using less tissue and implanting in different sites, hoping to avoid the side effects.

"To say you can't or shouldn't do human research because of an uncertain outcome, I think that would be a bad decision," Freed said.

Dr. Greene, Freed's counterpart at Columbia University, takes a different view.

"No more **fetal** transplants. We are absolutely and adamantly convinced that this should be considered for research only. And whether it should be research in people is an open question," Greene said.

Jerome Groopman, Professor of Medicine at Harvard, points out that this is not the first catastrophe caused by a new approach to a severe disease.

The first patients to get bone marrow transplants in the 1950s all died and a 1999 gene therapy experiment at the University of Pennsylvania killed a young man.

He said that while it may be difficult to "apply the brakes" to work on such a promising new treatment he feels workable cellular therapy for Parkinson's will not be attained without a going back to the laboratory.

He said that in retrospect the use of fragments of non-standardized **fetal** tissue seems naive.
URL: http://www.platts.com

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**March** 19, 2001, Monday, Late Edition - Final

**SECTION:** Section C; Page 2; Column 5; Business/Financial Desk

**LENGTH:** 568 words

**HEADLINE:** Companies Announce Setback In Treatment for Parkinson's

**BYLINE:** By ANDREW POLLACK

**BODY:**

An experimental therapy for Parkinson's disease suffered its second setback in a month when two companies announced on Friday that the treatment did not work in a clinical trial.

The companies, the Genzyme Corporation and Diacrin Inc., said that implanting **fetal** cells into the brains of patients had not improved their condition compared with a control group.

The announcement came a week after academic scientists reported in The New England Journal of Medicine that a similar effort had not only failed to improve the patients' conditions but had caused some of them to writhe and jerk uncontrollably.

"It's sort of a double blow for Parkinson's cell treatments," said Dr. Harry M. Tracy, a neuropsychologist who publishes NeuroInvestment, a newsletter about companies developing treatments for diseases that attack the nervous system. "I would not say this is dead by any means," Dr. Tracy added. "It means some of the assumptions they are operating on are open to question."

The hope is that **fetal** cells can take the place of brain cells that have died in patients with Parkinson's and other neurological diseases. Since Parkinson's was considered by many experts to be the easiest disease to treat with this approach, the recent failures could bode ill for use of the therapy on more complex neurological diseases.

While the academic study used cells taken from aborted fetuses, Diacrin and Genzyme, two Boston-area companies that worked together, used cells from pig fetuses. Pig cells are easier to obtain in large quantities and their use avoids the controversy attached to abortion. But pig tissue has its own drawbacks because some scientists worry that pig viruses can be transferred to people. Diacrin said it had not detected such viruses in any patient.

The clinical trial involved 18 patients, 10 of whom had the **fetal** pig cells put into their brains and 8 who had sham surgery. (They had holes drilled into the sides of their heads, but no cells were injected into their brains.) After 18 months, the two groups showed no difference on a standard rating scale used for Parkinson's disease. Dr. Thomas H. Fraser, chief executive of Diacrin, said that both the treated and the control group seemed to improve, indicating a strong placebo effect.

The treated patients did not suffer the uncontrolled movements found in the academic study -- in fact, they had fewer such problems than the control group. But the Diacrin and Genzyme patients did suffer some side effects, which the companies said seemed related to the drug used to suppress rejection of the implanted cells.

The companies said they would further analyze the data to decide whether to continue with more clinical trials. The one that just failed was a phase 2 trial, and three phases are usually needed for a drug to be approved.

Diacrin's shares plunged 39 percent Friday, falling $1.81 to close at $2.88. Shares of the Genzyme General division of Genzyme fell $3.69, or 4.2 percent, to $85.06.

Diacrin, based in Charlestown, Mass., has more to lose than Genzyme, since its business is based on cell therapy. It is also testing pig cells on patients with Huntington's disease, epilepsy and stroke, although the stroke clinical trial has been delayed because a couple of patients suffered seizures.

Genzyme, based in Cambridge, Mass., is a far bigger and more diversified company than Diacrin.

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Our position: There are no grounds for legal action to force taxpayers to pay for embryonic **stem cell** research.

Actor Christopher Reeve and seven scientists have filed a lawsuit charging the Bush administration with illegally withholding funds for **stem cell** research. They accuse the administration of doing "irreparable harm" by delaying the development of therapies they believe could save lives.

The suit is grounded in several questionable, even false, assumptions. The administration is not delaying science. Research continues in privately funded laboratories all over the country. Moreover, the suspension of funding concerns embryonic cells only. The administration is reviewing guidelines issued last August by the Clinton administration. Those permit funding for research that requires destroying human embryos for their **stem cells.**

Since 1996, Congress has prohibited federal funding of such research. Yet the Clinton guidelines say that although there is no funding for destroying embryos, destruction can be arranged by, or in some cases performed by, federally funded researchers. That was classic Clinton doublespeak.

Despite the dispute, embryonic **stem cells** are no longer the sole source for research. Experiments have found adult **stem cells,** placenta cells, umbilical cord blood and even human fat cells have the same therapeutic potential. The possibilities were cited recently by Dr. David Prentice, professor of life sciences at Indiana State University and an adjunct professor of medical and molecular genetics at the Indiana University School of Medicine.

In an interview with National Review Online, Prentice said, "In the last two years, we've gone from thinking that we had very few **stem cells** in our bodies to recognizing that many, perhaps most, organs maintain a reservoir of these cells." More, using one's own adult cells avoids transplant rejection. Embryonic cells will require drugs be taken indefinitely to avoid rejection.

Reeve, who was paralyzed in a horse-riding accident, is understandably eager for more research. But to date, stemcell experimentation has produced no unqualified success and haste has resulted in several disasters. That is a sad fact for which the Bush administration is not to blame.

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# Concrete case against embryonic research

**Dennis Byrne**
*July 16, 2001*

The second most disheartening feature of the stem cell debate is the dogmatic assertion that human embryonic stem cells are vastly superior to adult stem cells as a prospective cure for incurable diseases.

This, according to repeated media reports, is what "scientists say." It now is gospel truth that stem cells, taken from human embryos only a few days old, are hands down more promising than stem cells obtained from adults.

This is bunk, a shameful example of media laziness, ignorance, bias or deception. The phrase "scientists say" suggests a universality of opinion that doesn't exist. Such a suggestion isn't surprising because ideological, political or self-serving motives require public acceptance of the myth that adult stem cells won't do the job as well as embryonic stem cells.

In fact, many scientific reports suggest otherwise. In a little publicized letter on July 3 to Ruth Kirschstein, acting director of the National Institutes of Health, Do No Harm, a group of physicians, researchers and scholars, cited study after peer-reviewed study providing evidence that "the immense potential of stem cell research [does not require] the destruction of human embryos. . . .

"[R]esearch using human stem cells not derived from human embryos has confirmed what prior evidence had long suggested: that adult stem cells [and other `post-natal' stem cells] have vast biomedical potential to cure disease such as diabetes, Parkinson's disease, heart disease and other such degenerative diseases. This biomedical potential is as great or greater than the potential offered by human embryonic stem cell research.

"Simply stated, adult stem cell research is a preferable alternative for progress in regenerative medicine and cell-based therapies for disease because it does not pose the medical, legal and ethical problems associated with destructive human embryonic stem cell research."

Among the founding members of Do No Harm are Kevin

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Among the founding members of Do No Harm are Kevin Fitzgerald, research associate in hematology and oncology, and Dr Joseph Zanga, chairman of the department of pediatrics, both of Loyola University Medical Center; Dr. C. Christopher Hook, hematology/medical oncology, The Mayo Clinic and chair of the clinic's ethics council; David A. Prentice, a professor of life sciences, Indiana State University; and Dr. Frank E. Young, former commissioner of the U.S. Food and Drug Administration.

The group challenged NIH guidelines that find certain "shortcomings" in adult stem cells. Rather, the group said, recent scientific evidence indicates that adult stem cells can be "pluripotent" and transform into one cell type from another; that human adult stem cells are now being used successfully in clinical trials to combat many diseases that embryonic stem cells show only the potential to treat; that animal research strongly points to more therapeutic applications for adult stem cells and that human embryonic stem cells pose unique health risks, including a tendency to tumor formation and immune rejection. And contrary to the NIH claim that adult stem cells are present only in minute quantities, are difficult to isolate and purify and that they decrease with age, the Do No Harm letter cited a study in the May 4 journal Cell showing that only one transplanted adult stem cell may be able to regenerate tissue in several parts of the body.

Geron Corp., a biotech firm, found that human embryonic stem cells injected into rat brains remained in a disorganized cluster and brain cells near the cluster began to die.

An article in the journal Nature said the ethical debate over embryonic stem cells has "perhaps done science a favor" by encouraging research into other stem cell sources, instead of "putting all of its ococytes in one basket."

Such studies and citations on Do No Harm's Web page (www.stemcellresearch.org) will keep you busy reading. You may challenge the conclusions and evidence or individual members' religious beliefs, but the documents should end the media deception that the preference for embryonic stem cells is settled science.

The most disheartening aspect of the stem cell debate is the insistence that since human embryos are going to be thrown out anyway, they should be put to "good use." Thus the moral reservations about creating surplus embryos and the need for embryo adoption.

But most disturbing is the idea that if a human life isn't useful, it should be used for a purpose beyond what its essential dignity should allow. How sad that so many Americans don't see the similarities to the "logic" of the Holocaust.

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Chattanooganow
Electronic supplement to the
Chattanooga Times Free Press
Thursday, July 19, 2001

# Stem cells, yes -- but . . .

Heated, emotional, moral debate is raging: Should there be federal funding of medical research using embryonic stem cells with the hope of finding possible cures for diseases such as Parkinson's, Alzheimer's, strokes, diabetes, and other serious ills?

The possibilities are so great that there should be a clear understanding -- and a sound moral decision -- about what is at stake.

Stem cells are those that have not yet developed to the point of performing specialized functions in human bodies. The hope is that medical science may "guide" stem cells to develop the particular characteristics needed to alleviate or cure a disease.

That such a miraculous possibility exists should inspire unanimous approval for accelerating stem cell research with great anticipation -- but with one imperative caution: There should be no sacrifice of human life!

There are three general sources of needed stem cells: from discarded umbilical cords, doing no harm; from adults, doing no harm; or from human embryos -- causing the purposeful killing of human life.

A civilized society should not approve taking any innocent human life. We would not allow the killing of an adult human to take an organ for life-saving transplantation into another person. Neither should we approve killing an embryonic human to alleviate the disease of someone else.

"Embryonic stem cells" sounds quite impersonal, quite clinical. But what those words mean is that a human egg has been fertilized and human life has begun!

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Who has the right to kill that life?

It is disappointing that Sen. Bill Frist, R-Tenn., whom we highly respect personally, medically and politically, supports federal funding even for destructive embryonic stem cell experimentation. When he has transplanted hearts, they have come from donors whose lives have ended, not living individuals.

We are appalled by reports that Communist China is taking human organs from criminals for transplantation. Will we adopt a similar practice with innocent human embryos?

A company in Virginia has been reported to have created human embryos for the purpose of killing them to get stem cells, without federal funding. Such an atrocity should not be permitted, with or without federal funding.

Stem cell research? Yes -- but with stem cells derived by means that do no harm.

The American people should adopt the moral resolution to prohibit the taking of any embryonic human life.

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The Union Leader & NEW HAMPSHIRE SUNDAY NEWS

Web Edition The Online Edition of New Hampshire's Daily Newspapers Monday, Jul. 23, 2001

Editorials - July 18, 2001

## *A new kind of adoption: And hiding opportunities from infertile couples*

MANY COUPLES who desire children go down the arduous road of adoption: waiting for one of the tiny number of unwanted babies who won't be terminated by abortions, hoping birth mothers won't change their minds after delivery, conceding they will never experience the joys of labor and childbirth themselves.

But there is a new technology that can help infertile couples to adopt a baby as quickly as a few days after the child's conception. The unwanted baby, called a "blastocyst," is moved from a petri dish in a fertility clinic into the womb of the adoptive mother. What a beautiful, life-giving technology. Too bad the national media doesn't want infertile women to hear about it.

On Monday, two women and their husbands who had struggled with infertility but bore children by this technology testified on Capitol Hill. Lucinda and John Borden of California were joined by their 9-month-old twins Mark and Luke. Marlene and John Strege, also of California, brought their 2-year-old daughter Hannah to Washington for the event.

These couples praised the technology that bore them children, and asked the nation to make more "blastocysts" – frozen babies in petri dishes – available for adoption. There are 188,000 of these babies in the United States, most of them left over from fertility treatments sought by their biological parents. The groundbreaking story received scant attention from the Washington Post on Tuesday, which buried it in the fourth paragraph of a story on page A4 titled "Legislators see opening on stem cell studies." Huh?

Giving short shrift to the human stories of the Streges and Bordens, the news story focused on the possibility blastocysts can be used to cure diseases one day – if they are killed for research. The day of the hearing, the Washington Post devoted a front page, above-the-fold story to an interview with Elizabeth Jordan Carr, the nation's first "test tube" baby who favors killing blastocysts (which she once was) for this long-term scientific research.

Could the Washington Post and other mainstream media outlets have an agenda? Is it possible that they would prefer that couples desperate to have children not hear about this new opportunity to give birth? Do they prefer to gamble the lives of these frozen babies in fertility orphanages on research for diseases, treating them as concentration camp prisoners harvested for their organs?

Of course we want the sick to be cured and that's why we support extensive research on adult human stem cells and the embryonic stem cells found in human placentas. But when presented with the choice between killing a human being for research or letting a good couple adopt it, the choice is clear to us.

Because of media organizations such as the Washington Post, the public isn't getting enough information to make an informed choice.

*— Bernadette Malone Connolly*

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# Trust the government?

Merrill Matthews Jr.
Published 7/16/01

A number of prominent, pro-life conservatives, including Utah Sen. Orrin Hatch and former Florida Sen. Connie Mack, have recently voiced their support for federal funding of human stem cell research.

Many scientists believe that stem cells taken from human embryos, which are fertilized eggs only a few days old, have tremendous potential for treating a number of medical conditions, including Alzheimer's, Parkinson's and spinal cord injuries.

Currently, there are perhaps 100,000 such embryos that have been frozen and reside in in-vitro fertilization centers, left over from attempts to implant fertilized eggs in women wanting to become pregnant. These embryos are seen as a veritable gold mine of medical research, if only the federal government were allowed to underwrite the research.

Funding proponents make three basic arguments. First, it is very unlikely the tiny clumps of human cells that already exist will ever become people, so why not allow the federal government to fund research on the cells?

Second, many people with debilitating medical conditions would benefit from federal funding because scientists will find cures faster than they would without federal funding.

Finally, since federal funding would bring with it federal guidelines for research practices, we as a society can ensure that stem cell researchers will act ethically.

Opponents of federal funding believe that the embryos are human life and that it is wrong to experiment on or destroy them. It is important to note that the debate isn't over whether there will be stem cell research. Many private pharmaceutical and biotech companies and universities are already involved in such research.

Let me say that again, since this fact is often lost in the debate. Many private companies and organizations already fund both animal and human stem cell research. And the federal government currently funds animal stem cell research. The issue is only whether the federal government should dedicate tax dollars toward research on human embryonic stem cells.

Funding proponents' first argument is their strongest one. Even if everyone agreed that using the existing embryos were wrong, leaving them frozen in perpetuity doesn't seem like a much better option. Ethically speaking, sometimes our choices aren't between right and wrong, but between wrong and less wrong.

The second argument is much more tenuous. Indeed, any first-year philosophy student (or economics student, for that matter) should be able to tell you that more funding doesn't necessarily equal better research.

The fact that many conservatives have adopted this argument is particularly odd. Would they also say, for example, that more federal funding for public education leads to better educated children? More simply doesn't mean better, whether in research, education or anything else.

That some conservatives have adopted the third argument -- that federal funding will guarantee ethical research -- is nothing short of bizarre.

Since when did conservatives come to the conclusion that the federal government should serve as the Grand Ethicist, ensuring that researchers don't do immoral things?

Most conservatives criticize federal funding for public education because it means bureaucrats can

impose their values on our schools and our children values conservatives often disagree with.

Conservatives also generally oppose strengthening federal regulatory agencies that are constantly imposing new rules and restrictions on employers.

And many conservatives oppose new medical privacy regulations created during the Clinton administration out of fear that bureaucrats will have access to and misuse people's medical information.

So why do some conservatives now believe that government oversight can ensure that scientists act ethically?

Maybe we all need to be reminded of the Tuskegee Syphilis Experiment. From 1932 to 1972 scientists working for the Public Health Service studied the long-term effect of syphilis in 400 poor black males. The scientists could have treated the men for the disease but didn't. They deemed the research more important than the lives of poor blacks.

By the time a journalist broke the story in 1972, bringing the 40-year experiment to an end, 128 of the infected men had died of syphilis or related medical conditions. Forty of their wives had been infected, and several children were born with congenital syphilis. While the federal government eventually provided the men or their families with a cash settlement, no one at the Public Health Service admitted wrongdoing (though in 1997 President Clinton offered a formal apology).

Today, Tuskegee stands as perhaps the darkest moment in American medical research history. This atrocity led to the formation of federally mandated Institutional Review Boards (IRBs) that review all human and animal experimentation. (I have served as an ethicist on a medical school's IRB for nearly 10 years.)

Would government funding of human embryonic stem cell research be another Tuskegee Experiment in the making? Probably not, but a government that saw no shame in putting black Americans at risk for the advancement of scientific knowledge should move cautiously.

Before conservatives assume that the government will guarantee high ethical research standards, they ought to ask themselves why they fight government intrusion in almost every other area of life.

*Merrill Matthews Jr. is a visiting scholar with the Institute for Policy Innovation and policy director of the American Conservative Union Foundation.*

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OPINION

## Scientists Can Do Without Embryos

By David A. Prentice. David A. Prentice is a professor of life sciences at Indiana State University, an adjunct professor of medical and molecular genetics at the Indiana University School of Medicine and a founding member of Do No Harm: The Coal

THE "STEM cell debate" currently raging in Washington crosses lines of science, ethics and politics. Supporters of embryonic stem cell research say this is the most scientifically promising way to cure many diseases.

But the work they speak of requires destruction of living human embryos. An ethical alternative, adult stem cell research, has as great or greater potential for therapeutic applications.

In September, 1999, the National Bioethics Advisory Commission, in its review of stem cell research, called it a "mistaken notion" to think that there can be any meaningful separation between destroying a human embryo and research that relies on its destruction. The federal advisory panel, comprised of scientists, physicians, ethicists and theologians, reviews ethical questions at the request of the president and make recommendations regarding national policy.

The members, now holdovers from the Clinton administration, went on to say this: "In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research ... The claim that there are alternatives to using stem cells derived from embryos is not, at the present time, supported scientifically." The panel then added, "We recognize, however, that this is a matter that must be revisited continually as the demonstration of science advances." Since 1999, there has been an explosion of research using adult stem cells, umbilical cord blood stem cells and other non-embryonic stem cells. The scientific literature now clearly establishes that adult stem cells can and do provide this alternative. Adult stem cells have been found in many cell and tissue types, including that found in the brain, muscles, the liver, retina, pancreas, bone marrow and peripheral blood, the cornea, blood vessels, umbilical cord blood, placenta and, even, fat.

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Even more important is the fact that adult stem cells can regenerate healthy tissue. Many can transform from one cell type into another.

For example, plentiful adult stem cells from fat have been transformed into cartilage, muscle and bone. Readily accessible human adult bone marrow and blood stem cells have been transformed into muscle, heart tissue, brain, nerves, liver, bone, cartilage, lungs, digestive tracts, and skin.

Interestingly, even those who work with embryonic stem cells have grudgingly admitted that adult stem cells are much more capable at forming other functional tissues than previously imagined. One such researcher noted that: "Bone marrow stem cells probably can form any cell type." The scientific information backs up this statement.

In fact, adult stem cells are already being used successfully to treat a number of diseases in human beings, including cancer, muscular dystrophy, lupus, rheumatoid arthritis, cartilage defects and immune deficiencies in children. They have also been used to grow new corneas to restore sight to blind patients. They are now starting to be used to repair heart damage after a heart attack.

In research using animals, which precedes possible uses in human beings, adult stem cells have had many successes, including reversing diabetes in mice and repairing damage from heart attack, stroke, Parkinson's disease and muscular dystrophy.

Despite the often-extravagant claims made about them, embryonic stem cells have no such track record of success. They have never helped a single human patient. There are no reports of embryonic stem cells ever being even introduced into a human being. So, they obviously couldn't yet have helped any patients. They also have a poor record in animal research.

Even those who work with embryonic stem cells note that they are difficult to grow, hard to control and have a potential to form tumors. As one scientist said at a June 22 stem cell research workshop sponsored by the National Academy of Sciences: "There is no evidence of therapeutic benefit from embryonic stem cells." In addition, researchers who work with embryonic stem cells freely admit that the cells will face a significant risk of transplant rejection. And, a recent scientific report also indicated that embryonic stem cell gene expression is "extremely unstable." Obviously a key point in the debate revolves around the moral status of the human embryo. Many scientists say that embryos are the best source of stem cells for treating disease and that to deny this research denies hope for cures, balancing the lives of tiny embryos against those already born. But most also admit the embryo is a human being. (It's certainly not another species such as rat or monkey.) Is the human embryo a person or a piece of property? Everyone

admits that it is alive, but is it a life? If one takes the position (as many do) that it deserves respect as a form of human life, then destroying living human embryos for research violates the basic tenet of the healing arts: "First do no harm." Given the recent advances using adult stem cells, more researchers now say that embryonic stem cells may not be needed after all for medical progress. The use of adult stem cells for medical treatments looks much more promising at this point, and it avoids crossing any ethical divide.

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# Stemming the News Flow?

Do the political implications that attach to medical breakthroughs affect their reception by the media? Any biomedical research risks having it findings become symbols in the cultural and political landscape. Once that happens, especially if the results are made captive of the "culture wars," the reporting of the research becomes problematic. On the thorny issue of stem-cell research (the effort to develop potent cells with medical applications such as treatments for diabetes or Alzheimer's), some see advances where others see concerns.

Stem cells are "master cells" that, with chemical prompting, can develop into nearly any organ in the body. The current problem for stem cell research is the source of the cells. Some successes have involved embryonic cells, while other breakthroughs have come from a variety of adult sources that do not involve the embryo. In the context of the abortion controversy, advances with cells from embryos entail different policy responses than do those from other human tissue -- a perspective that was brought to bear explicitly this last month.

The latest news involving embryonic stem cells broke April 27. The *Washington Post* reported the developments under the headline, "New Potential for Stem Cells Suggested," and noted that the research "is likely to intensify an already heated debate over the ethics of human embryo cell research." The *Wall Street Journal* agreed, with their story "Advances in Stem Cells, Cloning Renew Controversy." For *The New York Times*, the story ("Scientists Report 2 Major Advances in Stem-Cell Work; Debate Likely to Heat Up") was important enough to appear on the front page, above the fold, where it was juxtaposed against another story announcing, "House Approves Bill Criminalizing Violence to Fetus." (*The Times* front-page positioning was found only in its

Washington edition, presumably because of its policy relevance. The New York edition of the paper ran the stem-cell story on page A-21.)

The research, one in a series of dramatic breakthroughs in the past year, became part of the overall embryo research debate at a time when the Bush administration is reconsidering the current ban on federal funding. Developments have been featured in commentaries beyond the science pages. For example, Anna Quindlen's April 9 Newsweek column was entitled "Stem-Cell Research May Cure Diabetes. It May Teach Us How to Think About Abortion, Too." The *Washington Post*'s Richard Cohen May 3 Op-ed on "Political Science" criticized the politics of stem cell research and accused the political right of Lysenkoism (for the notorious Soviet minister who politicized biological science) in its selective use of science findings.

Cohen objected to anti-abortion forces on Capitol Hill passing around the results of what he termed "one (questionable) study published in one (obscure) journal" showing that cells taken from human fat showed stem-cell potential. The reasoning was that if alternate sources were available, the ethical dilemmas of embryo research could be avoided. For Cohen, the touting of this research was driven by an ideological motive, since "the scientific community wasn't impressed." It's not clear why he judged the research "questionable," but the reception to the peer-reviewed article published in *Tissue Engineering* suggests that at least some in the scientific community were impressed. The research was also featured in a front-page story by the *Post*'s Rick Weiss without any such reservations ("Human Fat May Provide Useful Cells,"Apr. 10). To his credit, Weiss has been accurately (and non-ideologically) covering all developments in this area, as witnessed by an earlier (Mar. 31) article about marrow cell experiments and their potential for cardiac rejuvenation, similarly demonstrating the potential of non-embryo research.

Other researchers wondered about the media response more generally, but not to the "fat cell" report in particular. Rather, questions were raised about one component of the "breakthrough" research posted on April 27 which involved diabetes. The research (undoubtedly important and published in *Science*) utilized mouse embryonic cells to secrete insulin. But

those opposed to embryo research note that considerably superior success in insulin secretion was reported in research published over a year ago in *Nature Medicine* -- using, however, adult cells. That article was met with media silence. Why should a replicating study with less favorable outcomes garner more attention?

More troubling is the media treatment accorded two dramatic breakthroughs appearing in prestigious science journals scant days after the April 27 headlines and commentaries. The first appeared in the journal *Cell*, announced May 3. It offered the strongest evidence to date that the adult body harbors stem cells that are as flexible as embryonic stem cells. *Reuters* was impressed, running a headline, "Adult Stem Cells With Astounding Potential Found." Moreover, Reuters noted that "their achievement... could overcome the ethical obstacles of using stem cells derived from embryos."

The second finding (also May 3) was likewise remarkable (if somewhat creepy). As *Reuters* (again) put it, "Scientists Isolate, Grow Brain Cells from Corpses." Researchers at the Salk Institute reported in *Nature* that, astonishingly, they were able to take brain cells available for medical application from a range of cadavers up to 72 years old that were still viable up to 20 hours after death. As *USA Today* noted, the cadaver brains "may offer a reasonable alternative to embryos and fetuses as sources of cells."

Unfortunately, *USA Today*'s coverage was accompanied by only four other U.S. papers (including the conservative *Washington Times*, which has editorialized heavily against embryo research), along with *National Public Radio*. Neither the *Washington Post*, *The New York Times* nor the *Wall Street Journal* carried the cadaver story. Nor did the foremost policy-relevant papers mention the "astounding" research from *Cell*, though the *Associated Press* and a handful of regional papers did carry the findings, along with several European papers.

The eagerness to publicize embryo-related breakthroughs is understandable, but as the political stakes were elevated, the subsequent silence on non-embryo developments was striking. Medical advances will continue whether the media attend to them or not. But policy decisions (and public

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comprehension) are not served by selective attention (whether by the political right or left) to research on grounds other than strictly scientific merit.

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Reuters Medical News for the Professional

# Islet Cell Transplantation Showing 'Long-term' Results

WESTPORT (Reuters Health) Apr 03 - A total of 15 patients with unstable diabetes have undergone islet cell transplantation at the University of Alberta in Edmonton in the past few years. All became insulin-independent after the procedure and 12 have remained so — some for more than 2 years.

Dr. James Shapiro reported the results of his team's experience at this year's Experimental Biology 2001 meeting in Orlando this week.

Dr. Shapiro said that islet cell transplantation initially resulted in all patients becoming insulin-independent. Transplantation resulted in stable blood glucose levels and the first seven patients who received transplants "all remain insulin-free," Dr. Shapiro said.

"We've learned a couple of important lessons" from this series of transplant patients, Dr. Shapiro told Reuters Health in an interview during the meeting. First, the transplant team found that the immunosuppressant tacrolimus, which they use post-transplantation, has an adverse effect on kidney function in the few patients with poor kidney function at the time of transplantation. Second, immunosuppression has caused stomatitis and hyperlipidemia that has been correctable with drug therapy.

"Islet cell transplantation is not for every patient," Dr. Shapiro said. "It is for those patients with brittle disease who have wide swings in blood glucose levels." However, in that subpopulation, the procedure has proven to correct blood glucose levels and maintain them at stable levels over the long-term, he said. He added that there is little risk in the procedure. If it does not work, the patient simply resumes insulin therapy.

Dr. Shapiro noted that advances are being made in other areas of transplantation, where immunosuppression can be stopped after a finite period of time. He hopes the same can be true with islet cell transplantation.

Multicenter trials of islet cell transplantation are set to start soon.

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EXPAND STORY **DJ Fat Cells May Help Fight Insulin Resistance In Diabetics**

DJI via Dow Jones

WASHINGTON (AP)--Scientists may have found a hormone that helps fight diabetic insulin resistance in one of the least likely places - fat cells.

The hormone - called adiponectin or Acrp30 - helped diabetic mice overcome insulin resistance in tests conducted by researchers in New York and Japan.

Two independent groups both report their findings in papers in the August issue of the journal Nature Medicine.

Researchers led by Philipp E. Scherer at Albert Einstein College of Medicine in New York found the protein reduced insulin resistance over several hours after being given to diabetic mice.

And Takashi Kadowaki's team at the University of Tokyo got similar results in longer-term studies lasting several weeks.

While both researchers recorded reductions in blood sugar levels after administering adiponectin, they differed in their assessment of how the hormone works. Both stressed that their findings are preliminary and said they have no immediate plans for human testing.

Nonetheless, the findings could point the way to further research in combatting insulin resistance.

The papers show that, contrary to long-term belief, fat is more than just a storehouse for energy to be used later by the body. It also produces needed chemicals such as adiponectin.

"The main take-home messages from both papers is that fat tissue can release factors that influence insulin sensitivity in other tissues. Activation of this protein or its receptor may offer a way to improve insulin sensitivity in insulin resistant patients and may offer a complementary therapeutic approach to existing treatments," Scherer said.

Mice with little or no body fat lack adiponectin, they found, and it is reduced in obese mice, making them less able to use insulin.

"Levels are usually inversely correlated with fat mass - i.e. the more fat, the less adiponectin, which is surprising for a protein that exclusively originates in fat," Scherer explained.

Obesity has long been associated with diabetes.

Scherer's team concluded that adiponectin works on the liver, causing it to secrete less sugar into the bloodstream.

But the Japanese team believes the primary effect of adiponectin to be in skeletal muscle, where it causes fat to be burned for energy. This decrease in fat led to a reduction in fatty acids circulating in the blood and the liver, and that led to the drop in blood sugar, they concluded.

Kadowaki noted that the two experiments were conducted over different periods of time and said that since

they differed he couldn't comment on the findings of the New York team.

Scherer said he felt the "two papers are nicely complementary in their approaches and their focus. The findings in both papers are consistent and suggest that this protein may target both liver and muscle."

Alan R. Saltiel of the University of Michigan School of Medicine, who wasn't connected with either team, said the researchers had discovered an "exciting new property" for adiponectin.

In a commentary on their work in the journal, Saltiel said that while the findings are highly preliminary "it is hard to resist the speculation that adiponectin or synthetic analogs might be useful in the treatment of type 2 diabetes and perhaps other states characterized by insulin resistance."

"Either way, an agent that burns fat is certain to be a big hit," he added.

Indeed, a French pharmaceutical company, Genset, has said it found that adiponectin caused obese mice to lose weight and plans to conduct further trials on the hormone as a weight-loss drug.

Neither Scherer nor Kadowaki is connected to Genset.

(END) Dow Jones Newswires 30-07-01

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EXPAND STORY

## Adult stem cells can change to kidney cells-study

Release at 7:01 p.m. EDT

By Patricia Reaney

LONDON (Reuters) - Stem cells from bone marrow can change into kidney cells and may provide a new method to treat kidney disease that could reduce the need for transplants, British scientists said Wednesday.

Stem cells are master cells in the body that can transform into most other cell types. Researchers at Britain's Imperial Cancer Research Fund (ICRF) showed that kidney cells can be derived from stem cells in bone marrow.

``Until now people weren't entirely sure how the kidney took care of its normal wear and tear. People assumed that it was all done within the kidney. What we've shown is that cells from outside the kidney are able to contribute to the repair process," molecular biologist Dr. Richard Poulsom said in a telephone interview.

The finding opens up the possibility of mobilizing a patient's own bone marrow stem cells to repair or replace kidney cells destroyed through disease or injury.

It could also pave the way for using bone marrow stem cells containing genes resistant to cancer or other diseases to protect the kidney from further damage.

``In people whose kidneys are failing, we might be able to generate more functional kidney cells. That is something that has not been known before," Poulsom added.

POLITICAL AND ETHICAL MINEFIELD

Scientists believe stem cells could revolutionize medicine and provide new therapies for diseases like Alzheimer's and diabetes and severe injuries.

But stem-cell research is a political and ethical minefield because the richest source of the multipurpose cells is early stage human embryos. Religious and anti-abortion groups oppose using embryonic stem cells for research because harvesting them destroys the embryo.

Stem cells are also found in adult tissue but they are scarcer, more difficult to extract and grow than embryonic stem cells and make a limited range of specialized cell types.

Supporters and opponents of stem-cell research are embroiled in a heated debate in the United States where President Bush is expected to decide on whether federal funding should be used for embryonic stem-cell research.

Britain has already legalized the cloning of human cells to provide stem cells for research.

Poulsom and his colleagues studied adult bone marrow stem cells in mice and humans. Their research is published in the Journal of Pathology Online (www.interscience.wiley.com/jpages/0022-3417/).

The scientists found kidney cells derived from donated male bone marrow in female mice whose own bone

marrow had been destroyed by radiation.

In the human studies, biopsies from male kidney transplant patients who had received a kidney donated by a woman showed male kidney cells among the female cells. The man's bone marrow cells had transformed into kidney tissue.

``They are cells that could have only have come from the man, migrated around and set up shop and differentiated into functional kidney cells," said Poulsom.

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KEYWORDS: HEALTH-STEMCELL-KIDNEY (EMBARGOED)

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Reuters Medical News — for the Professional

# Patient's Stem Cells Used to Repair Myocardium Following MI

HAMBURG, Germany (Reuters Health) Jul 23 - A German man who received stem cells for repair of myocardium after a myocardial infarction is doing well two weeks after the ground-breaking procedure, physicians said Monday.

Hematopoietic cells and mesenchymal stem cells from the man's bone marrow were microinjected directly into the tissue of his heart during coronary artery bypass grafting, Professors Gustav Steinhoff and Mathias Freund, of the Clinic of Cardiac Surgery in Rostock, North-East Germany, told Reuters Health.

No complications were detected after the procedure, and the patient has now left the clinic to begin the process of rehabilitation, the doctors said.

The German group stresses that this is only the first step in a long-term study. "In the first analysis, we have no adverse effects," Steinhoff told Reuters Health. "We did not see rhythm disorders and the inflammation was the same as after a bypass operation." But he added: "We have to wait with this patient for several months and with further patients, just to make a realistic assessment of the possible and associated risks."

The physicians plan to perform the same operation on 20 more patients in the coming months.

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**April** 30, 2001 Monday ALL EDITIONS

**SECTION:** HEALTH AND SCIENCE; Pg. 02G

**LENGTH:** 479 words

**HEADLINE: Stem cell** use may help treat heart attacks

**BYLINE:** NICHOLAS WADE New York Times

**BODY:**
The basis of a possible revolution in treating heart attack patients has been laid by three reports of using **stem cells** from bone marrow to repair heart tissue in animals.

In one of the studies, apparently functional heart tissue was regenerated from the injected cells, the first such success in some two decades of effort. In another, the **stem cells** morphed into new blood vessels that rescued the heart cells around the damaged area from their usual course of overgrowth and death. In the third, **stem cells** were used to strengthen pig hearts.

The three groups of researchers, based at Columbia University, New York Medical College in Valhalla, N.Y., the National Institutes of Health and Osiris Therapeutics of Baltimore, said they were a year or more away from testing their animal techniques in people. Still, heart disease experts believe the **stem cell** work is highly promising.

"The health care industry would be revolutionized if the treatment of heart failure could be moved from organ transplants down to cell transplants," said Mark Sussman, a heart researcher at the Children's Hospital and Research Foundation in Cincinnati. The new research opened "some very exciting doors," he said, but required considerable further work to make sure it was as promising as it seemed.

Eugene Braunwald of Harvard, who is author of a leading textbook of cardiology, said the idea of putting **stem cells** into the heart to grow new heart muscle cells was

"a very interesting approach."

If their animal techniques work the same way in people, the researchers say, people suffering a heart attack would be treated by having cells extracted from their bone marrow. The cells would be sorted and amplified, then injected either directly into the heart, or maybe just into the bloodstream, from which they would home in on damaged heart tissue and on the enlarged heart muscle cells that soon grow around it.

It may even prove possible, though this concept has not yet been tested, to do no more than inject a heart attack patient with a cytokine, a natural protein that stimulates the bone marrow's **stem cells** to proliferate. The cells would home in on damaged heart tissue, and repair it. Biologists say it is too early to know whether the blood-forming **stem cells** of the bone marrow are also the heart's own **stem cells,** for which researchers have been looking in vain for years, or if their remarkable ability to repair the heart is just a general property of **stem cells.**

The new results all depend on the recent finding that the **stem cells** of the bone marrow are far more versatile than supposed and can generate other tissues besides the red and white blood cells, their best known function. It seems that the cells are a kind of universal clay, so responsive to local cues that if placed in the heart they will develop into heart tissue instead of blood cells.

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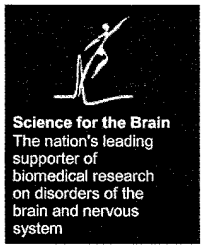


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# Turning Blood into Brain: New Studies Suggest Bone Marrow Stem Cells Can Develop into Neurons in Living Animals

For release: Thursday, November 30, 2000

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**Overview** For years, researchers studying stem cells have been intrigued by the possibility that these cells might be used to treat brain diseases. Recent studies have suggested that neural stem cells transplanted into the brain can migrate throughout the brain and develop into other types of cells. Now, two new studies show that bone marrow cells transplanted into mice can migrate into the brain and develop into cells that appear to be neurons. The studies suggest that bone marrow may be a readily available source of neural cells with potential for treating such neurological disorders as Parkinson's disease and traumatic brain injury.

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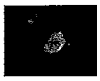

For years, researchers studying stem cells have been intrigued by the possibility that these cells might be used to treat brain diseases. Recent studies have suggested that neural stem cells transplanted into the brain can migrate throughout the brain and develop into other types of cells. Now, two new studies show that bone marrow cells transplanted into mice can migrate into the brain and develop into cells that appear to be neurons. The studies suggest that bone marrow may be a readily available source of neural cells with potential for treating such neurological disorders as Parkinson's disease and traumatic brain injury.

While previous research has shown that bone marrow cells can develop into neuron-like cells in culture, the new studies are the first to show that this process can also happen in living animals. The two studies reached the same conclusion despite many differences in how the studies were performed. The results are reported in the December 1, 2000, issue of *Science*.

"These are extraordinarily important studies, carefully done, with clear implications for brain disorders and for basic developmental biology," says Gerald D. Fischbach, M.D., director of the National Institute of Neurological Disorders and Stroke (NINDS).

In the first study,[1] NINDS investigator Eva Mezey, M.D., Ph.D., and colleagues injected bone marrow cells from normal male mice into newborn female mice that had no white blood cells of their own. Using marrow from male mice allowed the researchers to use the Y chromosomes in the transplanted cells as a marker to distinguish them from native cells. At different time intervals, the researchers examined cells from the brains of seven mice that had received the transplants and compared them to littermates that had not received the transplants. By 4 months after the transplants, they found a significant number of neuronal cells in several brain regions, including the cortex, the hypothalamus, and the striatum, that were descendants of the transplanted cells. This suggests that stem cells from elsewhere in the body can enter the brain and differentiate into neuronal cells, says Dr. Mezey.

In the second study,[2] Helen Blau, Ph.D., and colleagues from Stanford University injected bone marrow from adult mice that express a marker called green fluorescent protein (GFP) into adult mice that had been irradiated to eliminate their bone marrow. They found that bone marrow-derived cells migrated into several regions of the brain, including the olfactory bulb, the cortex, the hippocampus, and the cerebellum. Some of the marrow-derived neuronal cells also grew long fibers and produced a protein that indicates cell activity. These results suggest that the marrow-derived neurons not only entered the brain but also responded to their environment and began to function like the native ones.

These studies suggest that bone marrow, which is an easily available source of cells, could be used as a source of neurons to replace those damaged or lost in neurological disorders, the researchers say. It might also be possible to genetically engineer the cells in ways that would help them survive or work in beneficial ways. The fact that even bone marrow from adult mice generated neuronal cells shows an unexpected amount of flexibility in older cells and suggests that patients with brain disorders could be treated with their own cells, says Dr. Blau. Bone marrow cells taken from a patient's own body would not be rejected by the body's immune system.

While the results are very promising, researchers need to answer many remaining questions before marrow-derived neural cell therapies can be tested in humans. A key question is what growth factors and other signals prompt the bone marrow cells to develop into specific types of neurons. If researchers can describe how the normal process of cell differentiation works, they may be able to reproduce it in patients with disorders such as brain injury or Parkinson's disease where neurons are not normally replaced. Researchers might also be able to discover factors that help cells enter the brain or connect with other cells. "We need much more data, but I think it's a pretty encouraging start," says Dr. Mezey.

Since the studies used whole bone marrow, it is important to determine which population of bone marrow cells develop into neurons, the researchers say. Other questions for future studies include whether marrow-derived neurons function like normal neurons and if they can make appropriate connections with other cells. The findings in Science should speed the pace of research to answer these and other important questions, the researchers say. However, they believe it will be several more years before the results reported in these studies will lead to effective therapies.

The NINDS, part of the National Institutes of Health in Bethesda, Maryland, is the nation's leading supporter of research on the brain and nervous system. The NINDS is now celebrating its 50th anniversary.

[1]Mezey, E., Chandross K.J., et. al. "Turning Blood into Brain: Cells Bearing Neuronal Antigens Generated in Vivo from Bone Marrow." *Science*, Vol. 290, December 1, 2000, pp. pp. 1779-1782.

[2]Brazelton, T.R., Rossi, F.M.V., et.al. "From Marrow to Brain: Expression of Neuronal Phenotypes in Adult Mice from Adult Bone Marrow-Derived Cells." *Science*, Vol. 290, December 1, 2000, pp. 1775-1779.

**Image description:** Photograph of a neuronal cell derived from bone marrow. The green spot indicates the Y chromosome which distinguishes this cell from innate cells. Science/Dr. Eva Mezey, NINDS.

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**April** 16, 2001

**SECTION:** MEDICINE; Pg. 61

**LENGTH:** 485 words

**HEADLINE:** Belly-Button Brothers;
**Stem cells** from umbilical cords saved their lives

**BYLINE:** Frederic Golden, Reported by Dan Cray/Los Angeles

**BODY:**
When their 11-month-old son Layne died abruptly of liver failure after an infection with Epstein-Barr virus in 1994, Theresa and Scott LaRue were devastated. Layne, it turned out, had a rare inherited disorder that severely compromised his immune system. And when doctors at the UCLA Medical Center tested the three other LaRue children, two were found to be similarly afflicted.

As the disease's tongue-twisting name implies, instead of simply dispatching an invading virus--like the one that killed Layne--X-linked lymphoproliferative syndrome (XLP) allows white blood cells (including lymphocytes) to grow unchecked, destroying vital organs like the liver, lymph glands and spleen. Inherited by males on their X chromosomes, it usually means death by age 10.

The LaRues could have opted for bone-marrow transplants. But these are painful, require precise genetic matches that can take months to find and often fail. "The doctors basically told us [transplants] would either kill them or save them," says Theresa. So they chose an experimental alternative: transfusing the youngsters with a type of **stem cell** harvested from a newborn's umbilical cord and placenta. Unlike their more controversial cousins, embryonic **stem cells,** which are harvested from aborted fetuses and can develop into almost any cell, cord blood cells are used to rebuild blood and immune systems--exactly what the LaRue boys needed. In effect, says UCLA's Dr. E. Richard Stiehm, "we transplant another baby's immune system into the sick child's body."

There were risks, however. The new cells take longer to establish, exposing the child to infection. Also, as Stiehm explains, if the transplant doesn't work, "you don't have a second chance," because you're unlikely to find matching cord blood.

In early 1995 the LaRues let the UCLA doctors proceed with their son Blayke, then eight months old. "It was a horrible decision," Theresa says, and for a while they regretted it. Blayke languished in the hospital for two years. First, his new immune system began attacking his spleen. Surgery solved that problem, but he was still so sick he had to be fed intravenously for many more months.

In February 1997 it was four-year-old brother Garrett's turn. His ordeal was mercifully briefer. After four months, including 10 days of chemo, Garrett was out of the hospital--with a temporarily bald pate but a spanking-new immune system. Heartened, the UCLA doctors did a cord transplant on a third boy, Billy Bodine, 11, to correct a similarly inherited immune deficiency called X-linked hyper-immunoglobin M syndrome.

Last week, after two years of post-transplant observation, the UCLA doctors felt confident enough to pronounce all three boys cured. "They're as healthy as anyone," says Stiehm, who sees them as proof that cord blood can save many more young lives.

--By Frederic Golden. Reported by Dan Cray/Los Angeles

**GRAPHIC:** COLOR PHOTO: JAN SONNENMAIR--AURORA FOR TIME, THRIVING: Blayke and Garrett with new immune systems

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**April** 12, 2001, Thursday, Late Edition - Final

**SECTION:** Section A; Page 25; Column 1; National Desk

**LENGTH:** 772 words

**HEADLINE:** A New Source For **Stem Cells** Is Reported

**BYLINE:** By NICHOLAS WADE

**BODY:**
A New Jersey company said yesterday that it had developed a method to extract a novel kind of **stem cell** from the placenta and that the cells were the equivalent of human embryonic **stem cells,** which can transform into every tissue of the adult body.

"This will make obsolete the need to use human fetuses or blastocysts as sources of **stem cells,**" John Haines, chief executive of the Anthrogenesis Corporation of Cedar Knolls, N.J., said.

The assertion comes as opponents of abortion encourage the Bush administration to bar federal financing for research on embryonic cells, which are now derived either from very early human embryos, known as blastocysts, or from fetal tissue. These critics seem unlikely to object to research on cells from placentas.

But the articles describing the research have not yet been accepted for publication, an important step in the validation of scientific claims.

Biologists believe embryonic cells hold great promise for restoring damaged tissues, particularly in otherwise intractable diseases like Alzheimer's and Parkinson's.

Embryonic **stem cells** differ from adult **stem cells,** which are found in the various adult body tissues they help maintain. This week, a different group of researchers said it had isolated adult **stem cells** from fat tissue. But adult **stem cells,** which also

offer a promising way of repairing damaged tissues, differ in many ways from embryonic **stem cells.** Biologists are eager to explore both.

The Anthrogenesis scientists believe that they have found a possible new source of embryonic **stem cells,** though they cannot yet prove that their cells are embryonic in nature. The two known sources of embryonic cells are the blastocyst, a hollow sphere of cells produced a few days after an egg is fertilized, and fetal tissues that hold the future germ cells of the ovary and testis.

Within the blastocyst is a clump of cells known as the inner-cell mass, from which all the tissues of the fetus are generated. Some of these cells migrate to the ovary and testis and can be recovered from fetal tissue. Known as embryonic germ cells, they closely resemble the embryonic **stem cells** that can be derived from the inner-cell mass.

The Anthrogenesis scientists believe that some inner-cell mass cells also migrate to the placenta and are held there as a reserve in case the fetus needs them. If so, this would be a third source of embryonic-like cells.

Other experts said that this was a novel and interesting idea but that they knew of no evidence to support it, and Dr. Joseph Cioffi, the company's director of research and development, agreed there was no animal data bearing on the issue.

The company calls its cells placental multipotent **stem cells** -- multipotent, a characteristic of embryonic **stem cells,** because they can be induced to form several different kinds of mature cells, in this case those of cartilage, nerves and the lining of the blood vessels.

The company, though, has not yet examined its cells for a characteristic protein found in embryonic cells that is known as the oct4 marker. Nor has it shown that every type of mature cell can be derived from a single starting cell, a rigorous test of a **stem cell's** properties.

Anthrogenesis derives its cells by removing blood from the placenta and keeping a certain part of the placenta alive, though the company declined to give its anatomical name. The placental multipotent **stem cells** can be harvested in large numbers from this preparation, company officers said.

Dr. John Gearhart of Johns Hopkins University, who was the first to derive human embryonic germ cells, said that it was impossible to remove all blood from the placenta and that the company had yet to prove that its cells were different from blood-making **stem cells,** a kind of adult **stem cell.**

A company official said such proof lay in the fact that the cells did not produce a marker called CD34, but Dr. Gearhart called this definition outmoded and said that young blood-forming **stem cells** were now known to lack this marker.

If further tests should prove that the placental cells are a satisfactory substitute for embryonic **stem cells,** the company's finding could influence the political debate.

The National Conference of Catholic Bishops has opposed government financing of research on both human embryonic **stem cells,** taken from blastocysts, and embryonic germ cells, derived from fetuses aborted for the health of the pregnant woman.

Yesterday, Richard Doerflinger, a policy official at the bishops' conference, said he saw no ethical problem in using cells derived from the placenta of live births.

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# Umbilical Cord Stem Cells May Repair Brain Injury, University of South Florida Researchers Find

**TAMPA, Fla., Feb. 20 /PRNewswire/** -- Stem cells derived from human umbilical cord blood may help restore brain function after disease or injury, according to new studies from the University of South Florida (USF) in Tampa and Henry Ford Hospital in Detroit. Research was conducted by Paul R. Sanberg, Ph.D., D.Sc., Director of the USF Center for Aging and Brain Repair.

Results of several studies were presented Feb. 18 in San Francisco at a meeting of the American Association for the Advancement of Science.

For the first time, the researchers have shown that human umbilical cord stem cells, obtained after birth, can be reprogrammed to act as brain cells (neurons and glia). Until now, umbilical cord stem cells have been used to fight blood diseases, such as leukemia, in children.

"What we know from this is that umbilical cord blood contains stem cells able to differentiate into neural cells," Dr. Sanberg said. Stem cells are multipotent cells -- able to grow into other kinds of cells.

"This finding suggests that umbilical cord blood is a noncontroversial, readily available source of stem cells for brain repair and could provide an alternative to using embryonic cells.

"We already know that stem cells derived from embryonic tissue may be effective in rebuilding the damaged brain in diseases like Parkinson's and stroke," Dr. Sanberg said.

In a related study, the team went on to inject human umbilical cord cells in rats with stroke and had surprising results that suggest that these stem cells can restore function after stroke.

"In the rats, the effects were fairly rapid, and new cord-derived cells could be seen clearly on the stroke side of the brain," Dr. Sanberg said.

The studies are funded through Florida's I-4 Corridor initiative. The state awarded its grant based on the USF group's collaboration and funding from CCEL Bio-Therapies, Inc., a subsidiary of CRYO-CELL International, Inc., of Clearwater, Fla., which provided the cord blood to the research team.

USF researchers are involved in several clinical trials using cell implants into the brain to treat Huntington's disease, Parkinson's disease, and the damage caused by stroke.

*SOURCE Paul R. Sanberg, Ph.D., D.Sc.*

# Open Letter to President of the United States

The Honorable George W. Bush
President of the United States
White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

Even prior to your inauguration you became aware and involved in the ongoing controversy regarding the use of certain stem cells for research. The passion of both opponents and proponents of embryonic or fetal stem cells for research has been aired and written about in media for years.

There are those who believe stem cell research is necessary to find cures for diseases which currently can cause the death of millions of citizens. Conversely, there are equally compassionate voices who believe no one should negate a single life (or millions) to save lives. It is doubtful that a solution could easily be found that would satisfy everyone.

However, Mr. President, we believe there is an effective and non-controversial way to help fund stem cell research, which could provide significant **life-saving** potential for patients in need of transplantation.

At present, there are approximately 4,000,000 babies born annually in the United States. Ninety-nine percent of all the stem cell rich umbilical cords are thrown away as hospital "bio-waste material". We believe this is a medical tragedy since the stem cells in discarded cord blood have the potential for saving a life.

The only reason any parent would allow their newborn's cord blood to be discarded rather than help save a life, is they are unaware of the medical importance of the stem cells in each cord. There is no question when we heighten the awareness of both expectant parents and their medical caregivers they will not opt to see any umbilical cords discarded.

We have already accomplished this in more than 25,000 instances. We have shown expectant parents and their medical caregivers the alternatives available for the use of newborns' umbilical cord blood. They can:

a. Cryopreserve cord blood stem cells exclusively for their family's use.
b. Donate them to a public (allogeneic) bank who try to find matches between donors and unrelated patients in need of a transplant.
c. Donate them to researchers who desperately need them to find cures for currently untreatable diseases.

Regardless of which of the above alternatives are selected **there should not be a single voice in opposition!**

The stem cells in every one of these umbilical cords come from babies brought to full term

who have been nurtured by their mother during the entire gestation period. No person who believes in protecting life could object to providing newborn babies and possibly other members of their family a longer, healthier and therefore, happier life! Moreover, this will be accomplished without negating a single life!

Every private cell banking firm will see increased clientele once expectant parents are made aware of the fact that the cryopreserved cells are a perfect match for their newborn baby for their entire lifetime. Moreover, this is a one in four or better chance to match a sibling if needed for a transplant. This information must be made known, especially since 59% of all pregnant women already have one or more children. Medical experts, as well as the New England Journal of Medicine, know sibling transplants can have an excellent chance for engraftment which is needed for success. Moreover, there would also be less graft vs. host disease complications and post transplant rejection. Since the family would own the cryopreserved stem cells they could be available immediately if needed in the future. In the case of our company and some other private cell banks, there is no cost for retrieval, where finding a match from some public banks could cost up to $15,000.

Despite this, the public banks would also see a tremendous increase in donations since informed parents (who opt not to store for their family) would rather see their newborn's cord blood save a life than being "thrown away".

The scientific community could receive an abundance of publicly donated stem cells from parents who are interested in finding cures for diseases that might well have ended the life of someone in their family. What wonderful memorial tributes there would be if a newborn baby's cord blood stem cells helped cure a disease that took the life of a loved one.

We believe that every single opposition group or individual would enthusiastically join in this new national medical "save all stem cells" program.

The only "loser" will be the hospital trash bins since millions of discarded umbilical cords will now become the source for needed life-saving stem cells.

Mr. President, if you were to use your voice and the prestige of your office with its ability to attract the nation's media it could help find a solution to this problem and provide future medical benefits for many. Simultaneously, it could significantly increase the number of donated stem cells available for research. This in turn could help reduce millions of dollars of the government's expenditures for necessary research.

If this information were made available to your Secretary of Health and Human Services, The Surgeon General, and the Congress, we believe it could have a profound positive medical impact for millions of families.

Respectfully,

CRYO-CELL International, Inc.

Daniel D. Richard

Founder and Chief Executive Office

Wanda D. Dearth
President, Chief Operating Officer

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*FOR IMMEDIATE RELEASE*

# CRYO-CELL Subsidiary's Collaboration with University of South Florida in Research Program for the Treatment of Neurodegenerative Diseases with Umbilical Cord Blood Detailed at AAAS Annual Meeting

**February 20, 2001** – Daniel D. Richard, CEO of both companies, announced today that CCEL Bio-Therapies, Inc., a subsidiary of CRYO-CELL International, Inc. (NASDAQ CCEL), was named at the American Association for the Advancement of Science Annual Meeting for its collaboration with University of South Florida research program for treating stroke and other brain injuries with umbilical cord blood stem cells.

Paul R. Sanberg, Ph.D., D.Sc., Director of the University's Center for Aging and Brain Repair in Tampa, presented the research team's results. The team consisted of Dr. Sanberg, Juan Sanchez-Ramos, M.D., Ph.D., Alison E. Willing, Ph.D., and Michael Chopp, Ph.D., who have been developing important alternatives to human embryonic cell transplantation in neurodegenerative diseases. Their findings indicate cord blood stem cells may be effective in treating brain injuries or diseases including stroke, Alzheimer's, and Parkinson's, among others.

Embryonic cells have proven effective because they have the potential to become any kind of cell in the body; however, their use is very controversial, according to Dr. Sanberg. "We now have a non-controversial cell which is usually discarded at birth that provides an alternative which should circumvent any objections to its use."

## Results of the initial research by the USF Team

In experiments so far, the researchers removed the stem cells from the cords and used retinoic acid and growth hormones to transfer them into immature nerve cells. They injected millions of these cells into the bloodstream of rats that had suffered stroke. The team found that the rats given the cells had recovered about twice as much from their stroke after one month compared to the untreated rats. Dr. Sanberg stated, "The treatment works best when given within 24 hours of the stroke, but still helps up to a week later." He noted that of the 4 million babies born each year in the U.S., 99% of the cords are thrown away. He believes that one or two cords could probably be enough to treat one human stroke victim.

## CRYO-CELL Participation in the USF Research Program

According to Mr. Richard, "The Company provided all of the umbilical cord blood used by the research team. These cord blood specimens were donated by families whose newborn babies were brought to full term, and would have otherwise been discarded. This should eliminate any controversy as to the source of the cells."

Along with the state of Florida, CCEL Bio-Therapies provided the funds for initial research

and the filing of the joint patent application. As a part of the agreement, CCEL Bio-Therapies will continue to fund the applications until the granting of any of the joint patents. In exchange, CRYO-CELL, or its assign, was granted a license for the world marketing rights to any pharmaceutical or therapy developed by the University of South Florida, which includes the use of umbilical cord blood in the treatment of any neurological disease or injuries. The research team has applied for additional grants from several national agencies.

CRYO-CELL is America's fastest growing and largest exclusive autologous private umbilical cord blood stem cell preservation firm. The Company pioneered affordable cord blood stem cell storage. Its initial fees are 1/4 to 1/5 the cost of many of its major competitors, and its $50 annual fee is fixed for specimens already in storage. This is why approximately 11,000 OB/GYNs and medical caregivers support their patients' decisions to preserve their newborns' U-Cord™ Stem Cells at CRYO-CELL's state-of-the-art lab in Clearwater, Florida.

CRYO-CELL is a publicly traded company (NASDAQ symbol...C C E L).

For additional media coverage of the AAAS meeting involving Dr. Sanberg, CRYO-CELL, or its subsidiary, CCEL Bio-Therapies, visit the following sites:

| | |
|---|---|
| Paul R. Sanberg, Ph.D., D.Sc. | Umbilical Cord Stem Cells May Repair Brain Injury, University of South Florida Researchers Find |
| MSNBC.com | Novel 'seeds' sprout new brain tissue |
| InteliHealth.com | Umbilical Cords Could Repair Brains |
| St. Petersburg Times | Cells from umbilical cords may repair brain damage |
| Houston Chronicle | Umbilical cord cells may be Rx for strokes |
| The Guardian | Stem cells may repair brain injuries damage |
| LA Times | Umbilical Cords Could Repair Brains |

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The San Diego Union-Tribune

**June** 6, 2001, Wednesday

**SECTION:** LIFESTYLE;Pg. F-4

**LENGTH:** 582 words

**HEADLINE:** Cord blood bank ships not just **stem cells** but also hope

**BYLINE:** Wendy Y. Lawton; NEWHOUSE NEWS SERVICE

**BODY:**
PORTLAND, Ore. -- Seattle tycoon Paul Allen plunked down $4 million in December 1999 to start a bank that stores blood from babies' umbilical cords -- delivery room castoffs that are rich in **stem cells.** The blood would be given to people battling disease.

Now, for the first time since Microsoft co-founder Allen's hefty deposit, cord blood is being sent to those in need.

In the most recent shipment, blood from Oregon was sent to help a 6-year-old girl in Michigan who is fighting leukemia.

A tiny bag of frozen blood was plucked from a vapor-spewing vat at the American Red Cross office in Portland. The packet was popped into a tub chilled to minus 250 degrees -- 100 degrees colder than the lowest temperature recorded on Earth -- to be shipped to the Midwest by plane.

The identities of the girl and the donors are confidential. But those two tablespoons of cells, drawn from a cord and placenta at a Portland area hospital after an August delivery, will give hope to a child with an aggressive disease and few options.

"We can't say for certain that we're saving a life," said Linda Goertz, executive assistant for the cord blood bank, which is run by the Red Cross in Portland. "But we're giving her a chance."

The cells will be slipped directly into one of the girl's veins in a 30-minute

procedure that normally is painless. If all goes well, the **stem cells** will travel to her bone marrow and start reproducing like mad, churning out new blood cells that carry oxygen, fight disease and aid in clotting.

For people with blood and immune systems hobbled by chemotherapy, this is a fresh start. And for some, it's a good alternative to a surgical bone marrow transplant.

Such transfers have been a long time coming. Although the storage operation -- dubbed the Western Area Community Cord Blood Bank -- has 1,160 units of cord blood from donors in Oregon, Montana, California and Ohio, only three shipments have been sent.

One bag collected in Columbus, Ohio, went to Minnesota for a patient with Hodgkin's disease. Another bag from Columbus went to Massachusetts, where the **stem cells** will be used in an experimental therapy aimed at attacking a bladder tumor. The Oregon shipment makes three.

Dr. Thomas Lane, a San Diego-based physician who serves as the medical director for the bank, said the small output reflects the struggles of any start-up.

The bank needed blood. The blood needed testing. Then a computer database to hold all donation information had to be built. The bank's inventory didn't get added to the Red Cross transplant list until April.

But Lane and others in the red-hot **stem cell** research and therapy field predict the bank will be very busy, very soon.

The number of cord blood transplants has risen sharply since 1995, bringing the U.S. tally to about 1,500 since the first procedure was done in 1988. According to the California-based Cord Blood Registry, 30 banks around the nation hold about 90,000 samples.

New ways to deliver cord blood to people with blood disorders will fuel the demand, advocates said. But new applications for **stem cells** could also speed up the pace, according to Dr. Rita Reik, chief medical officer for the Red Cross in Portland. Research shows that **stem cells** produce not only new blood cells but also heart, bone and muscle cells -- which could treat damaged tissue or even cure diseases.

"We don't have all the answers," Reik said. "But these cells are the new frontier of medicine."

**LOAD-DATE:** June 8, 2001

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EXPAND STORY

## Umbilical cord blood can rebuild adults' supply

Release at 5 p.m. EDT (2100 GMT)

By Gene Emery

BOSTON June 13 (Reuters) - Blood from a newborn's umbilical cord, once discarded as medical waste, can rebuild the blood supply of adults with leukemia and other fatal blood diseases, according to a study in Thursday's New England Journal of Medicine.

The technique, which works even if the donor and recipient are not a perfect match, appears to be safer than getting a bone marrow transplant from an unrelated donor.

Doctors have experimented with using umbilical cord blood cells for transplants because the cells are capable of rebuilding, albeit slowly, the body's blood supply. In addition, the cells are so immature, doctors hoped they would be accepted by the new host with less chance of rejection.

Among children, that hope has been borne out. Studies have already shown that the treatment is effective for youngsters with various life-threatening illnesses.

Until now, researchers have not been sure if the treatment would work in adults, whose immune systems tend to be less tolerant of mismatched tissue.

But a research team led by Dr. Mary Laughlin of Case Western Reserve University in Cleveland gave umbilical cord blood to 68 patients ages 17 to 58, all with life-threatening blood diseases.

To prepare for the transplant, doctors destroyed the defective bone marrow, where blood cells are produced, with radiation or drugs.

The key success of the work was that the donated tissue began producing blood cells in 90 percent of the recipients.

Umbilical cord blood from an unrelated donor ``is a feasible alternative source" of cells for replacing diseased bone marrow, the researchers said.

Forty months after their transplants, 19 patients were alive; 18 had no trace of their original disease. Seventeen deaths were attributed to the treatment used to destroy the defective marrow and 22 died from infection. Four had a relapse and three developed a different type of cancer.

One of the biggest risks of the procedure is that the new blood cells will launch an attack on the body, a condition known as graft versus host disease or GVHD.

Severe GVHD appeared in only 20 percent of the patients, while the normal rate is 35 to 55 percent among people who receive a bone marrow transplant from an unrelated adult donor. GVHD killed 3 volunteers in this study.

But among the rest of the patients, ``the durability of these grafts of umbilical-cord blood is clear," Laughlin and her team concluded. ``To date, there have been no late graft failures in the surviving patients."

Unlike the controversy surrounding the use of stem cells from aborted tissue, most people agree umbilical

cord blood is a waste product that would otherwise be thrown away.

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The Boston Globe

**June** 14, 2001, Thursday ,THIRD EDITION

**SECTION:** NATIONAL/FOREIGN; Pg. A3

**LENGTH:** 603 words

**HEADLINE:** CORD CELLS ARE FOUND TO FIGHT LEUKEMIA STUDY SEES INJECTIONS AS AN ALTERNATIVE TO MARROW-DONOR HUNT

**BYLINE:** By Kimberly Atkins, Globe Correspondent

**BODY:**
**Stem cells** from the umbilical cords of newborn babies show great promise in treating adults with leukemia and other life-threatening blood diseases, according to a study reported in today's New England Journal of Medicine.

Currently the best hope for leukemia sufferers is a bone-marrow transplant, which requires so close a match between donor and recipient that an estimated 4,000 to 6,000 people die each year before they find suitable marrow.

Umbilical **stem cells,** the new study shows, can be used for any patient - not just those who are an exact bone-marrow match.

The cells, which are retrieved from blood that would normally be discarded after an infant's birth, can be transplanted into cancer patients through an IV and are no more likely than bone marrow to be rejected by the recipient.

Doctors had previously used umbilical cord **stem cells** to treat only children.

"People in the field thought that there were not enough [**stem cells**] in cord blood to proliferate in adults," said Dr. Mary J. Laughlin, lead author of the study.

But the researchers found that just two ounces of blood can generate a new immune system in adult patients who have undergone chemotherapy or radiation treatment.

**Stem cells** are immature cells capable of developing into any kind of blood cell, including red blood cells, platelets, or the white blood cells that are produced by healthy bone marrow and fight infection.

In the umbilical **stem-cell** procedure, blood is retrieved from the umbilical cord attached to the placenta of a child after birth. The cord is generally considered medical waste, and that allows doctors to sidestep the issue of embryonic **stem-cell** use that has become a controversy at the federal level.

"This is even approved by the pope," Laughlin said.

Cancer patients undergo chemotherapy or radiation treatment that kills the white blood cells in the marrow, destroying the immune system. Until now, the only way to rebuild the system was with a bone-marrow transplant, or graft. But most patients have trouble finding a donor match, said Laughlin.

"The problem really is a lack of grafts for everyone who needs them," she said.

Usually, leukemia patients seek bone-marrow transplants from a sibling, but there is only a 25 percent chance that a sibling will be an exact match. The next option is to seek a match from a nonrelated donor, but Laughlin said that even with the efforts of the National Marrow Donor Program, a nonprofit group that helps match patients with donors, only 50 percent of white patients with blood disorders are able to find a match. For patients of color, the chance of finding a match is even lower - about 15 percent, she said.

Although the new study does not suggest that **stem cell** transplantation will replace bone-marrow transplants as the preferred treatment for blood disorders, it offers hope for patients who cannot find marrow donor matches, said Dr. Robert Soiffer, codirector of the Adult Hematopoietic **Stem Cell** Transplant Program at the Dana-Farber Cancer Institute.

"This gives a third option to patients that would otherwise die," Soiffer said.

He did, however, sound a note of caution. The rate for graft-versus-host disease - a complication in which patients have difficulty accepting the transplanted cells - is fairly low, comparable to that of patients who received bone-marrow transplants from matching donors. But it takes **stem cells** longer than transplanted bone-marrow cells to produce platelets, putting the recipients at greater risk of bleeding and infection, Soiffer said. "This is by no means a home run," he said.

**LOAD-DATE:** June 14, 2001

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**May** 3, 2001, Thursday

**SECTION:** NEWS; Pg. 7

**LENGTH:** 511 words

**HEADLINE:** BRAIN CELLS OF CORPSES ARE GROWN IN TEST TUBE

**BYLINE:** Steve Connor Science Editor

**BODY:**

TRANSPLANT OPERATIONS using the brain tissue of dead people could become reality after pioneering work has shown it is possible to grow nerve cells extracted from human corpses.

A team of medical researchers has taken a variety of living cells from the brains of dead people in an attempt to discover a new source of valuable **stem cells,** the "master" cells that can develop into the many specialised tissues of the body.

Using post-mortem samples from 23 children and adults, the scientists found they could grow at least three types of brain cell in a test tube for possible transplant operations on people with degenerative neurological conditions such as Parkinson's disease.

Past attempts at extracting brain cells from the dead and growing them in a laboratory have failed. This time, however, the scientists used specific growth factors known to sustain and stimulate isolated cells growing in a test tube.

The work, published in the journal Nature, was done by a team led by Fred Gage, of the Salk Institute in La Jolla, California. "I find it remarkable that we all have pockets of cells in our brains that can grow and differentiate throughout our lives and even after death," Professor Gage said.

The researchers took brain tissue from 23 dead people ranging in age from 11 weeks to 72 years old. They found that the younger the donor, the easier it was to grow a large number of viable cells in the laboratory.

The time after death when the cells were extracted varied from two hours to 20 hours. Three types of brain cell could be grown by the technique: neurons, which transmit messages in the form of electrical signals, astrocytes, which nourish and protect neurons, and oligodendrocytes, which insulate the nerve cells by wrapping them in a fatty sheath of myelin, a process disrupted in patients with multiple sclerosis.

So far the study had failed to discover whether these fully matured brain cells were merely transferred into the test tube, where they continued to live, or whether they developed from less specialised **stem cells** extracted from the dead patient, Professor Gage said.

"This study employed a pool of cells from extracted tissue. We haven't yet isolated individual cells from the pool and followed them to see if a single cell can give rise to multiple classes of brain cells," he said. "Such a cell would be a neural **stem cell** by a strict definition."

So far the work had concentrated on extracting brain tissue from people with neurological diseases but it might be more instructive to use post-mortem samples from individuals who were otherwise healthy, the scientists said.

"Cells recovered from healthy individuals could provide a model for understanding how to stimulate and guide the normal processes of brain cell growth and differentiation," Professor Gage said.

This could provide insights into how to stimulate cell growth in people with Parkinson's and Alzheimer's disease, where the degeneration of healthy brain cells might be reversed by transplants of healthy tissue.

**LOAD-DATE:** May 3, 2001

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CONGRESSMAN DICK ARMEY
26TH DISTRICT, TEXAS

MAJORITY LEADER

H-329 THE CAPITOL
WASHINGTON, DC 20515
(202) 225-4000

Congress of the United States
House of Representatives
Washington, DC 20515–6502

June 19, 2001

Honorable George W. Bush
President of the United States
The White House
Washington, DC 20500

Dear Mr. President:

I write to urge you to continue to enforce the law as intended by Congress and take all measures within your power to prohibit federal funding of human embryonic stem cell research. Such research is not only illegal, it is immoral and unnecessary.

Recent press reports have cast doubt on the future of the current policy. In 1996, Congress outlawed federal funding for harmful embryo experimentation and has maintained that ban ever since. The prohibition is broad-based and specific: funds cannot be used for "research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death." The current policy has been threatened ever since the National Institute of Health (NIH) published proposed guidelines to circumvent our prohibition.

Taxpayer funding of this kind of research is objectionable because it is tantamount to allowing our government to exploit and destroy human life for its own or somebody else's purposes. Federal tax dollars would be used by the government to "own" a vast supply of living human embryos. The idea of the government "owning" human beings is disturbing.

Human embryo stem cell research has been proven to be unnecessary. There are other alternatives, such as adult stem cells, which are more promising than the destructive embryo research. Clearly, stem cell research promises great good and can be a worthy scientific priority as long as we pursue it ethically. Good ends do not justify unethical means.

I urge you and your Administration to honor and uphold the current law. Please revoke the NIH guidelines that encourage killing human embryos for their stem cells. I

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would recommend increased funding for adult stem cell research or other morally acceptable alternatives.

Sincerely,

Dick

DICK ARMEY
Majority Leader

# Pope warns Bush of ``evils" of stem-cell research

By Philip Pullella

CASTELGANDOLFO, Italy, July 23 (Reuters) - Pope John Paul on Monday warned George W. Bush of the ``evils" of [embryonic] stem-cell research, as the U.S. president deliberates over whether to permit federal funding for such work.

After a 35-minute private meeting in the Pope's summer residence in Castelgandolfo, a town perched above a lake in the Alban hills about 20 km (12 miles) south of Rome, the Pope and Bush gave brief speeches.

In a strong voice, the 81-year-old pontiff warned Bush of ``evils such as euthanasia, infanticide and, most recently, proposals for the creation for research purposes of human embryos, destined to destruction in the process."

Bush is currently grappling with a decision on whether to permit federal funding for embryonic stem-cell research. He said last week he was still studying the issue, and needed to hear all sides and fully understand the ramifications.

Advocates believe research with embryonic stem cells, the early master cells formed soon after a human egg is fertilized, could lead to medical advances.

Opponents, including the Roman Catholic Church, condemn research that destroys human embryos.

The aging pontiff also took the opportunity to speak out against the death penalty, which Bush supports.

``A free and virtuous society, which America aspires to be, must reject practices that devalue and violate human life at any stage from conception until natural death," he said.

During Bush's six years as governor of Texas, the state carried out 152 executions, the highest rate in the United States.

Under his presidency, U.S. federal authorities resumed executions after a 38-year hiatus. Two men have been put to death.

BUSH STAYS AWAY FROM CONTROVERSY

Speaking to his wife Laura and daughter Barbara -- both clad in black and wearing mantillas for their meeting with Pope -- Bush said in the presence of journalists he had had a ``very good discussion" with the pontiff.

The president, fresh from a Group of Eight summit in Genoa which was overshadowed by violence and the death of an anti-capitalist protester, avoided controversial issues.

``You have urged men and women of good will to take to their knees before God and to stand, unafraid, before tyrants," said Bush, who like the Pope gave his speech seated at a microphone.

``And this has added greatly to the momentum of freedom in our time.

``Where there is oppression you speak of human rights, where there is poverty you speak of justice and hope. Where there is ancient hatred, you defend and and display a tolerance that reaches beyond every boundary of race and nation and belief," he said.

The Pope warned that many were excluded from the benefits of globalization.

``The church cannot but express profound concern that our world continues to be divided, no longer by the former political and military blocks, but by a tragic fault line between those who can benefit from these opportunities and those who seem cut off from them," said the Pope.

Reuters, 7-23-01

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EXPAND STORY

## BC-Vatican-Stem Cells,0388

Vatican dispels any doubt over Pope's stance to Bush, says all research on human stem cells immoral

By VICTOR L. SIMPSON=
Associated Press Writer=

VATICAN CITY (AP) _ The Vatican stressed Wednesday that it considers all research using stem cells from human embryos morally unacceptable, aiming to dispel any doubts about the stance Pope John Paul II laid out to President Bush.

In a meeting Monday, the pope urged Bush, who is weighing federal funding for work with stem cells, to reject research on human embryos.

Some observers and commentators later interpreted the pontiff's remarks as possibly exempting embryos created in fertility clinics and left over after a woman becomes pregnant.

In response, Vatican spokesman Joaquin Navarro-Valls issued a statement Wednesday saying the pope's condemnation applied to all research using stem cells from human embryos.

The statement quoted from a papal encyclical that said:

``This moral condemnation also regards procedures that exploit living human embryos and fetuses _ sometimes `produced' for this purpose by in vitro fertilization _ either to be used as `biological material' or as providers or organs or tissue for transplants in the treatment of certain diseases. The killing of innocent human creatures, even if carried out to help others, constitutes an absolutely unacceptable act.''

Embryonic stem cells are the basic building blocks for body tissue. To extract these cells for research requires killing the embryo _ an action consistently rejected by the Roman Catholic church and other abortion opponents as the taking of human life.

In stem cell research, Bush faces one of the toughest issues of his young presidency.

Allowing federal funding could alienate some of America's 44 million Catholics, who make up an important political bloc. If Bush cuts or restricts the funding, he risks being accused of bowing to the pope and other religious and conservative leaders.

Bush said after meeting with the pontiff that he would take John Paul's views ``into consideration.''

The pope's statement, along with the clarification issued Wednesday, rule out one of the potential compromises the president is considering: research on stem cells derived from fertility clinic surpluses that would otherwise be discarded.

Scientists believe research using stem cells might unlock cures for diseases including Alzheimer's, Parkinson's and diabetes, as well as spinal cord injuries. The pope himself suffers from symptoms of Parkinson's disease.

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# Three largest U.S. religious denominations criticize stem cell research that destroys human embryos

August 1, 2001, 11:08 EDT

WASHINGTON (AP) The United Methodist Church has urged one of its best-known members, President Bush, to maintain a moratorium on government-aided stem cell research using human embryos.

That view unites the three biggest U.S. denominations. The Roman Catholic Church and Southern Baptist Convention also oppose research that destroys human embryos.

James Winkler of the Methodists' Board of Church and Society, the church's social action agency, wrote Bush noting that the denomination last year urged a ban on human cloning and ``procedures that intentionally generate 'waste (human) embryos' which will knowingly be destroyed.''

Winkler said, ``The moral and ethical issues surrounding the beginning of life demand enormous caution in proceeding with activities that result in the destruction of human embryos.''

He opposed policies that turn ``life into a commodity to be manipulated, controlled, patented and sold.''

In June, the Presbyterian Church (U.S.A.) assembly took a different view, endorsing use of embryo stem cells for research only if there are medical goals that cannot be achieved any other way, if embryo donations are kept separate from decisions to abort, and if commerce in human embryos is prohibited.

[Note: On July 23, the 2.6-million member Lutheran Church -- Missouri Synod sent President Bush a letter opposing embryo-destructive research.]

# New Poll: Americans Oppose Destructive Embryo Research, Support Alternatives

WASHINGTON (June 8, 2001) -- As two very different bills are introduced in the House of Representatives this week on stem cell research, a new poll commissioned by the National Conference of Catholic Bishops shows that Americans strongly prefer one approach over the other.

Rep. Jim McDermott (D-WA) has introduced the "Stem Cell Research Act of 2001" to change the law so federal funds can be used to destroy human embryos for their stem cells. Rep. Chris Smith (R-NJ) has introduced the "Responsible Stem Cell Research Act of 2001" to increase funding for stem cell research that does not require destruction of human life at any stage.

Questions about these two approaches to stem cell research were included in a multi-issue survey conducted by International Communications Research (ICR), a national polling firm headquartered in Media, Pennsylvania. A weighted sample of over a thousand American adults was surveyed by telephone between June 1 and June 5 to obtain the results.

The poll suggests that Americans oppose federal funding of stem cell research that requires destroying human embryos, by a factor of almost three to one (70% to 24%). Asked to choose between funding all stem cell research (both adult and embryonic), and funding only adult stem cell research and similar alternatives to see if there is no need to destroy embryos for research, Americans prefer the latter approach by an even wider margin (67% to 18%).

"Polls sponsored by groups promoting destructive embryo research claim to show broad support for their agenda," says Richard Doerflinger, Associate Director for Policy Development at the NCCB Secretariat for Pro-Life Activities. "They create this illusion by using what political campaigns call 'push polls' – presenting false and misleading claims as though they are fact, to push the respondent to a favorable answer. They even avoid mentioning the destruction of human embryos, asking only if people support the use of stem cells 'that come from excess fertilized eggs.' Perhaps they use this scientifically absurd euphemism out of fear that many Americans recognize a 'human embryo' as a human life."

"Even the Clinton Administration's guidelines for embryonic stem cell research insist that parents donating embryos for this research must be told that the embryos will not survive the harvesting process," said Mr. Doerflinger. "Federal officials recognized that failing to mention this important fact would violate parents' right to informed consent. Why do some advocacy groups want to deny Americans that right of informed consent when they conduct polls?"

The results of the new ICR survey are as follows:

1. Stem cells are the basic cells from which all of a person's tissues and organs develop. Congress is considering whether to provide federal funding for experiments using stem cells from human embryos. The live embryos would be destroyed in their first week of development to obtain these cells. Do you support or oppose using your federal tax dollars for such experiments?

Support 23.9%
Oppose 69.9%
Don't know 4.8%
Refused 1.3%

2. Stem cells for research can be obtained by destroying human embryos. They can also be obtained from adults, from placentas left over from live births, and in other ways that do no harm to the donor. Scientists disagree on which source may end up being most successful in treating diseases. How would you prefer your tax dollars to be used this year for stem cell research?
(Options rotated)
Supporting all methods, including those that require destroying human embryos, to see which will be most successful 17.6%
or
Supporting research using adult stem cells and other alternatives, to see if there is no need to destroy human embryos for research. 66.8%

Neither (volunteered) 8.6%

Don't know 6.3%

Refused 0.7%

The survey of 1013 adult Americans has a margin of error of plus or minus 3%.

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Office of Communications
National Conference of Catholic Bishops/United States Catholic Conference
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Article March 26, 2001/Vol 6, Number 27

# The Politics of Stem Cells

## The good news you never hear.

**By Wesley J. Smith**

Stem cells are undifferentiated "master cells" in the body that can develop into differentiated tissues, such as bone, muscle, nerve, or skin. Stem cell research may lead to exponential improvements in the treatment of many terminal and debilitating conditions, from cancer to Parkinson's to Alzheimer's to diabetes to heart disease. Indeed, breakthroughs in stem cell research reported just in the last six months take one's breath away:

- Italian scientists have generated muscle tissue using rat stem cells, a discovery that may have significant implications for organ transplant therapy.

- University of South Florida researchers report that rats genetically engineered to have strokes were injected with rat stem cells that "integrated seamlessly into the surrounding brain tissue, maturing into the type of cell appropriate for that area of the brain." The potential for stem cell treatments to alleviate stroke symptoms such as slurred speech and dizziness—therapy that would not require surgery—has the potential to dramatically improve the treatment of many neurological diseases.

- The group of scientists who achieved worldwide fame for cloning Dolly the sheep have successfully created heart tissue using cow stem cells. The experiment demonstrated that stem cells could be transformed into differentiated bodily tissues, offering great impetus to further research.

- Scientists at Enzo Biochem, Inc., inserted anti-HIV genes into human stem cells. The stem cells survived, grew, and

developed into a type of white blood cell that is affected adversely by HIV infection. In the laboratory, these treated cells blocked HIV growth. The next step is human trials, in which stem cell therapy will be attempted using bone marrow transplantation techniques currently effective in the treatment of some cancers.

What will surprise many people is that *none* of these remarkable achievements relied on the use of stem cells from embryos or the products of abortion. Indeed, all of these experiments involved *adult stem cells* or undifferentiated stem cells obtained from other non-embryo sources. The rat muscle tissue in the first example was generated using adult rat brain cells. The brain tissue generated in the Florida research was obtained using human stem cells found in umbilical cord blood—material usually discarded after birth and a potentially inexhaustible source of stem cells, since 4 million babies are born in the United States alone each year. Dolly's creators obtained cow heart tissue by reprogramming adult cow skin tissue back into its primordial stem cell state and thence to cardiac cells. The exciting HIV experiments were conducted using stem cells found in the patients' own bone marrow, spleen, or blood.

The opportunities for developing successful therapies from stem cells that do not require the destruction of human embryos should be very big news. But where are the headlines? These and other successful experiments have been all but drowned out by breathless stories extolling the miraculous potential of embryonic stem cell research. How many readers are aware, for example, that French doctors recently transformed a heart patient's own thigh muscle into contracting muscle cells? When these cells were injected into the patient's damaged heart, they thrived and, in association with bypass surgery, substantially improved the patient's heartbeat. Such research is now on the fast track, offering great hope for cardiac patients everywhere.

With all of the hype surrounding embryo research, it is important to note that embryo stem cell research—and its first cousin, fetal tissue experiments—may not actually produce the therapeutic benefits its supporters have told us to anticipate. Such worries are not mere speculation. The March 8, 2001, *New England Journal of Medicine* reported tragic side effects from an experiment involving the insertion of fetal brain cells into the brains of Parkinson's disease patients. The patients thus treated showed modest if any overall benefits by comparison with a control group who underwent "sham surgeries" without receiving fetal tissue. But over time, some 15 percent of the patients who had received the transplants experienced dramatic over-production of a chemical in the brain that controls movement. The results, in the words of one disheartened researcher, were "utterly devastating," with the unfortunate patients exhibiting permanent uncontrollable movements: writhing, twisting, head-jerking, arm

flailing, and constant chewing. One man was so badly affected he no longer can eat, requiring the insertion of a feeding tube.

While some studies using stem cells culled from embryos to treat Parkinson's type symptoms in mice have been encouraging, grafts of fetal and embryonic tissue may provoke the body's immune response, leading to rejection of the tissue and potentially death, since once the cells are injected they cannot be extracted. Even more alarming, a May 1996 *Neurology* article disclosed a patient's death caused by an experiment in China in which fetal nerve cells and embryo cells were transplanted into a human Parkinson's patient. After briefly improving, the patient died unexpectedly. His autopsy showed that the tissue graft had failed to generate new nerve cells to treat his disease as had been hoped. Worse, the man's death was caused by the unexpected growth of bone, skin, and hair in his brain, material the authors theorized resulted from the transformation of undifferentiated stem cells into non-neural, and therefore deadly, tissues.

Even some of the most enthusiastic boosters of embryo stem cell research see trouble ahead. For example, University of Pennsylvania bioethicist Glenn McGee admitted to *Technology Review*, a Massachusetts Institute of Technology publication, "The emerging truth in the lab is that pluripotent stem cells are hard to rein in. The potential that they would explode into a cancerous mass after a stem cell transplant might turn out to be the Pandora's box of stem cell research." Thus, it could be that adult tissue-specific stem cells are actually safer than their counterparts culled from embryos since, being extracted from mature cells, they may not exhibit the propensity for uncontrolled differentiation.

These concerns arise just as the long-time ban on using federal funds for research that destroys human embryos is under renewed scrutiny. That longstanding ban was effectively reinterpreted out of existence in the waning months of the Clinton administration, and the National Institutes of Health are currently accepting grant proposals for research using embryos originally created for in vitro fertilization but now deemed "in excess of clinical need." The new administration is taking a long, hard look at the policy; during the campaign, George W. Bush declared his opposition to research that involved destroying human embryos.

All of this raises intriguing questions: Why is federal funding for embryo and fetal research pushed so hard and so publicly—while adult stem cell and other alternative therapies are damned with faint praise? Why do the media applaud fetal stem cell experiments and provide klieg-light coverage of stories promoting the use of embryos, while they mention uncontroversial research not requiring the destruction of human life as an afterthought, if that? Indeed, why do some scientists assert that alternative stem cell research offers but uncertain hope, while they promote embryo and fetal tissue research

as the keys to the Promised Land?

I suggest three answers: celebrities, abortion, and eugenics.

In a society that has often denigrated its true heroes, the only people who now stand head above the clouds are figures from the world of entertainment. Increasingly, these celebrities are using their power to promote public policies. They know that their participation can define issues and shape the debate by attracting media coverage, generating fan support, and, most important, stimulating a Pavlovian response in politicians.

Three high-powered celebrities have weighed in recently in the stem cell controversy, each promoting full federal funding of embryo research: the popular Michael J. Fox, stricken at a tragically young age with Parkinson's disease; the television icon Mary Tyler Moore, a diabetes patient; and actor Christopher Reeve, paralyzed from the neck down in an equestrian accident. With such kiloton star power favoring federal funding of embryo research, promoters of research relying on adult stem cells and other alternative sources, along with those opposed to the destruction of embryos on ethical grounds, have been reduced to background noise or, worse, made to look heartless by denying these celebrities medical breakthroughs they need.

At a deeper level, just as in the nineteenth century many national issues led back to slavery, today numerous public policy disputes lead ultimately to abortion. The controversy over destroying human embryos to obtain their stem cells has brought an outcry from the pro-life movement, which views human life as sacred from the moment of conception. This has led to reflexive support for embryo research by many pro-choicers, who have seized on the issue as a way to further their depiction of pro-life forces as caring little about people once they are born. Thus the embryo stem cell debate offers abortion rights advocates a "two-fer": It furthers their primary political goal of isolating and marginalizing pro-lifers, and it enables them to seize the PR high ground by "compassionately" pressing for research that offers hope against debilitating diseases. To acknowledge the tremendous potential of adult stem cell research would interfere with this political pincer movement.

Finally, in my view, the ultimate purpose of promoting federal funding for embryo experiments over adult stem cell research—particularly among many in the bioethics movement—is to open the door to the eugenic manipulation of the human genome. Once embryos can be exploited for their stem cells to promote human welfare, what is to stop scientists from manipulating embryos to control and direct human evolution—equally for the purpose of improving the human future?

Indeed, some of those who signed a recent open letter to President

Bush urging an end to the ban on federal funding for human embryo research were scientists and bioethicists well known as favoring eugenics. For example, James D. Watson, a co-discoverer of the DNA helix, has written that newborns should not be considered "alive" for three days, to permit genetic screening. Newborns who fail to pass genetic muster should be discarded—much as the ancient Romans left unwanted babies outdoors to die of exposure. Another co-author of this letter, Michael West, head of the for-profit research company Advanced Cell Technology, proposes permitting human cloning as a way to obtain genetically matched stem cells for transplants, which might overcome the problem of tissue rejection in embryo stem cell therapy. Not coincidentally, many neo-eugenicists in the bioethics and science communities view cloning as a prime vehicle for directing the eugenic manipulation of human evolution.

All of this will come to a head in the coming weeks and months. Some recent news stories indicate that Health and Human Services secretary Tommy Thompson may be troubled by a federal ban on embryo stem cell research and thus inclined to retain the Clinton administration's funding policy. But why go down that controversial path, when adult stem cells and alternative sources offer such tremendous hope for treating every malady that research using embryos and fetal tissue seeks to ameliorate? Instead of turning this important field of medical research into another battlefield in America's never-ending culture war (the first lawsuit has already been filed to prevent federal funding), why not focus our public resources with laser-like intensity on the incredible potential of adult and alternative sources of stem cells?

**By Wesley J. Smith**

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Bone marrow cells that become neuronlike cells in the brain fascinate scientists, but ample uncertainties must be resolved before such results can be translated into therapeutics

# Stem Cells: New Excitement, Persistent Questions

If only bodies were as easy to fix as automobiles, diseases like diabetes or heart disease would be vanquished. Worn-out, defective cells would be readily replaced, new organs inserted, and impossible illnesses cured. Sometimes, such a world seems just around the corner—if you don't read the caveats too closely. Almost each week brings another report of the uncanny abilities of versatile stem cells, when transplanted into mice or rats, to form new blood vessels, strengthen weak bones, and even seek out and begin to repair damaged spinal cords and brains (*Science*, 24 November, p. 1479).

Much of the excitement has focused on the ability of these partially developed cells present in early embryos, fetal tissue, and several adult tissues to change course and become different types of cells—a proto-brain cell morphing into a muscle cell, say, or a bone marrow cell into a liver cell. For many years researchers assumed that a cell's fate was sealed, irrevocably, early in development. But increasingly, experiments are undermining that idea. In the latest example, two independent research teams report in this issue that, in mice, adult cells from the bone marrow can enter the brain and become neuronlike cells. The two papers strengthen the notion that cells from adult tissue, when prodded with the right signals, can change trajectories, abandoning their original identity and assuming a new one. If a similar phenomenon occurs in human brains—still a big if—it could mean that easily accessible cells from bone marrow might someday be used to treat a wide range of neurological diseases—without raising the ethical concerns that accompany the use of embryonic cells.

But there's a catch. Can the dramatic findings that so far have grown out of work with stem cells taken from mice be repeated in humans? Research on human cells lags behind, in part because of ethical debates restricting the use of cells derived from human embryos and fetuses (see sidebar), but also because of certain characteristics of human cells themselves. Human cells grow more slowly and divide less often in culture than their mouse counterparts. And once transplanted, usually into rodents, human stem cells are proving decidedly less predictable. What's more, scientists are at a loss to explain the surprising behavior of both human and mouse stem cells. The molecules that control the unusual fate-switching and tissue-rescuing cells remain elusive, making it difficult to test the observations with human cells, especially, in culture. Any human treatments, suffice it to say, are years away.

**Tantalizing interlopers.** Cells derived from bone marrow transplants, identified by green fluorescent protein *(top)* or a green-stained Y chromosome, expressed neuronal markers, stained red, in the brains of mice.

The latest papers highlight the personality-switching abilities of mouse stem cells while also reflecting some of the uncertainty typical of the field. Eva Mezey of the National Institute of Neurological Disorders and Stroke (NINDS) and her colleagues describe on page 1779 how they transferred bone marrow cells from normal adult mice into a strain of mice that cannot produce immune system cells. Usually, mice without immune systems die within a day of birth, but a bone marrow transplant can rescue them, and they grow normally following the transplant. To trace the fates of the transplanted cells, the team members injected bone marrow from adult male mice into newborn female recipients. One to 4 months after the transplants, the scientists killed the mice and examined their brains. In all of them, the researchers found cells containing Y chromosomes—unmistakable proof that they came from the male donors.

That observation in itself was not surprising: Scientists have known for years that cells from the immune system can enter the brain, and recent reports have shown that cells present in bone marrow could become astrocytes and glia, the brain's supporting cells. The unexpected result was that a small percentage of the male-derived cells expressed protein markers typical of neurons, the brain's key signaling cells, suggesting that the bone marrow cells had, upon reaching the brain, become neurons. Until a few years ago, scientists did not think mammals produced any new neurons at all after childhood—much less that foreign bone marrow cells could be coaxed into such a feat.

In independent work, cell biologist Helen Blau, graduate student Tim Brazelton, and their colleagues at Stanford University also found evidence for the versatility of adult bone marrow cells. As reported on page 1775, the team members injected bone marrow cells from adult mice into otherwise nor-

CREDITS: (TOP TO BOTTOM) T. BRAZELTON; E. MEZEY

## Stem Cell Scorecard

As researchers continue to explore the potential uses of stem cells obtained from a variety of sources (see main text), governments around the world are grappling with whether to allow research on stem cells derived from human embryos. Governments are cautious yet increasingly open to the new research, which may eventually yield treatments for a variety of diseases from Parkinson's to diabetes.

**Japan:** The Council for Science and Technology, the country's highest scientific advisory group, was scheduled to begin discussions of final guidelines governing the use of stem cells this week. Those guidelines are expected to closely resemble a draft document released last spring (*Science*, 11 February, p. 949). Until those guidelines are in place, scientists in Japan are not allowed to derive or work with human embryonic stem (ES) cells, says Shin-Ichi Nishikawa of the University of Kyoto. One use of the technology is likely to be banned: A law prohibiting human reproductive cloning has passed the lower house of parliament and is expected to pass the upper house, says Koichi Morimoto, science counselor at the Japanese embassy in Washington, D.C.

**Germany:** Although German law forbids research that harms an embryo, it does not prohibit import of already-derived ES cells, according to Oliver Brüstle of the University of Bonn. Brüstle has applied for a grant to do just that and is waiting to hear back from Germany's funding agency, the DFG. Legislation is unlikely to change in the near future, he says.

**Sweden:** The government is reviewing its guidelines for stem cell and cloning research, even as plans are under way at Stockholm's Huddinge Hospital to launch a project to derive new stem cell lines from embryos that will be available for basic research, says neuroscientist Anders Bjorklund of Lund University.

**United Kingdom:** The U.K. may be the most permissive. In a report supported by Prime Minister Tony Blair, an advisory committee recommended in May that researchers be allowed to conduct nuclear transfer experiments with human cells (*Science*, 25 August, p. 1269). Some scientists would like to learn how to transfer the nucleus from a patient's cell into an enucleated egg in order to derive perfectly matched stem cells for treating the patient. Parliament is expected to debate revisions to the law governing research on embryos in the next few months.

**Australia:** In Australia, policies are in flux. State law varies across the country. Victoria, for example, prohibits the derivation of ES cells, but other states have no regulations. The National Health and Medical Research Council, the country's biomedical funding agency, has issued guidelines on research in human-assisted reproduction technology; these state that human ES cells may not be developed with the aim of cloning an individual. A National Parliamentary Committee is currently considering the status of therapeutic cloning, stem cell research, and related matters. They are expected to report before the end of the year.

**European Union:** An E.U. ethics advisory board recommended in November that the E.U. fund research using all types of stem cells, especially those derived from adult tissue. Because research on ES cells is still preliminary, the advisory board discouraged work that would create new embryos for research. Plenty of "excess" embryos already exist in fertility clinics, destined to be discarded, the report says.

**United States:** Although the National Institutes of Health (NIH) issued guidelines for funding work with human pluripotent stem cells in August, federally funded researchers will not be able to begin such work until next spring at the earliest. The guidelines allow NIH-funded scientists to use embryonic or fetal stem cells only after careful ethical review of the methods used to derive those cells. Because no scientist has yet submitted all the documentation needed for the review, says NIH associate director for policy Lana Skirboll, the Human Pluripotent Stem Cell Review Group will not meet this month as originally scheduled. Committee members should be announced before year's end, Skirboll says, and the next scheduled meeting is in April 2001.

**Hopeful.** Actor Michael J. Fox urged a congressional committee to approve research on embryonic stem cells that may someday cure Parkinson's disease.

That will be well into the new presidential Administration, and if Governor George W. Bush prevails, the climate at NIH may change. Bush has stated that he is opposed to the NIH funding work with ES cells, and a Bush-appointed director could prohibit any ES cell work.

Such an outcome could prompt stem cell supporters in Congress to act. Senator Arlen Specter (R–PA), for instance, last year introduced a bill that would have authorized the NIH to fund work on the derivation and use of human ES cells. But despite star-studded hearings in which actors Mary Tyler Moore, Michael J. Fox, and Christopher Reeve testified in favor of the research, the bill died in the Senate (*Science*, 13 October, p. 261). Specter has said he will reintroduce the bill in the new Congress. –G.V.

mal mice that had received a lethal dose of radiation to kill their bone marrow cells. The researchers used bone marrow from mice genetically engineered to express green fluorescent protein in their cells so they could track the injected cells. Several months after the transplant, the researchers found glowing green cells throughout the brains of recipient mice. To determine what type of brain cells the bone marrow had become, the team members stained brain sections to detect neuronal-type markers. To their surprise, they, too, found transplant-derived cells expressing multiple neuronal proteins.

Despite both teams' independent results, other scientists caution that protein markers can be misleading. Mature, functional neurons can be notoriously difficult to identify using cell markers, and both teams failed to detect more than a few cells with the characteristic shape of a mature neuron, with long extensions reaching out to other cells. The transplanted cells are "expressing certain features of neurons, but there's a lot we don't know," says developmental neuroscientist Ron McKay of NINDS.

And if the cells truly are neurons, the scientists still need to decipher exactly which bone marrow cells enter the brain and what molecular signals draw them there. Neuroscientist Anders Bjorklund of Lund University in Sweden suspects that the age and condition of the recipient mouse might influence the recruitment of bone marrow cells to the brain. Mezey and her colleagues worked with newborn mice, and it might be easier for stem cells to infiltrate those still-developing brains. In Brazelton and Blau's work, the adult recipient mice received a

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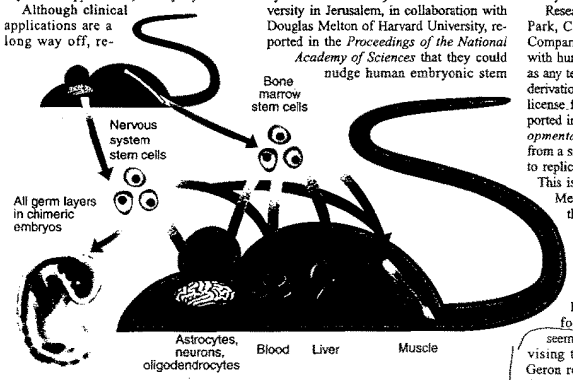
high dose of radiation that killed not only bone marrow but also any dividing cells in the brain. Perhaps such an assault prompted the migration of cells, Bjorklund speculates.

Blau's team is now working to characterize the molecules that control the recruitment process. "We need to find out what factors we can deliver to make cells divide and home in and take up residence in the right place," she says. Indeed, a detailed understanding of such factors would probably have to precede any clinical applications, McKay says.

Although clinical applications are a long way off, recent work supports the idea that human bone marrow might also have multiple talents, although exploiting them may still be a challenge. Researchers led by Darwin Prockop of Tulane University in New Orleans and Ira Black of Robert Wood Johnson Medical School in Piscataway, New Jersey, reported in the August *Journal of Neuroscience Research* that human marrow stromal cells, a subset of bone marrow, began to resemble neuronal-type cells in culture. And this summer, Malcolm Alison of the Imperial College School of Medicine in London and his colleagues reported in *Nature* that at least a few human bone marrow cells became liver cells in patients who had received bone marrow transplants. In the study, women who had received bone marrow transplants from male donors had liver cells that contained Y chromosomes—most likely derived from the transplanted bone marrow cells. That finding is consistent with previous reports of similar phenomena in mice (*Science*, 14 May 1999, p. 1168), suggesting that bone marrow cells might someday be useful in treating liver disease.




**A web of possibility.** In mice, stem cells from adult brain and bone marrow have shown encouraging potential for repairing a variety of tissues and organs and perhaps curing disease.

In contrast, the human embryonic stem cells and fetal germ cells that made headlines in November 1998 because they can, in theory, develop into any cell type have so far produced relatively modest results. Only a few papers and meeting reports have emerged from the handful of labs that work with human pluripotent cells, whose use has been restricted by legal and commercial hurdles. Last month, a group led by Nissim Benvenisty of The Hebrew University in Jerusalem, in collaboration with Douglas Melton of Harvard University, reported in the *Proceedings of the National Academy of Sciences* that they could nudge human embryonic stem cells toward a number of different cell fates. But the results did not produce easy answers; some cells expressed markers from several kinds of lineages.

The work suggests that it will not be simple to produce the pure populations of certain cell types that would be required for safe and reliable cell therapies—much less the hoped-for replacement organs, says stem cell researcher Oliver Brüstle of the University of Bonn in Germany. Brüstle was one of the first to show that mouse embryonic stem cells could help treat an animal disease model, in which neurons lack their insulating coat of myelin. Even so, he is cautious about the near-term prospects in humans. Says Brüstle: "At present, it looks like it is really difficult to differentiate these [human] cells into more advanced cell types." Melton agrees. "It's unlikely anyone will ever find a single growth factor to make a dopaminergic neuron," as some might have hoped, but the work provides "a starting place," he says.

Simply keeping human embryonic stem cells alive can be a challenge, says Peter Andrews of the University of Sheffield in England. For more than a year, he and his colleagues have been experimenting with embryonic stem cell lines that James Thomson derived at the University of Wisconsin, Madison. "They're tricky," Andrews says. It took several false starts—and a trip to Wisconsin—before the researchers learned how to keep the cells thriving, he says. Melton uses almost the same words: Human embryonic stem cells "are trickier than mouse," he says. "They're more tedious to grow."

Researchers from Geron Corp. in Menlo Park, California, are having some luck. Company researchers have been working with human embryonic stem cells as long as any team has, because Geron funded the derivation of the cells and has an exclusive license for their commercial use. They reported in the 15 November issue of *Developmental Biology* that cell lines derived from a single embryonic stem cell continue to replicate in culture for 250 generations. This is important, says Geron researcher Melissa Carpenter, because it means that a single human embryonic stem cell, which might be modified in the lab, could produce an essentially unlimited supply of cells for therapy. That was known for mouse embryonic stem cells but had not been shown in humans before. Even so, Geron researchers seem no closer than other groups to devising therapeutic uses for stem cells. Geron researchers reported last month at the annual meeting of the Society of Neuroscience that they had attempted to transplant human embryonic stem cells into rats. When they injected undifferentiated cells into the brain, they did not readily differentiate into brain cells, the researchers found. Instead, they stayed in a disorganized cluster, and brain cells near them began to die. Even partially differentiated cells, the team reported, tended to clump together; again, nearby brain cells died.

Still, Melton is optimistic. "How easily can we translate what we know in the mouse to the human? There's nothing we've found that makes me think it can't be done," he says.

The most important next step, say several stem cell researchers, is to identify the molecular processes that underlie the impressive feats of stem cells. Many of the purported breakthroughs are simply observations, Bjorklund says, which may eventually be explained by events unrelated to stem cell versatility. "That is going to be one challenge for those working in the field," he says. "One has to come up with a deeper understanding of the mechanisms involved to get anywhere." Blau agrees: "We have to understand the rules" to find out how to better play the cell-replacement game. —GRETCHEN VOGEL

ILLUSTRATION: CAMERON SLAYDEN

## Hematopoietic Stem Cell Therapy

*Edited by Edward D. Ball, John Lister, and Ping Law. 757 pp., illustrated. Philadelphia, Churchill Livingstone, 2000. $299.50. ISBN 0-443-07622-7.*

RECENT developments are revolutionizing our understanding of the potential therapeutic role of what used to be called bone marrow transplantation but is now called hematopoietic stem-cell therapy. Over the past three decades, much empirical knowledge has been accumulated to provide a sound basis for the optimal use of this approach in the treatment of hematopoietic cancers, especially acute myelogenous leukemia, Hodgkin's disease and other lymphomas, and (more recently) multiple myeloma. This approach has also been used in the treatment of some solid tumors, most notably breast cancer, for which its value is still in dispute because of poor accrual in randomized trials and because it takes many years to obtain definitive answers, even from well-designed trials. Hematopoietic stem-cell therapy is also being tried in sickle cell disease and thalassemia and recently in progressive multiple sclerosis, systemic scleroderma, severe systemic lupus erythematosus, and rheumatoid arthritis with a poor prognosis.

The broadening therapeutic applications of hematopoietic stem cells also reflect an increased understanding of how to modulate the cells of the immune system to minimize both rejection and graft-versus-host disease and to improve the management of the infectious complications of immunosuppression. Tolerance and graft-versus-tumor effects are now better understood, as is the use of donor-lymphocyte infusions. This, in turn, has recently led to the concept of the "mini"-transplant; the primary goal of this approach is to make the recipient tolerant of subsequent donor-lymphocyte infusions with the use of as little cytotoxic conditioning therapy as possible. In the treatment of cancer, the effectiveness of this type of transplantation would thus be due primarily to an immunologic effect on the malignant cells rather than to a direct cytotoxic effect of high-dose chemotherapy. With this approach, it should be possible to reduce the incidence of post-transplantation cytopenia and other complications, thereby extending the potential benefits of hematopoietic stem-cell transplantation to a much larger group of older patients.

The reduction in transplantation-related morbidity and mortality will also accelerate the use of stem-cell transplantation in the treatment of inherited diseases that are not immediately life-threatening and the use of hematopoietic stem cells for gene therapy. Moreover, since adult bone marrow has recently been found to contain stem cells of previously unrecognized "plasticity" that are able to form a variety of types of cell — muscle, liver, neural, bone, cartilage, endothelial, and perhaps others — it may be possible to use marrow stem cells in cytotherapeutic approaches to a wide spectrum of diseases, such as cardiac disorders, muscular dystrophy, liver disease, neurodegenerative conditions, and joint diseases.

*Hematopoietic Stem Cell Therapy* is a new textbook that captures some of the excitement of these new developments, although it focuses primarily on the practical aspects of high-dose chemotherapy and hematopoietic stem-cell rescue. Its authors are knowledgeable about this approach and about the diverse and serious complications that may be encountered in its use. The roughly 700-page text is divided into three main sections covering topics relevant to the periods before, during, and after transplantation. The first section, broken down into nine chapters, covers aplastic anemia, the individual leukemias, Hodgkin's disease, other lymphomas, and multiple myeloma. It also includes chapters on solid tumors (including breast, ovarian, and germ-cell tumors and childhood cancers) and on congenital immunodeficiencies, metabolic diseases, hemoglobinopathies, Gaucher's disease, autoimmune disease, and in utero transplantation. Of interest to physicians who refer patients for transplantation are chapters on the evaluation of candidates for transplantation, the choice of donors, and the care of long-term venous access, as well as on procurement of grafts from bone marrow, peripheral blood, and umbilical-cord blood. For laboratory-based readers, there are seven chapters on stem-cell quantitation, processing and storage, purging, T-cell depletion, immunomodulation, ex vivo stem-cell expansion, and gene therapy.

The second and third sections of the book deal with the actual transplantation and its complications. Covered appropriately are conditioning regimens, infections, graft-versus-host disease, graft failure, coagulopathies, the use of growth factors, nutritional support, and liver, gastrointestinal, respiratory, and neurologic complications. Also of interest to referring physicians are chapters on late complications, including infection and immunization, endocrine and metabolic complications, myelodysplasia and second cancers, chronic graft-versus-host disease, and psychosocial issues. The book concludes with specialized chapters on nursing, data management, biostatistics, economics, and regulatory issues that will be of considerable interest to both trainees and specialists in this area.

The strength of this book lies in its practical and readable approach to hematopoietic stem-cell transplantation. All the authors are close to their subject matter, and many are well-established experts. Chapters on stem-cell biology, the history of transplantation, and the excitement and future of hematopoietic stem-cell therapy would have further embellished this otherwise highly informative textbook, which I recommend for the libraries of specialists in this technique, their trainees, and referring physicians.

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## Hematopoietic Stem Cell Transplantation

*Edited by Anthony D. Ho, Rainer Haas, and Richard E. Champlin. 604 pp., illustrated. New York, Marcel Dekker, 2000. $185. ISBN 0-8247-0273-5.*

HEMATOPOIETIC stem-cell transplantation was undoubtedly one of the most important medical advances in the second half of the 20th century. The 1990 Nobel prize in physiology or medicine was awarded to Joseph E. Murray and E. Donnall Thomas for their discoveries concerning organ and cell transplantation in the treatment of human diseases. This award served to acknowledge not only the enormous contributions made by these pio-

EXPAND STORY

# Washington Not Alone in Cell Debate

NYT via Dow Jones

Publication Date: Monday July 23, 2001 National Desk; Section A; Page 12, Column 1 c. 2001 New York Times Company By SHERYL GAY STOLBERG

WASHINGTON, July 22 -- As President Bush and Congress struggle with the question of regulating embryonic stem cell research, one fact is being overlooked: nearly two dozen states already have laws that govern research on embryos and fetuses, and at least nine ban any experimenting with human embryos.

Some of the laws date back decades, having been enacted in response to Roe v. Wade, the 1973 Supreme Court decision legalizing abortion. Just one state, South Dakota, explicitly forbids stem cell studies; last year, at the urging of abortion opponents, South Dakota made it a misdemeanor to experiment with cells or tissues obtained from human embryos.

Nonetheless, legal experts say the existing statutes could impede university scientists and biotechnology companies, not only because of the bans but also because some states prohibit payment for embryonic tissue. Broadly construed, these experts say, such a provision could prevent scientists from buying the cells -- even if President Bush approves federal financing for research with them -- and prevent companies from selling stem cell-based therapies.

"There are some hidden land mines working in this area," said Lori B. Andrews, a professor at Chicago-Kent College of Law who has analyzed state restrictions on embryo research for the National Bioethics Advisory Commission. She added, "I think the states will become a fertile battleground for the larger social question of should embryo research be permissible."

As past controversies surrounding abortion, fetal tissue experiments and cloning suggest, state lawmakers often step into the ethical debates posed by medicine and science. So no matter what President Bush and Congress decide, the questions about embryonic stem cell research may ultimately be settled piecemeal, in the states. And state laws may lead to challenges in courts.

"If you look at the history of abortion, it seesaws between federal and state legislation and federal and state courts," said R. Alto Charo, a professor of bioethics at the University of Wisconsin. "In the end, we may end up with different rules in different places."

Already, legislators in Professor Charo's home state are debating a ban on future studies involving stem cells derived from human embryos. And Wisconsin is the birthplace of embryonic stem cell science. In 1998, a University of Wisconsin researcher, Dr. James A. Thomson, became the first to isolate the cells, which hold promise for treating disease.

"I can't stop what happens elsewhere," said the measure's author, State Representative Sheryl K. Albers, a Republican. "If nothing is changed on the national level, something does need to change in Wisconsin."

Since Dr. Thomson's discovery, embryonic stem cells have generated great excitement in science, and great angst in Washington. These primordial cells, which may grow into any cell or tissue in the body, are extracted from the inner mass of an embryo when that embryo is just a tiny cluster of 100 to 300 cells, small enough to fit on the tip of a sewing needle. Scientists regard embryonic stem cells as the building blocks of a new era of regenerative medicine, in which the body will someday be used to heal itself.

But the research draws intense criticism from religious conservatives and abortion opponents because the embryos, which they regard as nascent human life, are destroyed. Currently, embryonic stem cell experiments must be conducted entirely with private money, because Congress has imposed a ban on federal financing for the studies.

The issue before President Bush is whether to make an exception so that taxpayer money could be used to study cells derived from embryos frozen at fertility clinics; scientists would not, however, be permitted to work directly on embryos.

Congress may also weigh in. Senator Arlen Specter, a Pennsylvania Republican who is a strong supporter of the research, has introduced legislation to allow government-financed scientists to derive stem cells from embryos.

But the discussion in Washington centers on federal financing, so it will have no effect on the private sector. This month, scientists at a private Virginia fertility clinic announced that they had created embryos expressly to extract stem cells. And a Massachusetts biotechnology company, Advanced Cell Technology, is trying to use cloning technology to make embryos -- 100- to 300-cell copies of existing people -- that would yield stem cells with an exact tissue match for patients.

The Food and Drug Administration has little jurisdiction over such experiments; it typically oversees research only when a therapy is being tested in people. So the matter is left to the states. Virginia does not have laws governing embryo research. A Massachusetts law, enacted in 1974, prohibits using "any live human fetus" in experiments.

"We have looked at it about 40 times," said Mike West, the chief executive of Advanced Cell Technology. "We believe the law applies to fetuses," not embryos.

But Professor Andrews, of Chicago-Kent College of Law, says that over the years, the Massachusetts law has often been interpreted to define an embryo as a fetus, and it has had a "chilling effect" on scientists. When in vitro fertilization was first being performed in Massachusetts, she said, fertility specialists sought opinions from district attorneys on the legality of their work.

"I think some of these laws will be challenged in the wake of desires to do embryo research," she said. "It is an issue, because we have not yet come to a societal consensus on the moral or legal status of the embryo."

Should legal challenges occur, it would not be the first time the promise of science has collided with state law. In the early 1990's, when research on tissue from aborted fetuses began to look promising for treating Parkinson's disease, doctors and patients began bringing lawsuits. Research bans in Illinois, Louisiana, Utah and, most recently, Arizona were overturned; courts found them unconstitutional, saying the laws were vague.

Proponents of stem cell research say they are ready to take up their cause in the states, if necessary. "I think we have to be prepared to take this fight to state Capitols around the country," said Daniel Perry, executive director of the Alliance for Aging Research, a patients' group. But such battles are often difficult, Mr. Perry said, because the issues and science are complex.

"Let's face it, this is not highway legislation," he said.

South Dakota is one example. Last year, Jay Duenwald, a farmer from Hoven who is also a Republican

state representative, decided to introduce legislation to ban embryonic stem cell research. Mr. Duenwald likened the work to Nazi experiments, saying in an interview, "If you can destroy some section of society at will, where does it stop?"

Mr. Duenwald, an abortion opponent, called the National Right to Life Committee in Washington for help. Together, they drafted a bill that overwhelmingly passed in the South Dakota Legislature. It prohibits experiments on cells and tissues derived from human embryos, thus making embryonic stem cell research a crime in South Dakota, punishable by as much as a year in jail and a $1,000 fine.

But Mr. Duenwald's legislative co-sponsor, Jim Lawler, a retired Democratic state senator from Aberdeen, said he did not see the bill that way. Mr. Lawler explained that while he has trouble with "taking one life to save another," he would not be opposed to studies using frozen embryos that would otherwise be discarded if the researchers' aim was to treat disease, like diabetes.

"We just didn't want to do negative stuff," he said, "like cloning people."

Some experts, including Professor Andrews, say the public would be better served with one national policy. If laws vary from state to state, Ms. Andrews said, a kind of "biotechnological tourism" might occur, with companies and scientists moving from one state to the other in search of permissive laws.

But Glenn McGee, an assistant professor of bioethics at the University of Pennsylvania, thinks otherwise.

Last year, Professor McGee gave his undergraduates an assignment to draft legislation addressing stem cell research. The students then pitched their bills to legislators in their home states; to earn an A, they were required to have their proposals debated by a state legislature. About a half-dozen made it that far.

"This kind of localized political action is what is missing from the stem cell debate," Mr. McGee said. "If a group of 19-year-olds working under a philosopher can move 20 or 30 states into a position of reflecting on stem cells, why in the world would we need federal action?"

Chart: "States' Restrictions on Embryonic and Fetal Research" A 1999 report by the National Bioethics Advisory Commission listed the bans under embryo and fetal research laws and abortion laws. The bars indicate which bans were approved in each state. Chart showing the bans on embryonic and fetal research laws and abortion laws that were approved of various states. *The Arizona law was overturned by a federal court in December 2000. Also last year, South Dakota passed a law explicitly prohibiting stem cell research.

(END)

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April 4, 2001

Dr. Ruth Kirschstein
Acting Director
The National Institutes of Health
Bethesda, Maryland 20892

Dear Dr. Kirschstein,

As you know, many scientists believe that pluripotent stem cells may offer great promise for advances in health care and possible cures for numerous debilitating diseases and injuries. The breakthroughs in stem cell research reported in the last six months have been quite remarkable.

- Two teams of researchers reported using bone marrow stem cells to repair the hearts of rodents in which heart attack damage had been induced.
- Italian scientists have generated muscle tissue using rat stem cells, a discovery that may have significant implications for organ transplant therapy.
- University of South Florida researchers report that rats genetically engineered to have strokes were injected with rat stem cells that "integrated seamlessly into the surrounding brain tissue, maturing into the type of cell appropriate for that area of the brain." The potential for stem cell treatments to alleviate stroke symptoms such as slurred speech and dizziness—therapy that would not require surgery—has the potential to dramatically improve the treatment of many neurological diseases.
- The group of scientists who achieved worldwide fame for cloning Dolly the sheep have successfully created heart tissue using cow stem cells. The experiment demonstrated that stem cells could be transformed into differentiated bodily tissues, offering great impetus to further research.
- Scientists at Enzo Biochem, Inc., inserted anti-HIV genes into human stem cells. The stem cells survived, grew, and developed into a type of white blood cell that is affected adversely by HIV infection. In the laboratory, these treated cells blocked HIV growth. The next step is human trials, in which stem cell therapy

will be attempted using bone marrow transplantation techniques currently effective in the treatment of some cancers.

All of these remarkable achievements involved adult stem cells or cells obtained from other non-embryo sources. Experiments using embryo or fetal cells have reported less encouraging results.

- An experimental fetal cell therapy for Parkinson's disease being conducted by Genzyme Corporation and Diacrin Inc. caused study participants to develop uncontrollable movements, including constant chewing, writhing, twisting, jerking of the head and flexing and distending of the wrist. One of the researchers, Dr. Paul E. Greene of Columbia University College of Physicians and Surgeons said the results were "absolutely devastating" to some of the patients. According to Dr. Green, the patients with side effects are "tragic, catastrophic" and his position is clear: "No more fetal transplants."
- A May 1996 Neurology article disclosed a patient's death caused by an experiment in which fetal nerve cells and embryo cells were transplanted into a human Parkinson's patient. After briefly improving, the patient died unexpectedly. His autopsy showed that the tissue graft had failed to generate new nerve cells to treat his disease as had been hoped. The man's death was caused by the unexpected growth of bone, skin, and hair in his brain, material the authors theorized resulted from the transformation of undifferentiated stem cells into non-neural, and therefore deadly, tissues.
- Dr. T.F. Warner, professor of pathology at the University of Wisconsin-Madison has stated that "embryonic stem cell technology is fraught with danger and is not the panacea being presented by the media." According to Dr. Warner, the embryonic stem cells extracted by Dr. James Thomson of the University of Wisconsin, who was one of the two biologists who reported in November 1998 that they had derived human embryonic cells, produced "monstrous tumors after injection into immune deficient mice." Dr. Warner concludes "primitive embryonic cells can also be expected to produce malignant tumors such as teratocarcinomas and embryonal carcinomas."
- New findings from the Geron Corporation's researchers, printed in the journal Science on December 1, 2000, indicate that when embryonic cells are transplanted into a brain, they do not direct themselves to form only nerve cells but form varied clumps of tissue, as brain cells around them begin to die.

In light of these findings, adult stem cells have proven thus far to be the more successful and likely source for future medical treatments derived from stem cells.

Because of the ethical and moral concerns involved with research involving stem cells derived from human embryos and from elective abortions, Federal law prohibits organizations and entities receiving federal funding from conducting experiments with such stem cells. We believe that adult stem cells offer an ethical alternative.

Has the NIH reviewed the ethics of conducting stem cell research using human embryos and tissue derived from aborted fetuses? If so, could you provide us with a complete listing of those who participated in the ethical review(s) including their credentials and affiliations?

What is your view regarding the value of adult stem cell research? Could you provide a full list of NIH funded research involving adult stem cells along with any published or preliminary data from such studies (including that mentioned within this letter)? Please also include the total amount of NIH funding which was provided for adult stem cell research in the last fiscal year.

Stem cells may also be derived from umbilical cords, yet 99 percent of umbilical cords are disposed as hospital "bio-waste material" according to Cryo-Cell International, Inc. Is the NIH funding any research utilizing stem cells derived from umbilical cords? If so, what is the total amount of such funding in the last fiscal year? Also what is the NIH doing to promote the collection of umbilical cords for research?

Could you also provide a complete listing of those institutions, entities and researchers that have submitted grant proposals for research using human embryos?

Finally, to date, has any evidence of the efficacy of stem cells derived from human embryos and fetuses for use in human therapy been published in a peer-reviewed scientific journal?

Thank you for your prompt attention to this matter.

Sincerely,

Mark Souder

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

July 16, 2001

The Honorable Mark E. Souder
Chairman
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Washington, D.C. 20515

Dear Mr. Souder:

Thank you for your letter regarding pluripotent stem cell research. The Department of Health and Human Services (DHHS) and the National Institutes of Health (NIH) received a large volume of correspondence both supporting and opposing funding of this research. We understand and respect the compelling ethical and legal issues surrounding human pluripotent stem cell research, as well as the great potential these cells have for the development of treatments for many devastating diseases and disabilities.

Current appropriations law prohibits the use of DHHS funds for: (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under the Common Rule. It is important to note, however, that NIH funds may be used to support research to derive pluripotent stem cells from fetal tissue, as well as for research utilizing such cells. Such research is governed by Federal statutory restrictions regarding fetal tissue research at 42 U.S.C. § 289g-2(a) and Federal regulations at 45 CFR § 46.210. In addition, because cells derived from fetal tissue at the early stages of investigation may, at a later date, be used in human fetal tissue transplantation research, it is the policy of NIH to require that all NIH-funded research involving the derivation or utilization of pluripotent stem cells from human fetal tissue also comply with the fetal tissue transplantation research statute at 42 U.S.C. § 289g-1 and with 42 U.S.C. § 289g-2(b).

The Department is currently reviewing the legal issues regarding funding of research utilizing stem cells derived from human embryos. In addition, the NIH has submitted a comprehensive report to the Secretary on the state of the science of stem cell biology, including adult stem cells and those derived from embryos and fetal tissue.

In your letter, you ask whether the NIH reviewed the ethics of conducting stem cell research using human embryos and tissue derived from aborted fetuses. Recognizing the ethical and legal issues surrounding human pluripotent stem cell research and the need for stringent oversight of this class of research — oversight that goes beyond the traditional rigorous NIH scientific peer review process — the NIH issued a moratorium on the funding of this research until Guidelines could be developed and an oversight process could be implemented. In April 1999, the NIH convened a working group of the Advisory Committee to the Director (ACD), NIH (Enclosure 1), to provide advice to the ACD relevant to guidelines and oversight for this research. The working group met in public session and included scientists, clinicians, ethicists, lawyers, patients, and patient advocates. During its deliberations, the group considered advice from the National Bioethics Advisory Commission, the public, and scientists, including the American Association for the Advancement of Science (Enclosure 2). Draft guidelines for this research were published for public comment, and, after reviewing and considering all comments received, the NIH Guidelines for Research Using Human Pluripotent Stem Cells (NIH Guidelines) were published in the Federal Register and became effective on August 25, 2000. (Because the NIH Guidelines contained a few incorrect citations and other minor errors, a notice of correction (65 FR 69951) was published on November 21, 2000). The revised NIH Guidelines and other information about stem cell research can be found at the URL: <http://www.nih.gov/news/stemcell/index.htm.> The purpose of the NIH Guidelines is to set forth procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner. At the present time, the Administration is reviewing these Guidelines.

Because most diseases and disabilities involve the degeneration, destruction, or injury of human tissues and/or organs, much of NIH's research focuses on the basic biology of cell and tissue development. Stem cells will likely help answer some of the many remaining important questions about the tissue development and, therefore tissue repair, with the goal of developing new treatments and even cures. Coupling stem cell research with the vast knowledge available about the human genome will bring a powerful combination to support discovery about cell function, the genes that control it, and what accounts for the dysfunction in cells.

There has been much discussion about the relative merits of research on adult stem cells and stem cells from cord blood. We agree that both avenues of research hold great promise, and NIH has and will continue to support both animal and human research on both adult stem cells and stem cells from cord blood. In fiscal year 2000, NIH spent $256 million on animal and human stem cell research. The list of NIH-funded adult stem cell research projects is enclosed as requested (Enclosure 3); funding in FY 2000 for adult human stem cell research totaled $226 million.

With regard to adult stem cells, we do not yet know if they hold the same potential as do embryonic stem cells. The recent discovery that some adult cells appear to able to develop into a greater variety of cells than was previously thought possible is a remarkable scientific advance. However, stem cells of all cell and tissue types have not yet been found in the adult human. So

far, unlike the embryonic stem cell, no single adult stem cell has been shown to have the capability to develop into cells from all three embryonic germ layers. Because some adult stem cells are present in very minute quantities, they can be difficult to isolate and purify and they, therefore, may be limited in their potential for research and future applications in transplantation. Adult stem cells may also have more mutations than embryonic stem cells, as a result of exposure to environmental factors such as sunlight, toxins, and random errors in replication. Most importantly, there is no evidence that human adult stem cells have the same capacity to proliferate in an undifferentiated state as stem cells derived from embryos. This ability to multiply is important to both their usefulness as a research tool and their potential availability as transplantable tissue for treatment. For example, the longest studied stem cells are hematopoietic or blood-forming stem cells, and scientists have developed sufficient understanding to actually use them as a therapy. Currently, no other type of stem cell, adult, fetal, or embryonic, has attained this status. Human hematopoietic stem cell transplants are now routinely used to treat patients with cancers and other disorders of the blood and immune systems. Despite the vast experience with hematopoietic stem cells, scientists face a major roadblock in expanding their use for replacing cells other than blood and immune cells. Hematopoietic stem cells are unable to proliferate in the test tube or culture dish. Furthermore, scientists do not yet have an accurate method to distinguish stem cells from other cells recovered from the blood or bone marrow. Research on embryonic stem cells will, however, likely hasten our knowledge about adult stem cells and their therapeutic potential. Until scientists overcome these technical barriers, they believe it is unlikely that hematopoietic stem cells will be used as cell replacement therapy in diseases such as diabetes, Parkinson's disease, spinal cord injury, and many others.

You also asked about research using stem cells derived from umbilical cord blood. The blood obtained from the umbilical cord after the delivery of an infant is an important source of one type of stem cell—cord blood stem cells—but these stem cells have had limited applications. An appropriate descriptor of umbilical cord blood stem cells would be "neonatal stem cells;" that is, they are on the way to developing into adult stem cells. They are sometimes referred to as progenitor or precursor cells. To date, cord blood stem cells have only been successfully used to regenerate certain types of mature blood cells and components of the immune system. There is no scientific evidence that stem cells derived from cord blood have the same characteristics as pluripotent stem cells derived from human embryos or fetal tissue. NIH spent $18 million in FY 2000 on research on stem cells from umbilical cord blood. An NIH report on the "Status of NIH-Sponsored Basic and Clinical Research on Transplantation," is enclosed for your information. This report provides information about NIH research on stem cells from umbilical cord blood, including the Cord Blood Transplantation Study (Enclosure 4). The National Heart, Lung, and Blood Institute has issued numerous grant announcements seeking research applications in this area, including Blood and Marrow Transplant Clinical Research Network Request for Applications (RFA), released on January 4, 2001; Specialized Centers of Research in Hematopoietic Stem Cell Biology RFA, released August 16, 1999; and Specialized Centers of Research in Transfusion Biology and Medicine RFA, released August 2, 1999 (Enclosure 5).

In response to your question about whether the NIH has received proposals to conduct research using human embryos, the NIH has received no such grant proposals. As stated above, current appropriations law prohibits the use of DHHS funds for such research.

You also asked about whether there is evidence published in a peer-reviewed scientific journal of the efficacy of stem cells derived from human embryos and fetal tissue for use in human therapy. Human pluripotent stem cells were first derived from embryos and fetal tissue less than three years ago. Although many uses have been proposed for such stem cells, including their potential use in transplant therapy and diseases that might be treated by transplanting stem cells derived from human embryos, including Parkinson's disease, diabetes, traumatic spinal cord injury, Duchenne's muscular dystrophy, and heart failure, there probably has not been sufficient time for such publications to have occurred. While the private sector has been conducting research using these cells, much basic research must still be conducted before they or the differentiated cells derived from them can be tested in human trials.

I appreciate your interest in this issue and hope that we can work together to improve the health of our citizens.

Sincerely yours,

Ruth L. Kirschstein

Ruth L. Kirschstein, M.D.
Acting Director

Enclosures

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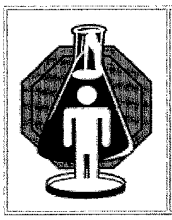

# Adult Stem Cell Advances Continue to Challenge "Need" for Destructive Embryonic Research

Time to "revisit" adult stem cell progress

*"In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research ... The claim that there are alternatives to using stem cells derived from embryos is not, at the present time [9/99], supported scientifically.* ***We recognize, however, that this is a matter that must be revisited continually as the demonstration of science advances."***

-- "Ethical Issues in Human Stem Cell Research," National Bioethics Advisory Commission, September, 1999 (emphasis added).

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"'This [isolating stem cells from fat] could take the air right out of the debate about embryonic stem cells,' said Dr. Mark Hedrick of UCLA, the lead author. The newly identified cells have so many different potential applications, he added, that 'it makes it hard to argue that we should use embryonic cells.'" -- Thomas H. Maugh II, "Fat may be answer to many illnesses," *Los Angeles Times*, 4/10/01

"With the newest evidence that even cells in fat are capable of being transformed into tissue through the alchemy of biotechnology, some scientists said they are beginning to conclude they'll be able to grow with relative ease all sorts of replacement tissues without resorting to embryo or fetal cells…'It's highly provocative work, and they're probably right,' said Eric Olson, chairman of molecular biology at the University of Texas Southwestern Medical Center in Dallas…Like many biologists, Olson believes that adult, fetal and embryonic stem cell research all merit support…it's heartening, he said, that almost "every other week there's another interesting finding of adult stem cells turning into neurons or blood cells or heart muscle cells. Apparently our traditional views need to be reevaluated.'" --Rick Weiss, "Human Fat May Provide Stem Cells," *The Washington Post*, 4/10/01

"In a finding that could offer an entirely new way to treat heart disease within the next few years, scientists working with mice and rats have found that key cells from adult bone marrow can rebuild a damaged heart—actually creating new heart muscle and blood vessels…Until now researchers thought that stem cells from embryos offer the best hope for rebuilding damaged organs, but this latest research shows that the embryos, which are politically controversial, may not be necessary. 'We are currently finding that these adult stem cells can function as well, perhaps even better than, embryonic stem cells,' [Dr. Donald] Orlic [of the National Human Genome Research Institute] said." --Robert Bazell,

"Approach may repair heart damage," *NBC Nightly News*, 3/30/01.

"[Dr. Donald] Orlic said fetal and embryonic stem cell researchers have not been able to show the regeneration of heart cells, even in animals. 'This study alone gives us tremendous hope that adult stem cells can do more than what embryonic stem cells can do,' he said." --Kristen Philipkoski, "Adult Stem Cells Growing Strong," *Wired Magazine*, 3/30/01

"Like several other recent studies, the new work with hearts suggests that stem cells retrieved from adults have unexpected and perhaps equal flexibility of their own, perhaps precluding the need for the more ethically contentious [embryonic] cells." --Rick Weiss, "Studies Raise Hopes of Cardiac Rejuvenation," *The Washington Post*, 3/31/01

"Umbilical cords discarded after birth may offer a vast new source of repair material for fixing brains damaged by strokes and other ills, free of the ethical concerns surrounding the use of fetal tissue, researchers said Sunday." --"Umbilical cords could repair brains," *Associated Press*, 2/20/01.

"PPL Therapeutics, the company that cloned Dolly the sheep, has succeeded in 'reprogramming' a cell -- a move that could lead to the development of treatments for diseases such as diabetes, Alzheimer's and Parkinson's. The Scotland-based group will today announce that it has turned a cow's skin cell into a beating heart cell and is close to starting research on humans... The PPL announcement...will be seen as an important step towards producing stem cells without using human embryos." --"PPL follows Dolly with cell breakthrough," *Financial Times*, 2/23/01

"Because they have traveled further on a pathway of differentiation than an embryo's cells have, such tissue specific [adult] stem cells are believed by many to have more limited potential than E[mbryonic] S[tem] cells or those that PPL hopes to create. Some researchers, however, are beginning to argue that these limitations would actually make tissue-specific stem cells safer than their pluripotent counterparts. University of Pennsylvania bioethicist Glenn McGee is one of the most vocal critics on this point: 'The emerging truth in the lab is that pluripotent stem cells are hard to reign in. The potential that they would explode into a cancerous mass after a stem cell transplant might turn out to be the Pandora's box of stem cell research.'" --Erika Jonietz, "Biotech: Could new research end the embryo debate?" *Technology Review*, January/February, 2001

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*Since 1999, when the National Bioethics Advisory Commission issued the statement cited above, scientific advances have demonstrated that adult stem cells can and do provide a "less morally problematic alternative" for advancing research. Do No Harm: The Coalition of Americans for Research Ethics urges the government to reject destructive embryonic stem cell research. Instead, it should take full advantage of the ethical alternative which adult stem cells offer for curing disease -- an alternative that protects the inviolability of all individuals and the integrity of medical research.*

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# NIH GUIDELINES (STILL) MISLEAD ON STEM CELLS

NIH unaware or indifferent to adult stem cell research advances

*In Guidelines issued 8/23/00 for Research Using Human Pluripotent Stem Cells, the National Institutes of Health (NIH) makes several misleading statements regarding the potential of adult stem cells for scientific and medical advancement. The following critique was first issued by Do No Harm on 8/28/00; it has been updated (5/01) to reflect new research developments. The NIH statements on adult stem cells remain unchanged. The facts then, and even more so now, undermine the NIH's rationale for funding destructive human embryonic stem cell research:*

**NIH**: "[S]tem cells for all cell and tissue types have not yet been found in the adult human. Significantly, cardiac stem cells or pancreatic islet stem cells have not been identified in adult humans."

**FACT**: Neither have cultured human embryonic stem cells been made to differentiate into all tissue types, including cardiac or pancreatic stem cells. However, adult stem cells for these tissues *have* been identified in mice, and adult pancreatic stem cells have been used to reverse diabetes in mice ("Reversal of insulin-dependent diabetes using islets generated in vitro from pancreatic stem cells," *Nature Medicine* 6, 278-282; March, 2000). This advance with adult stem cells took place over a year *before* any report of making insulin-producing cells from mouse embryonic stem cells; and the adult stem cells successfully reversed diabetes in the mice, whereas mice receiving embryonic stem cells still died from diabetes. As with most biological discoveries, animal models have paved the way for clinical uses in humans; we should expect that these same adult stem cells to be present in humans.

Moreover, while human embryonic stem cells have yet to be shown to undergo differentiation to insulin-secreting cells, scientists at Harvard Medical School cultured human pancreatic ductal cells under specific conditions, inducing the cells to form islet buds and secrete insulin. They report: "Thus, duct tissue from human pancreas can be expanded in culture and then be directed to differentiate into glucose responsive islet tissue in vitro. This approach may provide a potential new source of pancreatic islet cells for transplantation" ("In vitro cultivation of human islets from expanded ductal tissue," *Proc Natl Acad Sci USA* 97, 7999-8004; July 5, 2000.) Researchers in France have found further evidence for adult pancreatic stem cells in humans. The pancreatic cells from healthy donors, when placed into culture, proliferated and expressed characteristics critical for production and secretion of insulin ("Adult human cytokeratin 19-positive cells reexpress insulin promoter factor 1 in vitro: Further evidence for pluripotent pancreatic stem cells in humans," *Diabetes* 49, 1671-1680; Oct. 2000.) The results are another step toward treatment of diabetes using adult stem cells.

A recent comprehensive review (1/01) in the *British Medical Journal* of possible stem cell treatments for diabetes notes: "Human pancreatic duct cells have also been grown successfully *in vitro* and induced to differentiate," and "Not only does the use of adult donor ductal cells avoid the controversy of using fetal cells but there are fewer biological problems associated with making beta cells from duct cells than from, for example, embryonic stem cells." The authors conclude: "Of the techniques described above, the most promising is generation of beta cells from pancreatic duct cells. It is inherently a shorter biological step to make a beta cell from a duct cell than it is from other possible cells, such as embryonic stem cells and haemopoietic stem cells" ( P. Serup *et al.*, "Islet and stem cell transplantation for treating diabetes," *British Medical Journal* 322, 29-32; 6 Jan 2001).

Regarding cardiac tissue, research using adult stem cells to treat heart disease has been done with mice and in clinical trials in humans. Adult stem cells in mice have been shown not only to form cardiac tissue, but also to successfully regenerate damaged heart tissue ("Bone marrow cells regenerate infarcted myocardium," *Nature* 410, 701-705; Apr. 5, 2001; "Marrow stromal cells for cellular cardiomyoplasty: Feasibility and potential clinical advantages," *The Journal of Thoracic and Cardiovascular Surgery* 120, 999-1006; Nov. 2000).

In human clinical trials, patients have been successfully treated for heart disease using their own muscle stem cells ("Myoblast transplantation for heart failure." *Lancet* 357, 279-280, Jan 27, 2001; "Doctor Puts Arm Muscle Cells Into Patient's Heart," Associated Press, May 30, 2001; "First Percutaneous Endovascular Case of Heart Muscle Regeneration Completed with Bioheart's MyoCell(TM) Product," PRNewswire, May 30, 2001.) No embryonic stem cells have ever been reported to be used in human clinical trials.

Finally, it is fallacious to assume that there needs to be a separate adult stem cell for each tissue; there are numerous recent reports of adult stem cells being transformed from one tissue type to another (e.g., bone marrow to liver or nerve; nerve to blood). Thus adult stem cells have the capacity to form many more tissues than the one from which they are derived (e.g., "Multilineage potential of adult human mesenchymal stem cells," *Science* 284, 143-147, Apr. 2, 1999; "Liver from Bone Marrow in Humans," *Hepatology* 32, 11-16, July, 2000; "From marrow to brain: expression of neuronal phenotypes in adult mice," *Science* 290, 1775-1779; Dec. 1 2000; "Turning blood into brain: Cells bearing neuronal antigens generated in vivo from bone marrow," *Science* 290, 1779-1782; Dec. 1 2000; "Adult Bone Marrow Stromal Cells Differentiate into Neural Cells In Vitro," *Experimental Neurology* 164, 247-256; Aug. 2000; "Turning Brain into Blood: a hematopoietic fate adopted by adult neural stem cells in vitro," *Science* 283, 534-537, Jan. 22, 2000). In this respect, adult stem cells are considered by some researchers (including NIH funded researchers) to be pluripotent, similar to embryonic stem cells, with the ability to form *any* tissue necessary (*e.g.*, "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell," *Cell* 105, 369-377; May 4, 2001; "Generalized Potential of Adult Neural Stem Cells," *Science* 288, 1600-1663; June 2, 2000; Adult Rat and Human Bone Marrow Stromal Cells Differentiate Into Neurons," *Journal of Neuroscience Research* 61:364-370; Aug. 2000).

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**NIH:** "[S]tem cells in adults are often present in only minute quantities, are difficult to isolate and purify, and their numbers may decrease with age...Any attempt to use stem cells from a patient's own body for treatment would require that stem cells would first have to be isolated from the patient and then grown in culture in sufficient numbers to obtain adequate quantities for treatment."

**FACT**: Research is showing these claims not to be true. Research from April, 2001 shows that only ONE transplanted adult stem cell may be able to regenerate tissue in several parts of the body ("Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell"; *Cell* 105, 369-377; May 4, 2001).

In fact, research indicates that previously reported human stem cell frequencies and their self-renewal activity have been markedly underestimated and that sufficient numbers of adult stem cells can be easily generated for clinical applications ("High marrow seeding efficiency of human lymphomyeloid repopulating cells in irradiated NOD/SCID mice," *Blood* 96, 3979-3981; Dec. 1 2000; "Ex vivo expansion of human umbilical cord blood and peripheral blood CD34(+) hematopoietic stem cells"; *Experimental Hematology* 28, 1297-1305; Nov. 1 2000).

Canadian scientists have identified a way to make adult stem cells grow in the laboratory in much the same way as they do in the developing human embryo. Adult bone marrow stem cells and cord blood cells, when treated with a naturally-occurring protein dubbed "sonic hedgehog" by its discoverer, grow in culture similar to the way that embryonic stem cells grow. The protein stimulates growth of significant quantities of adult stem cells (G. Bhardwaj *et al.*, "Sonic hedgehog induces the proliferation of primitive hematopoietic cells via BMP regulation," *Nature Immunology* 2, 172-180; Feb. 2001

In March 2000, researchers in Philadelphia identified the conditions to allow large-scale expansion of adult stem cells in culture, making these cells an almost unlimited resource. The researchers achieved a billion-fold increase in a few weeks for bone marrow stem cells in culture. ("Rapid expansion of recycling stem cells in cultures of plastic-adherent cells from human bone marrow," *Proceedings of the National Academy of Sciences* 97, 3213-3218; March 28, 2000).

In August 2000 research funded by the NIH itself and the Christopher Reeve Paralysis Foundation found that adult human bone marrow stem cells can create a "virtually limitless supply" of nerve cells ("Christopher Reeve Paralysis Foundation Funds Breakthrough Research," Press Release of the Christopher Reeve Paralysis Foundation, 8/14/00). According to the published research results, the adult stem cells "grow rapidly in culture, precluding the need for immortalization, and differentiate into neurons exclusively with use of a simple protocol" ("Adult Rat and Human Bone Marrow Stromal Cells Differentiate Into Neurons," *Journal of Neuroscience Research* 61, 364-370: Aug. 2000).

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**NIH**: "[B]rain cells from adults that may be neural stem cells have been obtained only by removing a portion of the brain of an adult with epilepsy, a complex and invasive procedure that carries the added risk of further neurological damage."

**FACT**: Human neural stem cells have been isolated from other, more accessible regions of the brain from numerous volunteers ("Isolation and Characterization of Neural Stem Cells from the Adult Human Olfactory Bulb, *Stem Cells* 18, 295-300; July 2000), and even from cadavers ("Progenitor cells from human brain after death," *Nature* 411, 42-43; May 3, 2001).

The NIH/Christopher Reeve Paralysis Foundation research demonstrates that adult bone marrow stem cells can form nerve cells, eliminating the need to isolate such cells from the patient's brain: "The marrow cells are readily accessible, overcoming the risks of obtaining neural stem cells from the brain, and provide a renewable population. Autologous transplantation overcomes the ethical and immunological concerns associated with the use of fetal tissue" ("Adult Rat and Human Bone Marrow Stromal Cells Differentiate Into Neurons," *Journal of Neuroscience Research* 61, 364-370; Aug. 2000).

In addition, studies with mice have shown that, given appropriate signals, neural stem cells do not need to be removed from the brain at all for growth. Rather, they can be stimulated to regrow while still residing *within* the brain. The re-growth could take place even in regions of the adult mammalian brain that do not normally undergo new cell growth. The researchers report: "Our results indicate that neural replacement therapies for neurodegenerative diseases and CNS injury may be possible through manipulation of endogenous neural precursors *in situ*" ("Induction of neurogenesis in the neocortex of mice," *Nature* 405, 951-955, 6/22/00). Again, discoveries in animal models will almost certainly lead to applications in humans.

*

**NIH**: "[I]n disorders that are caused by a genetic defect, the genetic error likely would be present in the patient's stem cells, making cells from such a patient inappropriate for transplantation."

**FACT**: But such transplantation is *exactly* what was done for three children in France, as reported in April of this year. The infants, who had a genetic defect that caused severe immunodeficiency disease, had some of their own bone marrow cells removed. The cells were cultured, the defective gene causing the immune deficieny replaced, and the children were then treated with their own stem cells. This experiment using adult stem cells appears to be the first successful instance of a cure by human gene therapy ("Gene Therapy of Severe Combined Immunodeficiency (SCID)-X1 Disease," *Science* 288, 669-672, 4/28/00).

Moreover, correction of the genetic defect may not always be necessary to effect a cure with adult stem cells. The British medical journal *Lancet* reports researchers treating systemic lupus (an incurable and sometimes fatal autoimmune disease) using the patients' own bone marrow cells. When transplanted back into the patients, the cells appeared to have overcome the defect in all patients and repaired organ damage previously considered permanent. The scientists noted: "It is mysterious that the transplanted cells, which have the same genetic defect that made the patients' immune cells go wrong in the first place, did not grow up to repeat the mistakes of their siblings" ("Treatment of severe systemic lupus erythematosus with high-dose chemotherapy and haemopoietic stem-cell transplantation: a phase I study," *Lancet* 356, 701-707, August 2000).

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*Do No Harm: The Coalition of Americans for Research Ethics rejects the course of action taken by the National Institutes for Health to support destructive human embryonic stem cell research. Instead, our government should promote adult stem cell research which protects the inviolability of individuals, rejects harming some for the potential benefit of others, and holds as much, if not more, promise for medical progress.*

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# Potential Applications of Adult Stem Cells

## NEURAL STEM CELLS

**Progenitors from adult rat spinal cord using bFGF alone show stem cell properties including self-renewal. Cultures from single cells generate neurons, astrocytes, and oligodendrocytes. Transplantation into adult rat spinal cord resulted in differentiation into glial cells. Transplantation into hippocampus resulted in integration in the granular cell layer and differentiation of cells with astroglial and oligodendroglial phenotypes. Can generate region-specific neurons in vivo when exposed to appropriate environmental cues.

**Reference:**
Shihabuddin S *et al.*; "Adult spinal cord stem cells generate neurons after transplantation in the adult dentate gyrus"; J Neuroscience 20, 8727-8735; December 2000

**Adult stem cells from mouse bone marrow injected into mouse blood stream, could be found developing neuron characteristics in brain. Generation of brain cells from adult bone marrow "demonstrates a remarkable plasticity of adult tissues with potential clinical applications."

**Reference:**
Brazelton TR *et al.*; "From marrow to brain: expression of neuronal phenotypes in adult mice"; Science 290, 1775-1779; Dec 1 2000

**Showed in mice that transplanted adult bone marrow stem cells can migrate into brain and differentiate into neuronal cells. "These findings raise the possibility that bone marrow-derived cells may provide an alternative source of neurons in patients with neurodegenerative diseases or central nervous system injury"

**Reference:**
Mezey E *et al.*; "Turning blood into brain: Cells bearing neuronal antigens generated in vivo from bone marrow"; Science 290, 1779-1782; Dec 1 2000

**Implanted neural stem cells infiltrate brain tumors. The neural stem cells show the ability to migrate extensively throughout the brain to reach sites of damage. The results "suggest that NSC migration can be extensive, even in the adult brain and along nonstereotypical routes."

**Reference:**
Aboody KS, Brown A, Rainov NG, Bower KA, Liu S, Yang W, Small JE, Herrlinger U, Ourednik V, Black PM, Breakefield XO, Snyder EY ; "From the cover: neural stem cells display extensive tropism for pathology in adult brain: evidence from intracranial

gliomas"; Proc Natl Acad Sci U S A 97, 12846-12851; Nov 7 2000

**Characterized CCg, glycosylated form of cystatin C; required for FGF-2's mitogenic activity on neural stem cells. Combined delivery of FGF-2 and CCg to adult dentate gyrus stimulated neurogenesis.

**Reference:**
Taupin P *et al.*; "FSF-2-responsivie neural stem cell proliferation required CCg, a novel autocrine/paracrine cofactor"; Neuron 28, 385-397; February 2001

**Review of plasticity in neural tissues and possibilities for repair.

**Reference:**
Hodge CJ Jr. and Boakye M; "Biological Plasticity: The future of science in neurosurgery"; Neurosurgery 48, 2-16; Jan 2001

HUMAN and mouse adult neural stem cells could be reprogrammed to form skeletal muscle.
Italian researchers have transformed adult neural stem cells from humans and mice, changing the cells into muscle. The transformation to muscle not only took place in culture, but also after injection into mice. Dr. Luigi Vescovi, co-director of the Stem Cell Research Institute in Milan, said that the most obvious possibility for therapeutic development was in the area of muscular dystrophy. In its statement, the Institute noted, "With adult stem cells there would also be the possibility of auto-transplantation, eliminating all the problems of immunological compatibility and rejection." Transplant rejection would be a significant problem if using embryonic stem cells.

**Reference:**
Galli, R. *et al.*, "Skeletal myogenic potential of human and mouse neural stem cells", Nature Neuroscience 3, 986-991, October, 2000.

Adult neural stem cells from rat were shown to form various types of functional nerve connections in culture.

**Reference:**
Toda H *et al.*; "Neurons generated from adult rat hippocampal stem cells form functional glutamatergic and GABAergic synapses *in vitro*"; Experimental Neurology 165, 66-76; September 2000.

Mitogens in the cell culture medium confer conditional immortalization; removal of mitogens results in differentiation to the 3 fundamental cell types in the central nervous system

**Reference:**
Villa A *et al.*; "Establishment and properties of a growth factor-dependent, perpetual neural stem cell line from the human CNS"; Exp. Neurol. 161, 67-84; January 2000

Adult Stem Cells from Brain Able to Form Virtually Any Tissue
Research with mice indicates that adult stem cells from brain can grow into a wide variety of organs-heart, lung, intestine, kidney, liver, nervous system, muscle, and other tissues.

The study by Swedish scientists, reported in the June 2, 2000 issue of *Science,* confirms that adult stem cells are in fact much more adept at redefining themselves than previously thought. The study involved growing adult stem cells from brain with embryonic cells and within an embryo. Even lone neural adult stem cells had the ability to differentiate into various cell types. The authors observe that the "most striking indication" of this complete cellular redefinition was the finding of apparently normal and beating embryonic mouse hearts that contained very large amounts of the stem cells.

According to Dr. Ihor Lemischka, professor of developmental biology at Princeton University, "This is a very exciting and interesting result," and if the research can be confirmed in human cells it would "nip in the bud" the moral and ethical concerns that now block federal funding of human embryonic stem cell research. The authors of the study state that "This demonstrates that an adult neural stem cell has a very broad developmental capacity and may potentially be used to generate a variety of cell types for transplantation in different diseases." They also note that "…these studies suggest that stem cells in different adult tissues may be more similar than previously thought and perhaps in some cases have a developmental repertoire close to that of ES cells."

**Reference:**
Clarke *et al.*; "Generalized potential of adult neural stem cells"; Science 288, 1660-1663, June 2, 2000.

Adult Stem Cells in Brain Stimulated to Grow and Replace Damaged Brain Tissue
Studies in mice show that adult stem cells in the brain can be stimulated to grow and replace damaged neural tissue. The re-growth could take place even in regions of adult mammalian brain that do not normally undergo any new cell growth, and the neurons were able to re-form appropriate connections within the adult brain. The authors state that "Our results indicate that neuronal replacement therapies for neurodegenerative disease and CNS injury may be possible through manipulation of endogenous neural precursors *in situ*." Commenting on the report, Drs. Anders Bjorklund and Olle Lindvall of Lund University in Sweden noted that learning how to activate stem cells in the brain "might eventually lead to a powerful tool for brain repair in human disorders of the central nervous system." Scientists have already used implants of adult neural stem cells to cure mice of severe brain disorders.

**References:**
Magavi *et al.*; "Induction of neurogenesis in the neocortex of adult mice"; Nature 405, 951-955, June 22, 2000.

Bjorklund A and Lindvall O; "Self-repair in the brain"; Nature 405, 892-893, June 22, 2000.

Brain cells called "oligodendrocytes" could be "reprogrammed", forming complete adult neural stem cells which could generate all cell types of the brain.

**Reference:**
Kondo, T. and Raff, M. "Oligodendrocyte precursor cells reprogrammed to become multipotent CNS stem cells"; Science 289, 1754-1757; Sept. 8, 2000.

Adult neural stem cells isolated from different regions of the human brain (lateral

ventricle wall and hippocampus).

**Reference:**
Johansson CB *et al.*; "Neural stem cells in the adult human brain"; Exp. Cell Res. 253, 733-736; December 1999.

Adult neural stem cells identified in additional sites within the brain. The cells migrate to other regions as well (ependymal cells, migrate to olfactory bulb.)

**Reference:**
Johansson CB *et al.*; "Identification of a neural stem cell in the adult mammalian central nervous system"; Cell 96, 25-34; January 1999

Turning Brain Into Blood
Adult neural stem cells can be "retrained" for a new occupation-as blood stem cells. It has been known since 1997 that adult neural stem cells can regenerate the three major cell types in the brain. Working together, scientists in Canada and Italy now have shown that neural stem cells from mice can also form numerous blood cell types. The results are surprising because it was previously thought that adult stem cells were restricted to forming only cell types from the tissue in which they were found. Given that human neural stem cells can be expanded in culture for extended periods of time, the results open possibilities for future treatment of a number of disorders.

**Reference:**
Bjornson *et al.*; "Turning brain into blood: a hematopoietic fate adopted by adult neural stem cells in vivo"; Science 283, 534-537; January 22, 1999

Adult Stem Cells Possible for Repair of Spinal Cord Damage
Researchers in the UK announced that they have isolated a human adult stem cell which can function in repair of nerve damage, for example in spinal cord repair or other parts of the central nervous system (CNS). The human adult stem cell, known as an "olfactory ensheathing cell" (OEC), was able to repair nerve axons in damaged rat spinal cord. The scientists noted that "Thus, the human OEC represents an important new cell for the development of transplant therapy of CNS diseases."

**Reference:**
Barnett *et al.*; "Identification of a human olfactory ensheathing cell that can effect transplant-mediated remyelination of demyelinated CNS axons"; Brain 123, 1581-1588, August 2000

Adult neural stem cells identified in a relatively accessible part of the human brain, allowing easier removal. The cells can be expanded, established in continuous cell lines and differentiated into the three classical neuronal phenotypes (neurons, astrocytes, and oligodendrocytes). Also, after exposition to leukemia inhibitory factor, we are able to improve the number of neurons, an ideal biological source for transplantation in various neurodegenerative disorders.

"similar to human embryonic stem cells" "The fact that this revolutionary strategy uses autologous neuronal material means that it has all of the advantages of biosafety, histocompatibility, and neurophysiological efficiency. Furthermore, it does not raise the

ethical and moral questions associated with the use of embryonic or heterologous material."

**Reference:**
Pagano S *et al.*; "Isolation and Characterization of Neural Stem Cells from the Adult Human Olfactory Bulb"; Stem Cells 18, 295-300; 2000

**Marrow stem cells injected into mouse brain migrated through forebrain and cerebellum without disrupting host brain structure. The marrow stem cells populated various regions of the brain, and differentiated into astrocytes. These stem cells are proposed as methods for treating a variety of central nervous system disorders.

**Reference:**
Kopen GC *et al.*; "Marrow stromal cells migrate throughout forebrain and cerebellum, and they differentiate into astrocytes after injection into neonatal mouse brains"; Proc. Natl. Acad. Sci. USA 96, 10711-10716; Sept 14 1999

Review of methods which now enable cell immortalization, purification and safety mechanisms, and genetic therapy using neural stem cells.

**Reference:**
Foster GA, Stringer BM; "Genetic regulatory elements introduced into neural stem and progenitor cell populations"; Brain Pathol. 9, 547-567; July 1999.

Adult neural stem cells transplanted into mice which have a condition similar to Parkinson's disease. The cells migrated through the brain, repairing tissue and decreasing tremors in the mice.

**Reference:**
Yandava BD *et al.*; " 'Global' cell replacement is feasible via neural stem cell transplantation: evidence from the dysmyelinated shiverer mouse brain"; Proc. Natl. Acad. Sci. USA 96, 7029-7034; June 8, 1999

Treatment of damaged spinal cord with added growth factors allowed re-growth of damaged spinal cord neurons in rats.

**Reference:**
Ramer MS *et al.*; "Functional regeneration of sensory axons into the adult spinal cord"; Nature 403, 312-316; January 20, 2000

Adult neural stem cells could treat retinal problems. Researchers have found that adult neural stem cells may be useful in treating blindness due to problems with the retina. The eyes of rats that had degradation of their retinas were injected with adult neural stem cells. The cells migrated to the retina and began to take on characteristics of retinal cells. Interestingly, this only occurred if the retina was damaged and not in undamaged retinas. Dr. Michael Young of the Schepens Eye Research Institute, who led the study, said "These cells somehow sense that they are needed and begin to differentiate into cells that could take on the job of retinal neurons." The finding raises the possibility of using adult stem cells for patients with macular degeneration and glaucoma.

**Reference:**
Young MJ *et al.*, "Neuronal differentiation and morphological integration of hippocampal progenitor cells transplanted to the retina of immature and mature dystrophic rats", Molecular and Cellular Neurosciences 16, 197-205; Sept., 2000.

Development of Stable Neural Stem Cell Lines. Stable clones of neural stem cells (fetal-derived); cells are self-renewing. Transplanted into mouse they migrate along established pathways to CNS regions, differentiate into multiple types, intersperse with host cells. Can be genetically engineered, cryopreservable.

**Reference:**
Flax JD *et al.*, "Engraftable human neural stem cells respond to developmental cues, replace neurons, and express foreign genes", Nature Biotechnol. 16, 1033; November, 1998

Establishment of human neural cell lines. Established immortalized human CNS cell lines, can differentiate into functional sensory neurons.

**Reference:**
Raymon HK *et al.*, "Immortalized human dorsal root ganglion cells differentiate into neurons with nociceptive properties", J. Neurosci 19, 5420; July 1, 1999

Used NTERA-2 (EC line, from teratocarcinoma) to demonstrate developmental regulation of neurogenesis.

**Reference:**
Przyborski SA *et al.*; "Developmental regulation of neurogenesis in the pluripotent human embryonal carcinoma cell line NTERA-2"; Eur. J. Neurosci. 12, 3521-3528; Oct. 2000

**"infused intraparenchymally, NGF rescues basal forebrain cholinergic neurons, alters the topography of axonal sprouting responses, and does not induce adverse affects over a 2-week infusion period. Intraparenchymal NGF delivery merits further study at longer term time points as a means of treating the cholinergic component of neuronal loss in Alzheimer's disease."

**Reference:**
Tuszynski MH; "Intraparenchymal NGF infusions rescue degenerating cholinergic neurons"; Cell Transplant 9; 629-636; Sept-Oct 2000

**Study identified reversible cellular atrophy as a potential aging mechanism in the brain; used neurotrophin gene transfer as potential effective method to prevent neural degeneration.

**Reference:**
Smith DE, Roberts J, Gage FH, Tuszynski MH; "Age-associated neuronal atrophy occurs in the primate brain and is reversible by growth factor gene therapy"; Proc Natl Acad Sci U S A 96, 10893-10898; Sept 14 1999

## RETINAL STEM CELLS

Neural Stem Cells in Adult Mammalian Eye. Researchers at University of Nebraska

Medical Center have isolated neural stem cells from adult mammalian eye. In culture the cells show the ability for self-renewal, and can differentiate showing characteristics of retina, neurons, and glia.

**Reference:**
Ahmad I *et al.*; "Identification of neural progenitors in the adult mammalian eye"; Biochem. Biophys. Res. Commun. 270, 517-521; April 13, 2000

Retinal Stem Cells Found in Adult Eye

Researchers at the University of Toronto have identified retinal stem cells in the adult mammalian eye. The adult stem cells were found in humans, cows, and mice. While still in the eye, the cells appear to be under an inhibitory control, but once removed and placed in culture the cells grow. The scientists hope to learn how to stimulate the stem cells inside the eye so that proper function can be restored. The results open the way to possible regeneration of retinal tissue.

**Reference:**
Tropepe *et al.*; "Retinal stem cells in the adult mammalian eye"; Science 287, 2032-2036, March 17, 2000.

## MUSCLE STEM CELLS

**"Transplantation of fetal cardiomyocytes improves function of infarcted myocardium but raises availability, immunologic, and ethical issues that justify the investigation of alternate cell types, among which skeletal myoblasts are attractive candidates." "These results support the hypothesis that skeletal myoblasts are as effective as fetal cardiomyocytes for improving postinfarction left ventricular function. The clinical relevance of these findings is based on the possibility for skeletal myoblasts to be harvested from the patient himself."

**Reference:**
Scorsin M, Hagege A, Vilquin JT, Fiszman M, Marotte F, Samuel JL, Rappaport L, Schwartz K, Menasche P ; "Comparison of the effects of fetal cardiomyocyte and skeletal myoblast transplantation on postinfarction left ventricular function"; J Thorac Cardiovasc Surg 119; 1169-1175; June 2000

**Autologous skeletal myoblast (SM) transplantation improves function of infarcted myocardium in rats.

**Reference:**
Pouzet B, Vilquin JT, Hagege AA, Scorsin M, Messas E, Fiszman M, Schwartz K, Menasche P; "Intramyocardial transplantation of autologous myoblasts : can tissue processing Be optimized?"; Circulation 102; III210-215; Nov 72000

Blood Cells From Muscle
Researchers at Baylor College of Medicine have found that skeletal muscle contains stem cells which can form all the major types of blood cells. Using adult mice, they isolated skeletal muscle cells, grew them in culture, and placed the stem cells into mice whose bone marrow cells were destroyed. The transplanted stem cells took up the job of forming all blood cells for the mice.

**Reference:**
Jackson K *et al.*; "Hematopoietic potential of stem cells isolated from murine skeletal muscle"; Proceedings National Academy of Sciences USA 96, 14482-14486; December 7, 1999

Adult stem cells to treat muscular dystrophy
Used a mouse model of Duchenne's muscular dystrophy. Purified adult muscle stem cells from these mice. Intravenous injection of these muscle-derived adult stem cells back into the mice resulted in muscle regeneration and partial restoration of dystrophin expression in the mice. Transplantation of these cells engineered to secrete a bone protein results in their differentiation into bone cells and acceleration of healing of a skull defect in immunodeficient mice.

**Reference:**
Lee JY *et al.*; "Clonal isolation of muscle-derived cells capable of enhancing muscle regeneration and bone healing"; J. Cell Biology 150, 1085-1100; September 4, 2000

An animal model of Duchenne's muscular dystrophy which indicate that the intravenous injection of either normal haematopoietic stem cells or a novel population of muscle-derived stem cells into irradiated animals results in the reconstitution of the haematopoietic compartment of the transplanted recipients, the incorporation of donor-derived nuclei into muscle, and the partial restoration of dystrophin expression in the affected muscle. These results suggest that the transplantation of different stem cell populations, using the procedures of bone marrow transplantation, might provide an unanticipated avenue for treating muscular dystrophy as well as other diseases where the systemic delivery of therapeutic cells to sites throughout the body is critical. Our studies also suggest that the inherent developmental potential of stem cells isolated from diverse tissues or organs may be more similar than previously anticipated.

**Reference:**
Gussoni E *et al.*; "Dystrophin expression in the mdx mouse restored by stem cell transplantation"; Nature 401, 390-394; 23 September 1999

Obtained stem cells from skeletal muscle, which in culture could form skeletal myotubes, smooth muscle, bone, cartilage, fat.

**Reference:**
Williams JT *et al.*; "Cells isolated from adult human skeletal muscle capable of differentiating into multiple mesodermal phenotypes"; Am. Surg. 65, 22; January 1999

Proposed use of numerous stem cells which have shown promise for cardiac repair, incl. myogenic cell lines, adult skeletal myoblasts, immortalized atrial cells, adult cardiomyocytes, altered fibroblasts, smooth muscle cells, and bone marrow-derived cells. Best developed option is mesodermally derived cells.

**Reference:**
Kessler PD, Byrne BJ; "Myoblast cell grafting into heart muscle: cellular biology and potential applications", Ann. Rev. Physiol. 61, 219; 1999

## SKIN STEM CELLS

Taylor G; "Involvement of follicular stem cells in forming not only the follicle but also the epidermis"; Cell 102, 451-461; August 2000

## PANCREATIC STEM CELLS

**Review of possible stem cell treatments for diabetes. The review notes that "Human pancreatic duct cells have also been grown successfully in vitro and induced to differentiate", and "Not only does the use of adult donor ductal cells avoid the controversy of using fetal cells but there are fewer biological problems associated with making beta cells from duct cells than from, for example, embryonic stem cells." It points out that "…differentiation into endodermal cell types has not yet been reported" for human embryonic stem cells; pancreatic cells are an endodermal cell type. The authors also point out that insulin producing cells had been derived from mouse embryonic stem cells, but "this procedure gives rise to proliferating cells, and thereby potentially malignant cells, rather than mature, post-mitotic cells." The authors note "When the nature of pancreatic beta cell ontogeny is fully understood we may be able to mimic this process in vitro to propagate beta cells-either starting with duct cells derived from pancreatic donor specimens or by the use of other appropriate human stem cells (such as from bone marrow or even blood samples). This development would clearly be welcome because it would avoid the need for therapeutic cloning, with all the attendant controversy of creating human embryos solely for medical use." The authors conclude that "Of the techniques described above, the most promising is generation of beta cells from pancreatic duct cells. It is inherently a shorter biological step to make a beta cell from a duct cell than it is from other possible cells, such as embryonic stem cells and haemopoietic stem cells."

**Reference:**
Serup P, Madsen OD, Mandrup-Poulsen T; "Islet and stem cell transplantation for treating diabetes"; British Medical Journal 322, 29-32; Jan 6 2001

**"Genetic engineering of non-beta cells to release insulin upon feeding could be a therapeutic modality for patients with diabetes. The workers derived a mouse cell line that could be induced to produce human insulin. Mice expressing this transgene produced human insulin specifically in gut cells. This insulin protected the mice from developing diabetes and maintained glucose tolerance after destruction of the native insulin-producing beta cells in their pancreas.

**Reference:**
Cheung AT, Dayanandan B, Lewis JT, Korbutt GS, Rajotte RV, Bryer-Ash M, Boylan MO, Wolfe MM, Kieffer TJ; "Glucose-dependent insulin release from genetically engineered K cells"; Science 290; 1959-1962; Dec 8 2000

Evidence for Human Adult Pancreatic Stem Cells - Researchers in France have found further evidence for pancreatic stem cells in humans. The pancreatic cells from healthy donors, when placed into culture, proliferated and expressed characteristics critical for production and secretion of insulin. The results are another step toward treatment of diabetes using adult stem cells.

**Reference:**
V Gmyr *et al.*, "Adult human cytokeratin 19-positive cells reexpress insulin promoter factor 1 in vitro: Further evidence for pluripotent pancreatic stem cells in humans",

Diabetes 49, 1671-1680; Oct. 2000

**Cultured human pancreatic ductal cells under specific conditions. The cells formed islet buds and secreted insulin. "Thus, duct tissue from human pancreas can be expanded in culture and then be directed to differentiate into glucose responsive islet tissue in vitro. This approach may provide a potential new source of pancreatic islet cells for transplantation."

**Reference:**
Bonner-Weir S *et al.*; "In vitro cultivation of human islets from expanded ductal tissue"; Proc Natl Acad Sci USA 97, 7999-8004; July 5, 2000

Were able to reverse diabetes in mice using the animals' own adult stem cells; after treatment, the mice no longer needed insulin shots to survive.

**Reference:**
Ramiya VK *et al.*; "Reversal of insulin-dependent diabetes using islets generated in vitro from pancreatic stem cells"; Nature Medicine 6, 278-282; March 2000

## BONE MARROW STEM CELLS and PERIPHERAL BLOOD STEM CELLS

**Autologous transplantation of marrow stromal stem cells, injected into myocardium of rats. The marrow stromal stem cells showed myogenic differentiation, including indication that the injected stem cells, as well as native cardiomyocytes, were connected. The authors note that "In an appropriate microenvironment they will exhibit cardiomyogenic phenotypes and may replace native cardiomyocytes lost by necrosis or apoptosis. Because marrow stromal cells can be obtained repeatedly by bone marrow aspiration and expanded vastly in vitro before being implanted or used as autologous implants, and because their use does not call for immunosuppression, the clinical use of marrow stromal cells for cellular cardiomyoplasty appears to be most advantageous."

**Reference:**
Wang J-S, Shum-Tim D, Galipeau J, Chedrawy E, Eliopoulos N, Chiu Ray C-J; "Marrow stromal cells for cellular cardiomyoplasty: Feasibility and potential clinical advantages"; The Journal of Thoracic and Cardiovascular Surgery 120, 999-1006; Nov 2000

**Adult stem cells from mouse bone marrow injected into mouse blood stream, could be found developing neuron characteristics in brain. Generation of brain cells from adult bone marrow "demonstrates a remarkable plasticity of adult tissues with potential clinical applications."

**Reference:**
Brazelton TR *et al.*; "From marrow to brain: expression of neuronal phenotypes in adult mice"; Science 290, 1775-1779; Dec 1 2000

**Showed in mice that transplanted adult bone marrow stem cells can migrate into brain and differentiate into neuronal cells. "These findings raise the possibility that bone marrow-derived cells may provide an alternative source of neurons in patients with neurodegenerative diseases or central nervous system injury"

**Reference:**
Mezey E *et al.*; "Turning blood into brain: Cells bearing neuronal antigens generated in vivo from bone marrow"; Science 290, 1779-1782; Dec 1 2000

**Previously reported human stem cell frequencies and their in vivo self-renewal activity have been markedly underestimated.

**Reference:**
Cashman JD and Eaves CJ; "High marrow seeding efficiency of human lymphomyeloid repopulating cells in irradiated NOD/SCID mice"; Blood 96, 3979-3981; Dec. 1 2000

**Tested human peripheral blood stem cells injected into mice. Results showed stromal progenitor cells present in human peripheral blood or cord blood, which could be used to re-seed bone marrow.

**Reference:**
Goan *et al.*; "Donor stromal cells from human blood engraft in NOD/SCID mice"; Blood 96, 3971-3978; Dec 1 2000

**Transplanted human mesenchymal (bone marrow) stem cells into fetal sheep early in gestation. The cells engrafted and persisted in multiple tissues, and underwent site-specific differentiation into chondrocytes, adipocytes, myocytes, cardiomyocytes, bone marrow stromal cells, and thymic stroma. "Our data support the possibility of the transplantability of mesenchymal stem cells and their potential utility in tissue engineering, and cellular and gene therapy applications."

**Reference:**
Liechty KW *et al.*; "Human mesenchymal stem cells engraft and demonstrate site-specific differentiation after in utero transplantation in sheep"; Nature Medicine 6, 1282-1286; Nov 2000

**Intravenous injection of adult bone marrow stem cells in a mouse model of tyrosinemia type I rescued the mouse and restored biochemical function of its liver.

**Reference:**
Lagasse E *et al.*; "Purified hematopoietic stem cells can differentiate into hepatocytes in vivo"; Nature Medicine 6, 1229-1234; Nov 2000

**Used a mouse model of progressive and ultimately fatal systemic autoimmune disease; these mice develop degenerative coronary vascular disease with myocardial infarctions and hypertension. Transplanted bone marrow stem cells from mice which allowed survival of the recipients, and significant amelioration of degenerative coronary vascular disease.

**Reference:**
Kirzner RP *et al.*; "Prevention of coronary vascular disease by transplantation of T-cell-depleted bone marrow and hematopoietic stem cell preparation in autoimmune-prone w/BF(1) mice"; Biol. Blood Marrow Transplant 6, 513-522; 2000

**Identified role of the *Notch* gene as a signal regulating hematopoietic stem cell self-renewal. "Furthermore, the establishment of clonal, pluripotent cell lines provides the

opportunity to assess mechanisms regulating stem cell commitment and demonstrates a general method for immortalizing stem cell populations for further analysis."

**Reference:**
Varnum-Finney B *et al.*; "Pluripotent, cytokine-dependent, hematopoietic stem cells are immortalized by constitutive Notch1 signaling"; Nature Medicine 6, 1278-1281; Nov 2000

**Identification of expression of the *hiwi* gene in human stem cells; gene similar to that expressed in embryonic germline stem cells of Drosophila and shown to be important for stem cell renewal. The gene is not expressed in more differentiated cell populations. Expression also detected in many developing fetal and adult tissues. The *hiwi* gene appears to be an important negative developmental regulator which in part underlies the unique biologic properties associated with progenitor cells.

**Reference:**
Sharma AK *et al.*; "Human CD34(+) stem cells express the hiwi gene, a human homologue of the Drosophila gene piwi"; Blood 97, 426-434; Jan 15 2001

**Studied growth factors for stem cell replication in culture. Single-cell replication of self-renewing stem cells achieved with Stem Cell Factor and Thrombopoietin. Regenerated populations could be transplanted into secondary recipients. Study also shows evidence that one hematopoietic stem cell regenerates at least one stem cell in culture.

**Reference:**
Ema H *et al.*; "In vitro self-renewal division of hematopoietic stem cells"; J. Exp. Med. 192, 1281-1288; Nov 6 2000

**Review of techniques to isolate hematopoietic and mesenchymal stem cells from various sources, and expansion and differentiation in culture for potential clinical uses.

**Reference:**
Huss R; "Isolation of primary and immortalized CD34- hematopoietic and mesenchymal stem cells from various sources"; Stem Cells 18, 1-9; 2000

HUMAN and mouse bone marrow stem cells able to form nerve cells. Dr. Juan Sanchez-Ramos, lead scientist, noted that "It's striking that we can generate new kinds of cells from deep within the bone, including cells with the potential to become neurons for brain repair." Layton BioScience, Inc. has licensed the rights to this technology and is developing it for clinical use.

**Reference:**
Sanchez-Ramos J *et al.*; "Adult bone marrow stromal cells differentiate into neural cells in vitro"; Experimental Neurology 164, 247-256; August 2000

Adult human bone marrow stem cells can create a "virtually limitless supply" of nerve cells. According to the published results, the adult stem cells "grow rapidly in culture, precluding the need for immortalization, and differentiate into neurons exclusively with use of a simple protocol". The report also notes that "The marrow cells are readily

accessible, overcoming the risks of obtaining neural stem cells from the brain, and provide a renewable population. Autologous transplantation overcomes the ethical and immunological concerns associated with the use of fetal tissue."

**Reference:**
Woodbury D *et al.*; "Adult rat and human bone marrow stromal cells differentiate into neurons"; J. Neuroscience Research 61, 364-370; August 15, 2000

Generated large numbers of dendritic cells from HUMAN blood monocytes. Provides example of use for clinical immunotherapy.

**Reference:**
Cao H *et al.*; "In vitro generation of dendritic cells from human blood monocytes in experimental conditions compatible for in vivo cell therapy"; J. Hematother. Stem Cell Res. 9, 183-194; April 2000.

HUMAN bone marrow stem cells can form liver. According to Dr. Nick Wright, professor at the Imperial Cancer Research Fund,, since patients could use their own stem cells, "We could avoid problems with current liver transplants where the patient's body rejects the foreign organ." Dr. Markus Grompe, professor of molecular medical genetics at Oregon Health Sciences University, said "This would suggest that maybe you don't need any type of fetal stem cell at all-that our adult bodies continue to have stem cells that can do this stuff."

**Reference:**
Theise N *et al.*; "Liver from bone marrow in humans"; Hepatology 32, 11-16; July 2000

Alison M *et al.*; "Cell differentiation: hepatocytes from non-hepatic adult stem cells"; Nature 406, 257; July 20, 2000

Bone marrow cells able to form liver.

**Reference:**
Theise N *et al.*; "Derivation of hepatocytes from bone marrow cells in mice after radiation-induced myeloablation"; Hepatology 31, 235-240; January 2000

Bone marrow able to form liver.

**Reference:**
Petersen B *et al.*; "Bone marrow as a potential source of hepatic oval cells"; Science 284, 1168-1170; May 14, 1999

Bone-specific expression of gene in marrow cells, showing targeted gene therapy for transplantation.

**Reference:**
Lian JB, Stein GS, Stein JL, van Wijnen AJ; "Marrow transplantation and targeted gene therapy to the skeleton"; Clin Orthop 379 Suppl, S146-155; Oct. 2000.

Review of bone marrow as a source of cells for nervous system.

**Reference:**
Mezey E, Chandross, KJ; "Bone marrow: a possible alternative source of cells in the adult nervous system"; Eur. J. Pharmacol. 405, 297-302; Sept. 29, 2000

Conditions have been identified to allow large-scale expansion of adult stem cells in culture, making these cells an almost unlimited source. Able to achieve a billion-fold increase in cell number in just a few weeks.

**Reference:**
Colter D *et al.*; "Rapid Expansion of recycling stem cells in cultures of plastic-adherent cells from human bone marrow"; Proc. Natl. Acad. Sci. USA 97, 3213-3218; March 28, 2000

Able to achieve a significant increase in number of human hematopoietic stem cells in culture.

**Reference:**
Ueda T *et al.*; "Expansion of human NOD/SCID-repopulating cells by stem cell factor, Flk2/Flt3 ligand, thrombopoietin, IL-6, and soluble IL-6 receptor"; J. Clin. Invest. 105, 1013-1021; April 2000

Description of potential mechanism to direct bone marrow (mesenchymal) stem cells to differentiate into specific lineages.

**Reference:**
Jaiswal RK *et al.*; "Adult huma mesenchymal stem cell differentiation to the osteogenic or adipogenic lineage is regulated by mitogen-activated protein kinase"; J. Biol. Chem. 275, 9645-9652; Mar. 31, 2000

In culture, the cells were stimulated to form either bone, cartilage, or fat cells. The cells appear to have the potential to form other tissues as well, including tendon and muscle.

**Reference:**
Pittenger MF *et al.*; "Multilineage potential of adult human mesenchymal stem cells"; Science 284, 143-147; April 2, 1999

**Marrow stem cells injected into mouse brain migrated through forebrain and cerebellum without disrupting host brain structure. The marrow stem cells populated various regions of the brain, and differentiated into astrocytes. These stem cells are proposed as methods for treating a variety of central nervous system disorders.

**Reference:**
Kopen GC *et al.*; "Marrow stromal cells migrate throughout forebrain and cerebellum, and they differentiate into astrocytes after injection into neonatal mouse brains"; Proc. Natl. Acad. Sci. USA 96, 10711-10716; Sept 14 1999

Human peripheral (circulating) blood contains stem cells for endothelial (blood vessel) cells.

**Reference:**
Asahara T *et* al.; "Isolation of Putative Progenitor Endothelial Cells for Angiogenesis"; Science 275, 964-967; February 14, 1997

Shi Q *et al.*; "Evidence for Circulating Bone Marrow-Derived Endothelial Cells"; Blood 92, 362-367; July 15, 1998

Long, possibly unlimited lifespan of hematopoietic stem cells in culture. Using mouse bone marrow, a SINGLE stem cell could repopulate the marrow of a lethally-irradiated mouse.

**Reference:**
Yagi M *et al.*; "Sustained ex vivo expansion of hematopoietic stem cells mediated by thrombopoietin"; Proc. Natl. Acad. Sci. USA 96, 8126-8131; July 1999

Able to repopulate bone marrow of mice with ONE transplanted stem cell.

**Reference:**
Bhatia M *et al.*; "Purification of primitive human hematopoietic cells capable of repopulating immune-deficient mice"; Proc. Natl. Acad. Sci. USA 94, 5320-5325; May 1997

Circulating blood contains stem cells which are from bone marrow (study done in dogs.)

**Reference:**
Huss R *et al.*; "Evidence of Peripheral Blood-Derived, Plastic-Adherent CD34 -/low Hematopoietic Stem Cell Clones with Mesenchymal Stem Cell Characteristics"; Stem Cells 18, 252-260, 2000

Using rat system, transplanted cells migrate to ischemic cortex.

**Reference:**
Eglitis MA *et al.*; "Targeting of marrow-derived astrocytes to the ischemic brain"; Neuroreport 10, 1289; April 26, 1999

Multiple tissue types can be derived from bone marrow stem cells, with many potential clinical uses.

**Reference:**
Deans, RJ and Moseley, AB, "Mesenchymal stem cells. Biology and potential clinical uses", Experimental Hematology 28, 875-884, August, 2000.

Human Bone Marrow Can Help Repair Brain Tissue

Human marrow stromal cells transplanted into rat. Cells engrafted, no evidence of inflammatory response or rejection. Useful for autotransplantation, gene therapy for variety of CNS diseases incl Parkinson's.

**Reference:**
Azizi SA, Stokes D, Augelli BJ, DiGirolamo C, Prockop DJ, "Engraftment and migration

of human bone marrow stromal cells implanted in the brains of albino rats-similarities to astrocyte grafts", Proc. Natl. Acad. Sci. USA 95, 3908; March, 1998

Bone Marrow Stem Cells Can Regenerate New Bone

Human mesenchymal stem cells, expanded in culture, regenerate human bone implanted in rats.

**Reference:**
Bruder SP, Kurth AA, Shea M, Hayes WC, Jaiswal N, Kadiyala S, "Bone regeneration by implantation of purified, culture-expanded human mesenchymal stem cells", J Orthop Res 16, 155; 1998

Allogeneic peripheral blood stem cell transplants as good or better than bone marrow

**Reference:**
Ringden O *et al.*, "Peripheral blood stem cell transplantation from unrelated donors: a comparison with marrow transplantation", Blood 94, 455; July 15, 1999

Human Bone Marrow Cells Induced To Form Bone In Culture

**Reference:**
Jaiswal N, Haynesworth SE, Caplan AI, Bruder SP, "Osteogenic differentiation of purified, culture-expanded human mesenchymal stem cells in vitro", J Cell Biochem 64:295-312; 1997

Bone Marrow Cells Maintain Potential After Long-Term Cryopreservation

**Reference:**
Bruder SP, Jaiswal N, Haynesworth SE, "Growth kinetics, self-renewal, and the osteogenic potential of purified human mesenchymal stem cells during extensive subcultivation and following cryopreservation", J Cell Biochem 64, 278; 1997

## LIVER STEM CELLS

**Developed culture and separation system for liver stem cells. When isolated liver stem cells were transplanted in mouse spleen, the cells migrated to the recipient liver and differentiated into mature liver cells. The authors suggest this approach could be used to isolate human liver stem cells and supplant whole organ transplant.

**Reference:**
Suzuki A *et al.*; "Flow-cytometric separation and enrichment of hepatic progenitor cell sin the developing mouse liver"; Hepatology 32, 1230-1239; Dec 2000

**Commentary re: Suzuki *et al.* article on treatment of liver disease by "repopulation of the diseased liver by cell transplantation." "It should be noted that stem cells have also been found in other tissues and when transplanted, these cells differentiate into different mature phenotypes de-pending on the organ environment in which they are en-grafted. Thus, it is clear that liver stem/progenitor cells, their hematopoietic cousins, and perhaps other stem-cell rel-atives, have a bright future in the treatment of liver, as well as other diseases."

**Reference:**
Shafritz DA; "Rat liver stem cells: Prospects for the future"; Hepatology 32, 1399-1400; Dec 2000

**Intravenous injection of adult bone marrow stem cells in a mouse model of tyrosinemia type I rescued the mouse and restored biochemical function of its liver.

**Reference:**
Lagasse E *et al.*; "Purified hematopoietic stem cells can differentiate into hepatocytes in vivo"; Nature Medicine 6, 1229-1234; Nov 2000

First purification and expansion of adult hepatic stem cells accomplished. "The ability of these hepatic stem cells to expand extensively, even at single cell seeding densities, contrasts with the limited expansion potential of the majority of mature liver cells, which typically undergo only a few cell divisions and require high seeding densities in culture to survive," according to Dr. Reid. In addition to the antigenic profile and methods of purification of the cells, novel culture conditions were described that permit expansion of a single hepatic stem cell to a colony of cells containing both hepatocytes and bile duct cells, the most rigorous proof of the clonality and bipotentiality of the cells. Incara Pharmaceuticals Corporation has license to the technique and is applying discoveries in the field of liver stem cells to the development of cell therapies for liver diseases.

**Reference:**
Kubota H, Reid LM; "Clonogenic hepatoblasts, common precursors for hepatocytic and biliary lineages, are lacking classical major histocompatibility complex class I antigen"; Proc. Natl. Acad. Sci. USA 97, 12132-12137; Oct. 24, 2000

Strain AJ, Crosby HA; "Hepatic stem cells"; Gut 46, 743-745; 2000

## BLOOD VESSELS/HEART VALVES

Engineered replacement aorta using a matrix onto which were seeded the sheep's own cells. Previous work had shown this technique also works for heart valves.

**Reference:**
Shum-Tim D *et al.*; "Tissue engineering of autologous aorta using a new biodegradable polymer"; Ann. Thorac. Surg. 68, 2298-2304; December 1999

Human peripheral (circulating) blood contains stem cells for endothelial (blood vessel) cells.

**Reference:**
Asahara T *et* al.; "Isolation of Putative Progenitor Endothelial Cells for Angiogenesis"; Science 275, 964-967; February 14, 1997

Shi Q *et al.*; "Evidence for Circulating Bone Marrow-Derived Endothelial Cells"; Blood 92, 362-367; July 15, 1998

## FAT STEM CELLS

Adult Stem Cells from Fat

Scientists from the University of Pennsylvania have been able to isolate stem cells from fat and convert them into bone cells. "This is a potentially unlimited source of cells to turn into mature cells of different types," said Dr. Louis P. Bucky. He said that other researchers were investigating forming muscle from fat stem cells. Dr. Bucky noted that with fat, there is an ample supply of cells and it is easy to get at. The work was reported at a meeting of the American Society of Plastic Surgeons in Los Angeles.

**Reference:**
Amy Norton, "Stem cells from body fat-limitless supply," Reuters Health, Oct. 18, 2000

## LUNG STEM CELLS
Emura M; "Stem cells of the respiratory epithelium and their in vitro cultivation"; In Vitro Cell Dev. Biol. Anim. 33, 3; January 1997

## DENTAL STEM CELLS
**Identification and isolation of stem cells from human dental pulp. The stem cells could be induced to differentiate into tooth structures.

**Reference:**
Gronthos S *et al.*; "Postnatal human dental pulp stem cells (DPSCs) *in vitro* and *in vivo*"; Proc Natl Acad Sci USA 97, 13625-13630; Dec 5 2000

## MAMMARY GLAND
Evidence using rats of subpopulation of epithelial cells from mammary gland with large proliferation and differentiation potentials; results support conclusion that rat mammary clonogens are multipotent mammary stem cells.

**Reference:**
Kim ND *et al.*; "Stem cell characteristics of transplanted rat mammary clonogens"; Exp. Cell Res. 260, 146-159; Oct. 10, 2000

## SPERMATOGONIAL
Review of advances since the initial report of transplantation in 1994.

**Reference:**
Johnston DS *et al.*; "Advances in spermatogonial stem cell transplantation"; Rev. Reprod. 5, 183-188; Sept. 2000

## GENERAL
**"The committed stem and progenitor cells have been recently isolated from various adult tissues, including hematopoietic stem cell, neural stem cell, mesenchymal stem cell and endothelial progenitor cell. These adult stem cells have several advantages as compared with embryonic stem cells as their practical therapeutic application for tissue regeneration."

**Reference:**
Asahara T, Kalka C, Isner JM; "Stem cell therapy and gene transfer for regeneration"; Gene Ther 7; 451-457; March 2000

**Mammalian stem cell transformation similar to the transdetermination seen in Drosophila.

**Reference:**
Wei G *et al.*; "Stem cell plasticity in mammals and transdetermination in Drosophila: Common themes?"; Stem Cells 18, 409-414; Nov 2000

Xie T, Spradling AC; "A Niche Maintaining Germ Line Stem Cells in the Drosophila Ovary"; Science 290, 328-330; Oct. 13, 2000

**EMBRYONIC STEM CELLS**

**Human and primate ES cells, unlike those from mice, are "totipotent"; they can form trophoblast in culture. This indicates the potential to reform complete embryos in culture.**

**EMBRYONIC STEM CELLS**

The human embryonic stem cells differentiate in culture into 3 primary germ layers AND trophoblast…

**Reference:**
Thomson JA *et al.*; "Embryonic stem cell lines derived from human blastocysts"; Science 282, 1145-1147; November 6, 1998

Human ES cells differentiate in culture into extraembryonic (trophoblast) and somatic cell lineages.

**Reference:**
Reubinoff BE *et al.*; "Embryonic stem cell lines from human blastocysts: somatic differentiation in vitro"; Nature Biotechnology 18, 399-404; April 2000.

ES cells from rhesus monkey. Differentiate in culture into 3 primary germ layers AND trophoblast…

**Reference:**
Thomson JA *et al.*; "Isolation of a primate embryonic stem cell line"; Proc. Natl. Acad. Sci. USA 92, 7844-7848; August 1995

ES cells from marmoset. Differentiate in culture into 3 primary germ layers AND trophoblast…

**Reference:**
Thomson JA *et al.*; "Pluripotent cell lines derived from common marmoset (Callithrix jacchus) blastocysts"; Biol. Reprod. 55, 254-259; August 1996.

Review and comparison. Rhesus monkey and marmoset. Differentiate in culture into 3 primary germ layers AND trophoblast…

**Reference:**

Thomson JA and Marshall VS; "Primate embryonic stem cells"; Curr. Top. Dev. Biol. 38, 133-165; 1998

EMBRYONIC GERM CELLS

Isolation of embryonic germ cells from aborted fetuses. Cells are similar to embryonic stem cells.

**Reference:**
Shamblott MJ *et al.*; "Derivation of pluripotent stem cells from cultured human primordial germ cells"; Proc. Natl. Acad. Sci. USA 95, 13726-13731; November 1998

**EMBRYONIC STEM CELL DIFFERENTIATION**

Used human ES cells, added mixes of growth factors to try to get specialized cell types formed in culture. Got factors which induce mesoderm, ectoderm+mesoderm, or all 3 germ layers. No specific tissues derived. "The work presented here shows that none of the eight growth factors tested directs a completely uniform and singular differentiation of cells."

**Reference:**
Schuldiner M *et al.*; "Effects of eight growth factors on the differentiation of cells derived from human embryonic stem cells"; Proc. Natl. Acad. Sci. USA 97, 11307-11312; Oct. 10, 2000

Formed embryoid bodies (EB's) from embryonic germ (EG) cells, isolated and cultured cells from EB's. Cells show long-term population doubling (PD), normal karyotypes (checked at 20 PD, but not in the long-term cultures), can be stably transfected with extra genes for gene therapy. The cells are relatively uncommitted precursor or progenitor cells. "EB-derived cells may be suited to studies of human cell differentiation and may play a role in future transplantation therapies." "Although a compelling demonstration of the potential of human EG cells, the limited growth characteristics of differentiated cells within EB's and difficulties associated with their isolation would make extensive experimental manipulation difficult and limit their use in future cellular transplantation therapies." "For PSCs [pluripotent stem cells] to be of practical use, methods to generate large numbers of homogeneous cell types must be developed."

From UniSci News Report, Jan 7 2001

EBDs reproduce readily and are easily maintained, Gearhart said, and thus eliminate the need to use fetal tissues each time as a source - a step that should quell many of the political and ethical concerns that swirl around stem cell studies. **"We thought from the first that problems would arise using hPSCs [human pluripotent stem cells] to make replacement tissues," says molecular biologist Michael Shamblott, Ph.D. The early-stage stem cells are both difficult and slow to grow. "More important," says Shamblott, "there's a risk of tumors. If you're not very careful when coaxing these early cells to differentiate - to form nerve cells and the like -- you risk contaminating the newly differentiated cells with the stem cells. "Injected into the body, stem cells can produce tumors.** The EBDs bypass all this." EBDs readily divide for up to 70 generations, producing millions of cells without any apparent chromosomal abnormalities

typical of tumor cells. No tumors appeared in three cancer-prone test mice injected with the new cells. Moreover, EBD cells appear to accept "foreign" genes readily - a necessity, Shamblott says, for scientists to produce large quantities of differentiated "replacement" cells for human transplants.

**Reference:**
Shamblott MJ, Axelman J, Littlefield JW, Blumenthal PD, Huggins GR, Cui Y, Cheng L, Gearhart JD; "Human embryonic germ cell derivatives express a broad range of developmentally distinct markers and proliferate extensively in vitro"; Proc Natl Acad Sci USA 98, 113-118; Jan 2 2001

## EMBRYONIC STEM CELL DIFFERENTIATION

The following quotes are from an article in Science describing first exciting new results with adult stem cells, transforming bone marrow stem cells in brain and liver. The article then goes on to contrast the successes of adult stem cell research with the following description of human embryonic stem cell research.

**Reference:**
Vogel G; "Stem cells: New excitement, persistent questions"; Science 290, 1672-1674; Dec 1 2000

In contrast, the human embryonic stem cells and fetal germ cells that made headlines in November 1998 because they can, in theory, develop into any cell type have so far produced relatively modest results. Only a few papers and meeting reports have emerged from the handful of labs that work with human pluripotent cells, whose use has been restricted by legal and commercial hurdles. Last month, a group led by Nissim Benvenisty of The Hebrew University in Jerusalem, in collaboration with Douglas Melton of Harvard University, reported in the Proceedings of the National Academy of Sciences that they could nudge human embryonic stem cells toward a number of different cell fates. But the results did not produce easy answers; some cells expressed markers from several kinds of lineages.

The work suggests that it will not be simple to produce the pure populations of certain cell types that would be required for safe and reliable cell therapies-much less the hoped-for replacement organs, says stem cell researcher Oliver Brüstle of the University of Bonn in Germany. Brüstle was one of the first to show that mouse embryonic stem cells could help treat an animal disease model, in which neurons lack their insulating coat of myelin. Even so, he is cautious about the near-term prospects in humans. Says Brüstle: "At present, it looks like it is really difficult to differentiate these [human] cells into more advanced cell types." Melton agrees. "It's unlikely anyone will ever find a single growth factor to make a dopaminergic neuron," as some might have hoped, but the work provides "a starting place," he says.

Simply keeping human embryonic stem cells alive can be a challenge, says Peter Andrews of the University of Sheffield in England. For more than a year, he and his colleagues have been experimenting with embryonic stem cell lines that James Thomson derived at the University of Wisconsin, Madison. "They're tricky," Andrews says. It took several false starts--and a trip to Wisconsin --before the researchers learned how to keep the cells thriving, he says. Melton uses almost the same words: Human embryonic stem cells "are

trickier than mouse," he says. "They're more tedious to grow."

Researchers from Geron Corp. in Menlo Park, California, are having some luck. Company researchers have been working with human embryonic stem cells as long as any team has, because Geron funded the derivation of the cells and has an exclusive license for their commercial use. They reported in the 15 November issue of Developmental Biology that cell lines derived from a single embryonic stem cell continue to replicate in culture for 250 generations. This is important, says Geron researcher Melissa Carpenter, because it means that a single human embryonic stem cell, which might be modified in the lab, could produce an essentially unlimited supply of cells for therapy. That was known for mouse embryonic stem cells but had not been shown in humans before. Even so, **Geron researchers seem no closer than other groups to devising therapeutic uses for stem cells. Geron researchers reported last month at the annual meeting of the Society of Neuroscience that they had attempted to transplant human embryonic stem cells into rats. When they injected undifferentiated cells into the brain, they did not readily differentiate into brain cells, the researchers found. Instead, they stayed in a disorganized cluster, and brain cells near them began to die. Even partially differentiated cells, the team reported, tended to clump together; again, nearby brain cells died.**

Editorial from the journal Nature:

**Reference:**
"Ethics can boost science"; Nature 408, 275; Nov 16 2000

The article comments on the controversy in Great Britain over "therapeutic cloning" and the report from the European Union ethics committee.

"On the trail of the latest Holy Grail, researchers can sometimes lose sight of the wider issues and of alternative avenues. Scientist lobbying passionately for research on human embryonic stem cells, and in particular on 'therapeutic cloning', should pay heed."

The article details the hoped-for treatments proposed for human embryonic stem cells, and then describes the ethical alternative-adult stem cells.

"But the ethical controversy over the use of human embryos as a supply of embryonic stem cells has perhaps done science a favour....the controversy over the use of embryos is now encouraging research into 'alternative' sources that might otherwise have been ignored: adult stem cells."

After describing some of the exciting successes of adult stem cells, the editorial asks "Might all types of cells be regenerated from an adult human stem cell? Why not?"

"The intellectual appeal of human embryonic stem cells...should not be allowed to lead to a neglect of other avenues of research, particularly given the ethical issues involved."

"In the EU report, ethical concerns are not only doing science a service by providing a bridge to society's legitimate concern about issues such as the rights of the human embryo, but they are also giving science an opportunity to stand back and think of alternative approaches, rather than putting all of its oocytes in one basket."

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# Germany's Nazi past a factor in cell debate

Carter Dougherty
THE WASHINGTON TIMES

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BERLIN -- German politicians, like their American counterparts, are wrestling with whether the government should permit research into potentially life-saving therapies that use embryonic stem cells.

As in the United States, the debate is a complicated, emotionally charged affair in which politics, ethics and economics have collided. But unlike in America, the battle is complicated by the ghost of Germany's Nazi past.

German conservatives, convinced that embryos are full-fledged lives worth protecting, generally oppose stem-cell research.

But many liberals feel the same way, driven by a distrust of commercial biotechnology and memories of Nazi medical experiments on humans.

"Historically, Germany always wrestles with ethical questions like these," said Otmar Wiestler, a researcher at the University of Bonn. "Genetics, abortion, animal rights -- this is nothing new."

Scientists, who believe they are on the threshold of great discoveries, are frustrated. But most have accepted that politics and science move at different speeds.

"Because the Germans have such a difficult time with this question, it's important that we have public support," Mr. Wiestler said. "We need this debate."

The fight erupted in May when German President Johannes Rau, who frequently uses the bully pulpit his office provides to speak about moral issues, cautioned strongly against stem-cell research without a full debate.

"The lofty goals of scientific research must not be allowed to determine when the protection of human life begins," Mr. Rau said in a widely publicized speech.

He reminded the public that Germany's Embryo Protection Act of 1990 prohibits the creation of human embryos -- from which stem cells arise shortly after fertilization -- in laboratories.

However, as his opponents hasten to point out, the law does not explicitly ban imports of stem cells themselves.

Shortly after Mr. Rau's speech, Wolfgang Clement, the Social Democratic governor of the western state of North Rhine-Westphalia -- Germany's most populous ran headlong through this legal loophole.

During a visit to Israel, where stem-cell research is widely accepted, Mr. Clement negotiated a cooperative arrangement between the universities of Bonn and Haifa that foresaw bringing stem cells into Germany.

"I respect every opinion," he said. "But every opinion must also take into account that this research is already going on" in other countries. Mr. Clement had his eye on the economic benefits, particularly for his own constituency.

His state already boasts Germany's largest concentration of biotechnology companies, but the race to be the European leader is tight, with regions in Britain still a hair ahead.

"A huge market is developing here, and we have to be a part of that," said Michael Swoboda, executive director of the Chamber of Industry and Trade in Bonn, a center of research in Mr. Clement's state.

Mr. Clement's move strained his relations with Chancellor Gerhard Schroeder, normally a close ally,

because the chancellor is trying to manage the politics of scientific ethics through an independent ethics council that will deliver its report later this year.

It also laid bare the rift in Mr. Clement's state governing alliance with the Greens, the same coalition Mr. Schroeder has in Berlin.

Trying to contain the furor, Mr. Clement brought the issue before his provincial assembly for a vote, only to see the Greens vote with the center-right Christian Democratic Union.

But Mr. Clement still won the vote because the Free Democratic Party, Germany's free-marketers, supported him. That outcome irritated Mr. Clement's allies.

He had played into the hands of Juergen Moelleman, the state's wily Free Democrat chairman, who is angling to enter a national coalition with Mr. Schroeder after federal elections late next year, something many Social Democrats oppose.

At the federal level, Social Democrats and Greens have punted the question of changing the embryo law until after the elections.

Conservatives have their own problems. The Christian Social Union, the Christian Democrats' Bavarian sister party, is anchoring the right flank of the debate, promising no quarter in its war against the research.

"The clear majority opinion [in our party] holds human dignity and the protection of life in higher esteem than economic progress or growth," Erwin Huber, chief of staff to Bavarian Gov. Edmund Stoiber, told a local newspaper.

Right now, all parties to the debate are observing a tense truce, waiting out the summer holidays.

Researchers in Bonn, the first in line to seek imports of stem cells, have agreed to await a December decision on imports by Germany's top scientific research body, the equivalent of the National Institutes of Health in the United States. Politicians, in turn, have promised to grapple with the issue in the fall, when the ethics commission reports.

But the scientists reminded the politicians that they will not wait forever. Researchers can just as easily hop a plane to the United States or Israel and take the economic benefits of their miracle science with them, they warn.

"If stem cells don't come to me," said Bonn researcher Oliver Bruestle, "I'll go to them."

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July 23, 2001

**MEMORANDUM REGARDING THE ILLEGALITY OF NIH'S "GUIDELINES FOR RESEARCH USING HUMAN PLURIPOTENT STEM CELLS"**

The Department of Health and Human Services ("HHS") and the National Institutes of Health ("NIH"), with the assistance of the Department of Justice, are currently reviewing the legality of the NIH "Guidelines for Research Using Pluripotent Stem Cells," 65 Fed. Reg. 51,976 (Aug. 25, 2000) ("Guidelines"). For the reasons set forth below, the NIH Guidelines violate the plain language and the clear legislative purpose of Pub. L. No. 106-554, 114 Stat. 2763 Omnibus Consolidated Appropriations Act of 2001, § 510(a)(2), which strictly prohibits the funding of "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than allowed for research on fetuses in utero under 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. §289g(b))."

The Guidelines violate §510(a)(2) of the appropriations act in at least two respects. *First*, the Guidelines expressly and necessarily condition federal funding on the destruction of human embryos. Because, as NIH is well aware, the process of harvesting stem cells from human embryos necessarily results in the destruction of the embryos, *see* 65 Fed. Reg. 51,980 (donated embryos "will not survive the human pluripotent stem cell derivation process"), the NIH Guidelines authorize, *and indeed encourage*, the intentional destruction of human embryos solely for the purpose of medical research, and thereby render those human embryos unavailable for implantation in natural or adoptive mothers. In fact, the Guidelines themselves expressly mandate and regulate the process by which researchers must destroy the embryos in order to qualify for federal funding. The Guidelines thus plainly violate § 510(a)(2), which by its terms seeks to protect human embryos from such utilitarian destruction. Moreover, NIH's attempt to read the Congressional ban as prohibiting funding only for the specific act of destroying the embryos is contradicted by the plain terms, structure, and history of the funding ban.

*Second*, even under NIH's blinkered and clearly indefensible reading of § 510(a)(2), the Guidelines are unlawful because embryonic stem cells themselves fit within the statutory definition of "human embryos." Like the human embryos from which embryonic stem cells are derived, human embryonic stem cells are totipotent—*i.e.*, have the potential to form all of the cell and tissue types that comprise a mature human being—and thus embryonic stem cells satisfy even NIH's proposed definition of "human embryos," as that term is used in § 510(a)(2).

## I. Section 510(a)(2) Plainly Prohibits Funding Of Research Involving Human Embryonic Stem Cells.

The NIH Guidelines authorizing the funding of research involving human embryonic stem cells violate Congress's unambiguous prohibition against federal funding of "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than allowed for research on fetuses in utero under 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. § 289g(b))." Pub. L. No. 106-554, § 510(a)(2). By its plain terms, § 510(a)(2) precludes any federal funding for research, such as embryonic stem cell research, in which human embryos are destroyed or otherwise threatened.[1]

NIH seeks to avoid Congress's unambiguous ban on destructive embryo research by asserting that the funding ban applies only to the act of destroying human embryos, and not to the research that is dependent upon the destruction of embryos. 65 Fed. Reg. 51,976. That argument is pure sophistry, and is contradicted by the plain terms of § 510(a)(2), which prohibits funding not only for the act of destroying human embryos, but also for "research in which [] human embryo[s]...are ...knowingly subjected to risk of injury or death." The Guidelines expressly condition federal funding on the destruction of human embryos, and carefully regulate the process by which human embryos are to be destroyed. As a result, the Guidelines plainly fund research that, at a minimum, knowingly threatens human embryos.

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[1] The cited regulations governing fetuses in utero mandate that no federal funds shall be used to support research that subjects fetuses to more than "minimal risk," which is defined to mean "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 C.F.R. § 46.102(i). Since 1975, research on human fetuses has been subject to restrictions that parallel those for research on human subjects. *See* 45 C.F.R. § 46 Subpart B. These regulations require that any research-related risk to a human fetus be minimal and that the purpose of the research be either for "the health needs of the particular fetus" or for "the development of important biomedical knowledge which cannot be obtained by other means." 45 C.F.R.§ 46.208. Moreover, 42 U.S.C. § 289g(a), which is also expressly referenced in the § 510 funding ban, provides that HHS may fund *only* research that either (1) enhances the fetus's well-being or likelihood of survival, or (2) "pose[s] no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means." The statute further provides that "[i]n administering the regulations for the protection of human research subjects . . . the Secretary [of HHS] shall require that the risk standard . . . be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term." 42 U.S.C. § 289g(b). In other words, federal funds may be used for fetal research *only* if the risk posed to the fetus is minimal, and the calculus of risk does not change simply because a fetus is not expected to be carried to term. Section 510(a)(2) extends those same protections to human embryos.

Indeed, the Guidelines make clear that research involving embryonic stem cells is inextricably intertwined with the act of destroying human embryos. The Guidelines strictly regulate the process by which the human embryos must be selected and destroyed. As an express condition of funding, grant applicants are required to prove that they have complied with the NIH protocol for destroying embryos and harvesting their stem cells. 65 Fed. Reg. 51,979-80. Under the Guidelines, for example, the human embryos destroyed during the harvesting process must have been created for the purpose of fertility treatment, must be in excess of clinical need, must be voluntarily "donated" by the individuals who sought infertility treatment, and must not have reached the stage of development at which the mesoderm is formed. *Id.* The Guidelines further require that a separate NIH "Institutional Review Board" review and approve the procedures by which the embryos have been destroyed to ensure that funding is provided only to researchers who have complied with the NIH protocol. *Id.* In sum, the Guidelines not only offer a financial incentive—in the form of substantial federal grants—that is contingent upon the destruction of human embryos, they in fact regulate and mandate the process by which the embryos are selected and destroyed. NIH cannot plausibly contend that the embryonic stem cell research that it proposes to fund is separate and legally distinct from the destruction of human embryos.

In fact, the very purpose of public funding in this area is to encourage additional research using embryonic stem cells leading to the destruction of human embryos. As then-NIH Director Harold Varmus acknowledged in his testimony before the Senate Appropriations Committee regarding the Guidelines, "Federal support increases the fiscal resources and expands the pool of talented investigators—particularly in academia—both of which accelerate the tempo of scientific discovery." S. Hrg. 105-939, Subcomm. on Labor, Health and Human Services, and Education, Comm. on Appropriations, *Stem Cell Research*, at 122 (1999). Given the Guidelines' recognition that the destruction and stem cell harvesting of human embryos is inseparably connected to embryonic stem cell research, the Guidelines necessarily will "accelerate the tempo" of human embryo destruction. The Guidelines, therefore, knowingly and directly subject human embryos to risk of injury and death in violation of § 510(a)(2).

Moreover, NIH's assertion that Congress intended to ban only the act of destroying human embryos is further belied by the context and structure of Congress's funding ban. Section 510 separately bans funding for "the creation of a human embryo or embryos for research purposes." Pub. L. No. 106-554, § 510(a)(1). Under NIH's distorted reading, Congress could have accomplished its limited goal of banning only the act of destroying human embryos simply by prohibiting funding for "the creation *or destruction* of a human embryo or embryos for research purposes."

Congress, however, sought to protect human embryos by enacting a much broader ban regarding the destruction of embryos. Rather than banning funding only for the act of destroying human embryos, it prohibiting funding for any "*research* in which a human embryo or embryos are destroyed" or are "knowingly subjected to risk of injury or death." Both by its terms and by

necessary implication, that prohibition plainly bans the funding of research, such as embryonic stem cell research, that is necessarily dependent upon, *and indeed encourages*, the destruction of human embryos. NIH's contrary reading improperly ignores the important differences in the way Congress structured its ban on funding for the creation of human embryos, on the one hand, and its ban on all research that destroys or threatens embryos, on the other. *See Russello v. United States*, 464 U.S. 16, 23 (1983) (where Congress chooses different language in proximate subsections of the same statute, courts must construe the statute to give effect to those differences in language).

Furthermore, the legislative history of the § 510 funding ban also belies the government's interpretation that the funding ban restricts funding only for the act of destroying human embryos. Congress did not enact the funding ban in a vacuum. For years, the government had effectively refused to fund any embryo research. In late 1994, however, the Human Embryo Research Panel ("HERP"), an ad hoc advisory committee formed to advise the NIH Director on the moral, ethical, and scientific implications of funding research involving human embryos, recommended that NIH fund several types of embryo research. One of the principal areas of embryo-related research that HERP recommended for federal funding was "[w]ork on embryonic stem cells, their differentiation and their therapeutic potential." NIH, Report of the Human Embryo Research Panel, Vol. I at 49 (1994) ("HERP Report"); *see also id.* at xvii, 2, 8, 26-27, 47, 49, 50, 76 (recommending federal funding for destructive human embryonic stem cell research using "spare" embryos from *in vitro* fertilization clinics).

Although President Clinton intervened to prohibit federal funding for the creation of embryos for research purposes, 30 Weekly Comp. Pres. Doc. 2459 (December 2, 1994), NIH Director Varmus took steps to implement HERP's recommendations to fund research involving "spare" embryos stored in *in vitro* fertilization clinics—the very same embryos the Guidelines now propose to destroy for stem cell research. In testimony before the House Appropriations Committee, NIH Director Varmus was repeatedly asked about NIH's intention to move forward with destructive human embryonic stem cell research as recommended by HERP, despite President Clinton's disagreement with portions of the HERP report. Dr. Varmus indicated his willingness to consider funding for destructive human embryonic stem cell research, stated that he "firmly agree[d]" with several portions of the HERP report, and told the Committee that NIH was currently reviewing the HERP report to determine whether to go forward with funding. Department of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 1996: Hearings Before a Subcomm. of the House Comm. on Appropriations, 104th Cong., 1st Sess. 139, 144 (1995); *see also* NIH, *Background Information on the Impact of the Human Embryo Research Amendment* at 2 (June 30, 1996) (NIH would have funded six out of nine applications for grants involving embryo-related research "if the NIH had been able to proceed according to the [Human Embryo Research Panel's] recommendations and the President's directive").

Shortly thereafter, Congress adopted the sweeping language of the funding ban to prevent NIH from implementing the HERP report's recommendations regarding embryo research, including destructive human embryonic stem cell research. Indeed, the House Appropriations Committee specifically rejected an alternative rider, which would have codified President Clinton's directive by prohibiting only the funding of the *creation* of embryos for research purposes. H.R. Rep. No. 104-209, at 213-14 (1995). Instead, Congress adopted a much broader ban that prohibits federal funding for *all* research in which embryos are destroyed, discarded, or subjected to more than minimal risk.

This history clearly contradicts NIH's claim that the purpose of the funding ban is only to prevent federal funding for the creation or destruction of embryos. Rather, the chronology of events leading up to the enactment of the funding ban demonstrates that Congress intended to prohibit federal funding for *all* research that threatens human embryos, including research, such as embryonic stem cell research, that necessitates and is dependent upon the destruction of human embryos. Supporters of embryo research in Congress expressly recognized this true purpose of the funding ban, and they opposed the ban in part because it "*bans all federal funds for human embryo research*." H.R. Rep. No. 104-209, at 384 (emphasis added). In fact, they objected to the ban precisely because it would foreclose the recommendations of the HERP report and "segregate [human embryo] research into private laboratories, which are not subject to any set scientific or ethical guidelines." *Id.* at 385. Senator Boxer, for example, objected to the funding ban because it amounted to "a *total prohibition* of Federal funding for human embryo research." 142 Cong. Rec. S429, S433 (1996) (emphasis added). Notably, the objectors did not argue that the ban would segregate only the actual destruction of human embryos into private labs. Rather, they acknowledged that it segregated *all aspects* of embryo research into private labs; that is, it prohibited federal funding of all research dependent upon the destruction of human embryos.

Subsequent legislative history also confirms Congress's intent to prohibit all federal funding for research dependent upon the destruction of human embryos. Congress first enacted the funding ban in January 1996. *See* Balanced Budget Downpayment Act, Pub. L. No. 104-99, 110 Stat. 26, 34, Title I, § 128 (January 26, 1996). Not six months later, proponents of embryo research tried to repeal subsections (a)(2) and (b) of the ban. Representative Lowey of New York offered the amendment, which the full House debated for nearly an hour. 142 Cong. Rec. H7339 (July 11, 1996). The proponents and opponents of embryo research operated on the same premise—that the funding ban's language (which is identical to the language currently in § 510(a)) bans federal funding of *all* research dependent upon the destruction of an embryo—but they disagreed on the propriety of this ban. *Id.* at H7339-43. For example, Representative Porter of Illinois argued that repeal was necessary because federal funding of research "could also lead to breakthroughs *in the use of embryonic stem cells*." *Id.* at H7340 (emphasis added). This argument necessarily recognizes that the funding ban prohibits federal funding of embryonic stem cell research. No member of Congress expressed disagreement with Representative

Porter's clearly correct view that the funding ban prohibited funding for embryonic stem cell research. These statements, and the debate more generally, strongly reaffirm Congress's purpose to ban federal funding for all research dependent upon the destruction of an embryo, which purpose the House firmly supported by rejecting the Lowey amendment 167-256. *Id.* at H7364.

Under these circumstances, the conclusion that the NIH Guidelines violate Congress's funding ban is inescapable. Courts have repeatedly invalidated agency actions where, as here, those actions violated intended congressional prohibitions on spending federal dollars. *See Harbor Gateway Commercial Property Owners' Ass'n v. EPA*, 167 F.3d 602, 607 (D.C. Cir. 1999); *McHugh v. Rubin*, 220 F.3d 53, 58 (2d Cir. 2000); *AT&T v. United States*, 177 F.3d 1368, 1380 (Fed. Cir. 1999). The Guidelines, which expressly regulate and encourage the destruction of human embryos, plainly violate the funding ban, and are, therefore, contrary to law.

## II. The Guidelines Violate The Funding Ban Because Human Embryonic Stem Cells Are Human Embryos.

In promulgating the Guidelines, NIH asserted that human embryonic stem cells are not "human embryos" under the statutory definition of that phrase as it is used in § 510(a). 65 Fed. Reg. 51,976. Aside from a citation to the HHS legal counsel's memorandum, *see id.*, however, the Guidelines make no effort to explain how human embryonic stem cells do not qualify as human embryos under the statutory definition of that phrase. NIH's conclusion in this regard completely ignores considerable evidence indicating that human embryonic stem cells are "totipotent," and, thus, have the potential to develop into mature human beings. Contrary to NIH's unexamined assumption, therefore, human embryonic stem cells constitute "organisms," which qualify as "human embryos" within the meaning of Congress's funding ban.

Section 510 defines "human embryo" as "any organism, not protected as a human subject under 45 C.F.R. § 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells." Pub. L. No. 106-554, § 510(b). The funding ban does not define the term "organism." According to a legal memorandum drafted by HHS General Counsel Harriett Rabb, the term, "organism," means "an individual constituted to carry out all life functions." Rabb Memo at 2. NIH has separately stated that "[b]ecause [pluripotent cells'] potential is not total, they are not totipotent and they are not embryos." National Institutes of Health, *Stem Cells: A Primer*, May 2000, available at http://www.nih.gov/news/stemcell/primer.htm.

As discussed below, however, scientific evidence strongly demonstrates that embryonic stem cells are totipotent, *i.e.*, have the potential to form all cells comprising a mature human being and, thus, embryonic stem cells can carry out the various processes necessary for human

life.[2] Not only are embryonic stem cells totipotent, but uncontradicted scientific evidence indicates that embryonic stem cells, when implanted into a uterus, can congregate and form an individual that has the capacity to be born and carry out the various processes necessary for human life. Thus, embryonic stem cells are human embryos within the meaning of the statute.

Neither the Guidelines, themselves, nor the accompanying NIH documents make any reference to the question whether embryonic stem cells are totipotent. Instead, the Guidelines operate under the uncritical assumption that embryonic stem cells are merely pluripotent, *i.e.* have the ability to form many, but not all, cell types.[3] This crucial assumption is in error.

Indeed, NIH itself concedes that human embryonic stem cells "can form virtually every type of cell found in the human body." National Institutes of Health, *Stem Cells: A Primer*. Yet, the agency assumes that embryonic stem cells are pluripotent, as opposed to totipotent. The *sole*

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[2] NIH defines the term, "totipotent," as "having unlimited capability. Totipotent cells have the capacity to specialize into extra-embryonic membranes and tissues, the embryo, and all post-embryonic tissues and organs." *See* National Institutes of Health, *Stem Cells: A Primer*. By contrast, the term pluripotent is defined as "capable of giving rise to *most tissues of an organism*." *Id.* (emphasis added). Thus, the question of whether embryonic stem cells are totipotent or pluripotent is determinative of the question whether embryonic stem cells are organisms with the potential to develop into mature human beings and, thus, qualify as "embryos" for purposes of the funding ban.

[3] Similarly, the Rabb memo contains no discussion of the relevant scientific research that indicates that human embryonic stem cells are totipotent. Instead, the Rabb memo simply assumes and asserts as fact that human embryonic stem cells are only pluripotent. In fact, in subsequent testimony before the Senate Appropriations Committee, Rabb conceded that she was asked to assume that human embryonic stem cells were pluripotent and, therefore, were not "organisms," and that she is unaware of any scientific evidence to support that assumption. S. Hrg. 105-939, Subcomm. on Labor, Health and Human Services, and Education, Comm. on Appropriations, *Stem Cell Research*, at 143 ("I cannot respond on the science . . . The question that was asked of me was whether *if one were dealing with an entity that was not an organism*, would one violate the human embryo ban....") (emphasis added). Nevertheless, the Guidelines rely solely on Rabb's unexamined and unfounded assumption in concluding that human embryonic stem cells do not meet the statutory definition of "human embryos," because they purportedly are not "organisms." 65 Fed. Reg. 51,976.

Significantly, NIH's position on the allegedly pluripotent (as opposed to totipotent) nature of embryonic stem cells has been less than consistent. In September 1994, for example, the Human Embryo Research Panel, which was formed to advise NIH on the possibility of funding human embryonic research, stated that "[a]part from the distinction between the cells of the trophoblast and the inner cell mass, . . . the [embryonic stem]cells *are totipotent and have not yet differentiated into specific kinds of tissues*." HERP Report at 47 (emphasis added). Moreover, as recently as December 1999, NIH published a Request for Applications that expressly characterized embryonic stem cells as "totipotent," not pluripotent. *See* RFA RR-00-001, National Stem Cell Resource (Dec. 13, 1999), available at http://grants.nih.gov/grants/guide/rfa-files/RFA-RR-00-001.html. There is no formal explanation for this departure.

rationale for this assumption is that embryonic stem cells "are unable to give rise to the placenta and supporting tissues necessary for development in the human uterus." *Id.* The placenta and the supporting tissues come from the trophoblast cells of the human embryo. *Id.* Thus, in scientific terms, NIH's claim is that human embryonic stem cells can form all cell types, except trophoblast cells.

The scientific record conclusively refutes NIH's claim. As shown by the very same scientific studies that NIH cites to demonstrate the alleged potential for human embryonic stem cell research, *see* 64 Fed. Reg. 67,576 (Dec. 2, 1999) [discussing scientific findings of Thomson, James A. *et. al*, Embryonic Stem Cell Lines Derived from Human Blastocysts, 282 SCIENCE 1145 (Nov. 6, 1998)], human embryonic stem cells *can* form trophoblast cells, and thus can form all of the cells necessary for a live birth. Thomson, *Science*, Vol. 282 at 1145 ("After undifferentiated proliferation in vitro for 4 to 5 months, these cells still maintained the developmental potential to form trophoblast and derivatives of all three embryonic germ layers . . . ."). Human embryonic stem cell lines maintain the developmental potential to form trophoblast and derivatives of all three embryonic germ layers, which form all adult human tissues. Thus, the very evidence relied upon by NIH to support the Guidelines demonstrates that human embryonic stem cells are totipotent. Simply stated, these embryonic stem cells have the potential to develop into mature human beings, and thus are "human embryos" as that term is used in § 510.

Moreover, scientific evidence indicates that human embryonic stem cells, when implanted into a uterus, may develop into a born individual. Animal studies using mice have indicated that embryonic stem cells implanted into a host develop into a born individual. This individual has the genetic make-up of the embryonic stem cells. Andràs Nagy, *et. al*, Derivation of completely cell culture-derived mice from early-passage embryonic stem cells, 90 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCE USA 8424 (Sept. 1993). In other words, these mouse embryonic stem cells are clearly totipotent, and are a "mouse organism." Similarly, more recent experiments have demonstrated that the ability of embryonic stem cells to develop into born individuals is not confined to mice. *See* Shizue Iwasaki *et al.*, Production of live calves derived from embryonic stem-like cells aggregated with tetraploid embryos, 62 BIOLOGY OF REPRODUCTION 470 (Feb. 2000) (implantation of cattle embryonic stem cells into a host leads to the birth of live cattle). These experiments further demonstrate that human embryonic stem cells could also develop into a born individual.

Despite its conclusory assertions that human embryonic stem cells are not totipotent, NIH has, in fact, recognized the lack of scientific support for such a position. Even then-Director of NIH, Dr. Harold Varmus, a strong supporter of human embryonic stem cell research, conceded in his January 26, 1999 testimony before the Senate Appropriations Committee, he was unsure whether human embryonic stem cells could form an embryo in culture (and consequently, give rise to a born individual given the proper environment). Dr. Varmus stated:

> It is true that sometimes these cells can aggregate and may appear like one of the early phases in the development of a normal embryo. But to my mind nothing would be less ethical than to attempt to ascertain whether or not this was indeed a precursor to an organism, a viable embryo; that would require returning that mass of cells to a uterus to ask whether it had potential to develop into a fetus and a newborn, and the prospect for developing a severely impaired individual would be enormous and to my mind a reprehensible means of doing research.

S. Hrg. 105-939, Subcomm. on Labor, Health and Human Services, and Education, Comm. on Appropriations, *Stem Cell Research*, at 143. In other words, even then-NIH Director Varmus conceded that embryonic stem cells may give rise to the birth of an individual, but recognized that to determine whether this possibility could be realized would be unethical, because of the substantial risk that the born individual would be severely impaired.

Likewise, HHS General Counsel Rabb conceded that in drafting the legal opinion upon which NIH solely relies to defend the Guidelines, she was unfamiliar with any scientific evidence to support the assertion that embryonic stem cells are not totipotent (and, thus, do not qualify as an organism). Indeed, in startling testimony that lays bare the utterly baseless nature of NIH's arbitrary assumption that embryonic stem cells are not totipotent, Ms. Rabb conceded before the Senate Appropriations Committee:

> I cannot respond on the science... The question that was asked of me was whether *if one were dealing with an entity that was not an organism*, would one violate the human embryo ban, and the answer to that is no, one would not violate the ban if one were doing research with an entity that was not an organism.... But the science was not my domain, the law was.

*Id.* Nevertheless, even after Ms. Rabb's concession to Congress, NIH, in responding to numerous comments objecting to the Guidelines, once again relied solely on HHS General Counsel Rabb's unsupported assertion that "'federally funded research that utilizes [human embryonic stem cells] would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such cells are not human embryos.'" 65 Fed. Reg. 51,976 (*citing* Rabb memo). According to NIH, the numerous comments challenging the legality of the Guidelines "did not present information or arguments that justify reconsideration of the [HHS General Counsel's] conclusion." *Id.* But as Rabb's own testimony to Congress makes clear, that "conclusion" rests entirely on an unfounded and baseless assumption that is conclusively rebutted by the scientific record regarding the totipotency of embryonic stem cells.

NIH has never performed the necessary experiments to discover for itself whether human embryonic stem cells are totipotent. Instead, NIH has authorized experimentation on human embryonic stem cells—cells that have the potential to form a complete embryo and develop into

mature human beings—while intentionally turning a blind eye to the true nature of these cells and to the illegality of its actions even under its own view of the law.

## III. CONCLUSION

In conclusion, the NIH Guidelines violate the plain terms, structure, and history of Congress's funding ban, and do not pass muster even under NIH's strained and indefensible view of the law. Accordingly, HHS should immediately rescind the Guidelines and cease all efforts to fund human embryonic stem cell research.

# Christian Legal Society

*"Doing Justice with the Love of God"*
-Luke 11:42-

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**April 26, 2000**

**VIA HAND-DELIVERY**
Senator Arlen Specter, Chairman
United States Senate Appropriations Subcommittee on
Labor, Health and Human Services, Education
S-128, The Capitol
Washington D.C. 20510

**Re: Proposed Stem Cell Research Act of 2000 ( S.2015)**

Senator Spector:

This letter, and its accompanying attachments, are respectfully submitted as written testimony for inclusion in the record of the April 26, 2000 hearing of your subcommittee on embryonic stem cell research.

On behalf of the more than 3200 members of the Christian Legal Society,[1] we respectfully oppose the above-referenced bill to lift the existing ban on federal funding the research on human embryos. Insofar as it appears that the above-referenced bill is simply intended to provide the otherwise lacking congressional authority for the Draft NIH Guidelines for Research Involving Human Pluripotent Stem Cells (64 *Federal Register* 67576-67579, December 2, 1999), we hereby attach our comments (and accompanying appendices) to the draft NIH Guidelines in support of our opposition to the above-referenced bill.

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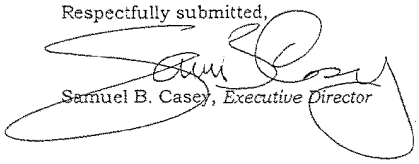
[1] The Christian Legal Society (CLS), founded in 1961, is a nonprofit ecumenical professional association of over 3200 Christian attorneys, judges, law professors, and law students located in every state and many foreign nations, who share a common confession of faith and are organized in 90 attorney chapters and more than 150 law school chapters throughout the United States. CLS is committed to defending and advocating the sanctity of human life in any legal proceeding where life is at issue. CLS is committed to such defense and advocacy because the founding instrument of this nation acknowledges as a "self-evident truth" that all human beings are divinely endowed with rights that no government may abridge nor any citizen waive. *Declaration of Independence* (1776). Among such inalienable rights is the right to life that inheres in all persons by virtue of its endowment by the Creator, Who is acknowledged in the *Declaration*. Because the source of human life, according to the nation's charter, is the Creator, not a constitution, statute or executive order, it is not merely one of many policy interests to be weighed against others by any of the several branches of federal or state government. Rather, it is foundational to the framers' notion of human existence and the proper purposes of government. The State has no higher duty than to protect inviolate the human right to life.

The United States does not need an unnecessary, unethical and socially divisive federal policy of human embryo destruction as would be advanced by S. 2015. To the contrary, we need a federal policy promotive of human life at all of its stages. Consequently, for the reasons set forth in the accompanying comments and appendices, CLS respectfully recommends

1. Maintaining the existing ban against federal funding of any research relying on the destruction of a human embryo.

2. Increased federal funding for the development of therapeutic interventions based on stem cells that can be and are obtained non-destructively, such as adult mesenchymal stem cells.

Respectfully submitted,



Samuel B. Casey, *Executive Director*

Enclosures: *CLS Comments on Draft NIH Guidelines, February 22, 2000*

S 723 IS

107th CONGRESS
1st Session
**S. 723**

To amend the Public Health Service Act to provide for human embryonic stem cell generation and research.

**IN THE SENATE OF THE UNITED STATES**

**April 5, 2001**

Mr. SPECTER (for himself, Mr. HARKIN, Mr. THURMOND, Mr. CHAFEE, Mr. SMITH of Oregon, Mr. HOLLINGS, Mr. REID, Mrs. MURRAY, Mrs. CLINTON, Mr. CORZINE, Mrs. FEINSTEIN, Mr. KERRY, and Mr. INOUYE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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**A BILL**

To amend the Public Health Service Act to provide for human embryonic stem cell generation and research.

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

## SECTION 1. SHORT TITLE.

This Act may be cited as the `Stem Cell Research Act of 2001'.

## SEC. 2. HUMAN EMBRYONIC STEM CELL GENERATION AND RESEARCH.

Part H of the Title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 498B the following:

## `SEC. 498C. HUMAN EMBRYONIC STEM CELL GENERATION AND RESEARCH.

`(a) IN GENERAL- Notwithstanding any other provision of law, the Secretary may only conduct, support, or fund research on human embryos for the purpose of generating embryonic stem cells and utilizing stem cells that have been derived from embryos in accordance with this section.

`(b) SOURCES OF EMBRYONIC STEM CELLS- For purposes of carrying out research under subsection (a), the human embryonic stem cells involved shall be derived only from embryos that have been donated from in-vitro fertilization clinics after compliance with the following:

`(1) Prior to the consideration of embryo donation and through consultation with the progenitors, it is determined that the embryos will never be implanted in a woman and would otherwise be discarded.

`(2) The embryos are donated with the written informed consent of the progenitors.

`(c) RESTRICTIONS-

`(1) IN GENERAL- The followin vgestriction shall apply with respect to human embryonic stem cell research conducted or supported under subsection (a):

`(A) The research involved shall not result in the creation of human embryos.

`(B) The research involved shall not result in the reproductive cloning of a human being.

`(2) PROHIBITION-

`(A) IN GENERAL- It shall be unlawful for any person receiving Federal funds to knowingly acquire, receive, or otherwise transfer any human embryos for valuable consideration if the acquisition, receipt, or transfer affects interstate commerce.

`(B) DEFINITION- In subparagraph (A), the term `valuable consideration' does not include reasonable payments associated with transportation, transplantation, processing, preservation, quality control, or storage.

`(d) GUIDELINES- The Secretary, in conjunction with the Director of the National Institutes of Health, shall issue guidelines that expand on the rules governing human embryonic stem cell research (as in effect on the date of enactment of this section) to include rules that govern the derivation of stem cells from donated embryos under this section.

`(e) REPORTING REQUIREMENTS.- The Secretary shall annually prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the preceding fiscal year, and including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.'.

*END*

# Christian Legal Society

*"Doing Justice with the Love of God"*
-Luke 11:42-

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**February 22, 2000**

**VIA HAND-DELIVERY**
Stem Cell Guidelines
National Institutes of Health (NIH)
NIH Office of Science Policy
1 Center Drive
Building 1, Room 218
Bethesda, MD 20892

**Re: Draft NIH Guidelines for Research Involving Human Pluripotent Stem Cells, 64 *Federal Register* 67576-67579 (December 2, 1999); Comment Period Ending: February 22, 2000**

Gentlemen and Ladies:

On behalf of the more than 3200 members of the Christian Legal Society,[1] we hereby respectfully submit the following comments (including the accompanying attachments) on the above-referenced guidelines (hereafter *"Guidelines"*). We request that this letter and attachments be made part of the public record of the proceedings and that NIH consider this letter and attachments as relevant matter to be taken into account in any statement of the basis and purpose of this rulemaking action under 5 U.S.C. § 553.

[1] The Christian Legal Society (CLS), founded in 1961, is a nonprofit ecumenical professional association of over 3200 Christian attorneys, judges, law professors, and law students located in every state and many foreign nations, who share a common confession of faith and are organized in 90 attorney chapters and more than 150 law school chapters throughout the United States. CLS is committed to defending and advocating the sanctity of human life in any legal proceeding where life is at issue. CLS is committed to such defense and advocacy because the founding instrument of this nation acknowledges as a "self-evident truth" that all human beings are divinely endowed with rights that no government may abridge nor any citizen waive. *Declaration of Independence* (1776). Among such inalienable rights is the right to life that inheres in all persons by virtue of its endowment by the Creator, Who is acknowledged in the *Declaration*. Because the source of human life, according to the nation's charter, is the Creator, not a constitution, statute or executive order, it is not merely one of many policy interests to be weighed against others by any of the several branches of federal or state government. Rather, it is foundational to the framers' notion of human existence and the proper purposes of government. The State has no higher duty than to protect inviolate the human right to life.

## GENERAL COMMENTS

For reasons set forth below, we respectfully request that the NIH immediately withdraw the *Guidelines* and take no further steps to fund research involving "human embryonic stem cells" (*Guidelines* at I., 64 Fed. Reg.67577). Any federal funding of such research at this time, on the basis of these *Guidelines*:

(1) Violates the plain language and clear intent of applicable federal law[2];

(2) Lacks necessary and sufficient safeguards assuring that human embryonic stem cells will not be derived from the criminal destruction of human embryos in violation of applicable state law, thus making the NIH and its grantees complicit in such criminal activity and violation of state public policy;[3]

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[2] The current funding ban is Section 510 of the Fiscal Year 2000 Labor/HHS Appropriations Act (reprinted in 145 Cong. Record H12400, November 17, 1999), enacted by cross-reference, Section 1000(a)(4) of the Fiscal Year 2000 Consolidated Appropriations Act (P.L. 106-113)

[3] The "laundering" requirement in the *Guidelines* (Part II.A.1.d.) that *"prior to the derivation of human [embryonic] stem cells for use in NIH-supported research, all identifiers associated with early human embryos should have been removed"* means that it will be impossible to prove that any particular stem cell line was not derived from the criminal destruction of a human embryo in violation of state law.

CLS further notes that this concern is already shared by at least one state, Michigan, whose House of Representatives have recently passed *House Resolution No. 253*. (A resolution memorializing the National Institutes of Health to withdraw proposed guidelines for federally funded research using stem cells destructively harvested from human embryos) (***emphasis added***):

*Whereas, The National Institutes of Health (NIH) has published, for public comment, guidelines for federally funded research projects using stem cells destructively harvested from human embryos; and*

*Whereas, Since 1996, Congress has prohibited federally funded research in which human embryos are harmed or destroyed; and*

*Whereas, The state of Michigan has a long legal and ethical tradition of respecting life at its earliest stages; and*

***Whereas, Michigan law prohibits any research that destroys human embryos, so the NIH guidelines, in effect, instruct researchers in how to harvest stem cells from embryos in ways that constitute criminal activity in this state; and***

*Whereas, Michigan has taken the unparalleled step in this country of respecting human life at its earliest stages by prohibiting the use of cloning to create human embryos for research; and*

*Whereas, Medical ethics historically have rejected justifying research in the name of medical progress when it requires harming or destroying innocent human lives; and*

*Whereas, Numerous avenues for developing new medical treatments from stem cells that do not require the destruction of human embryos have shown great clinical promise; now, therefore, be it*

*Resolved by the House of Representatives, That we strongly object to the National Institutes of Health proposed guidelines and policies regarding research on human embryos to ensure full accordance with federal laws that prohibit NIH involvement in destructive embryo research; and be it further*

*Resolved, That we urge the NIH to withdraw the proposed guidelines and to clarify NIH guidelines and policies regarding research on human embryos to ensure full accordance with federal laws that prohibit NIH involvement in destructive embryo research; and be it further*

*Resolved, That we urge the National Institutes of Health to direct all proposed funding for stem cell research to projects that do not use stem cells destructively harvested from human embryos;*

(3) Lacks necessary and sufficient "conflicts of interest" safeguards because:

(a) The *Guidelines* do not prohibit contractual, agency or corporate relationships between the IVF clinic that creates and then cryogenically stores the human embryo, the researchers (a/k/a the "derivers") who kill that human embryo to harvest its stem cells, and the researchers (a/k/a the "users") who will be funded by NIH to perform research upon these human embryo stem cells. Indeed, it appears that the Guidelines do not even prohibit the deriver and the user from being the *very same person*. See *Guidelines*, Part II.1.b.

(b) The *Guidelines* erroneously presume that the parents of the human embryo have the legal right under applicable state law, as well as the moral authority, to substitute their judgment for the judgment of the legally incompetent human embryo to withhold essential life-supporting medical care from the human embryo thereby assuring that their embryonic child will surely die. Not only is state law on this point far from settled, but the parents' moral authority to do so is far from accepted. At a bare minimum, the *Guidelines* as *a prerequisite for funding* should require a judicial proceeding and court order, where the human life interests of the human embryo(s) in question are represented and truly "handled respectfully" [*Guidelines*, Part II.A.2.a.(vii)] by a court-appointed attorney *pro vita* (for life), before such a parental "donation" would be deemed lawful under state law and free of the obvious conflicts of interest presented when the parents of an offspring initially conceived to be their child are now proposing to terminate its life solely for medical research purposes supported by federal tax dollars, particularly when there has been no showing that: (1) Other more life-preserving options have been explored for the embryonic child and reasonably excluded; and (2) the federally financed researcher has established that a compelling governmental interest exists to perform the research which *interest* cannot otherwise be satisfied without having to destroy the lives of *these* human embryos.[4]

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*(footnote 3 cont.)*

*and be it further*

*Resolved, That copies of this resolution be transmitted to the National Institutes of Health, the Secretary of the United States Department of Health and Human Services, the President of the United States Senate, the Speaker of the House of Representatives, the members of the Michigan congressional delegation, and the President of the United States.*

CLS understands that Michigan Senate approved a similar resolution on February 9, 2000.

[4] For a thoughtful analysis of the substituted judgment rule and the inherent conflicts of interests involved in health care decisions terminating life, *see* Walter Weber, *Substituted Judgment Doctrine: A Critical Analysis*, 1 Issues L & Med. 131 (1985).

(4) Lacks necessary and sufficient "informed consent" safeguards because the proposed guidelines do not even *require* the parents of the human embryos (a/k/a "the potential donors") be informed that:

(a) *Scientifically speaking*, each of their human embryos is a living human being, not just "human tissue" as erroneously suggested in the *Guidelines*, Part II. A. 2. a. (vii);[5]

(b) *Legally speaking*, in 38 states the law is that human life begins from fertilization and the "donation" of their human embryos for research will be deemed to be the taking of human life in those states. In at least nine of these states research involving human embryos is effectively banned; [6] and

(c) Insofar as each of these human beings is *"in excess of the clinical needs"* of the parents (*Guidelines*, Part II.A.1.a.), it is now possible for the parents to place each embryo up for adoption as an alternative to having the human embryo killed for research purposes; and that donating the human embryo for scientific research means that it will be frozen, then thawed and then killed, but not before its identity and relationship to them is entirely expunged.[7]

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[5] For an analysis of the scientific literature establishing that a human embryo from fertilization is considered by science to be a living human being, see the accompanying **Appendix A**, Dianne N. Irving, M.A., Ph.D., *WHEN DO HUMAN BEINGS BEGIN? "SCIENTIFIC" MYTHS AND SCIENTIFIC FACTS.*

[6] For an analysis of state law and public policy related to the beginning of human life, see the accompanying **Appendix B**, *The Legal Consensus on the Beginning of Life.* For an analysis of state regulation of human embryo research, *see generally* Lori B. Andrews, *State Regulation of Embryo Stem Cell Research* [DRAFT] (April 1999) (unpublished manuscript, on file with the National Bioethics Advisory Commission) (hereinafter Andrews I); Lori B. Andrews, *Bans Under the Embryo and Fetal Research Laws and Abortion Laws (April 1999)* (unpublished manuscript, on file with the National Bioethics Advisory Commission) (hereinafter Andrews II); Lori B. Andrews, *The Uniform Anatomical Gift Act and Embryo Stem Cell Research (April 1999)* (unpublished manuscript, on file with the National Bioethics Advisory Commission) (hereinafter Andrews III). Currently, the practice of basic embryo and fetal research is unrestricted in twenty-four states and the District of Columbia. Of the remaining twenty-six states that regulate embryo or fetal research in one form or another, basic embryological research is prohibited or restricted in ten states. New Hampshire's statute regulates the experimental use of human embryos to a degree not likely to impair research in that state. However, the remaining nine states have legislated more broadly, effectively banning all research involving *in vitro* embryos. Id.; *see also* Christine L. Feiler, *"Note:Human Embryo Experimentation: Regulation and Relative Rights,"* 66 Fordham Law Review 2435 (1998)

[7] For a legal analysis of the adoption alternative that legally and ethically should be part of any informed consent procedure involving frozen embryos in excess of clinical need, see the accompanying **Appendix C**, *The Frozen Embryos: The Adoption Solution.*

## SPECIFIC COMMENTS

1. The NIH in its own fact sheet defines "human pluripotent stem cells" to be *"a unique scientific and medical resource in that they can divide for indefinite periods in culture, and can develop into most of the specialized cells and tissues of the of body, such as muscle cells, nerve cells, heart cells, blood cells."* CLS does not object to *all* human pluripotent stem cell research. As defined by NIH, human *pluripotent* stem cells can be obtained from three sources: living human embryos (*Guidelines*, Part II.A.), fetal tissue derived from aborted deceased pre-born children (*Guidelines*, Part II.B.), and human *adult* stem cells (strangely, not even mentioned in *Guidelines*]. CLS supports federal funding for human pluripotent stem cell research using human *adult* stem cells. As yet, there is no reported scientific evidence that human *adult* stem cell research will not be sufficient to achieve all of the medical progress that is currently being offered as the excuse for ignoring all of the legal and ethical barriers and other scientific reservations involved in human embryo stem cell research.

As further discussed in **Comment 9** below, adult stem cell research promises great good and is a worthy scientific priority meriting federal funding so long as it is pursued in a lawful, ethical and scientifically appropriate fashion on the basis of broad public consensus as to what is socially acceptable for American taxpayers to fund. The public generally supports *adult* stem cell research that does no harm to anyone, but opposes research like human embryo stem cell research that relies on destroying one human life in the speculative hope of maybe making another human being's life better somehow someday. Under these circumstances it would be arbitrary and capricious for the NIH to force every American taxpayer to pay for research which many Americans believe is both unethical and unnecessary, particularly where alternative research avenues exist for pursuing the same goals in a more non-controversial, lawful and ethical fashion.

Insofar as it appears that there is no need for further *Guidelines* governing fetal tissue research because, as recognized in the *Guidelines* (Part II.B.1), such research is already "governed by federal statutory restrictions regarding fetal tissue research at 42 U.S.C. 289g-2(a) and the federal regulations at 45 C.F.R. 46.210", CLS suggests that Part II.B. of the *Guidelines* should be omitted. Indeed, it appears that the only reason Part II.B. is included in the *Guidelines* is to mask the fact that the Guidelines are only needed to deal with derivation and use of human pluripotent stem cells from *living human embryos*. Given this fact, it would be far less deceptive to delete Part II.B. and re-title the *Guidelines* as "Guidelines for Research Involving Human Embryonic Stem Cells." Likewise, throughout the *Guidelines*, substitute the word "embryonic" for the word "pluripotent." Such a change will also disclose to Congress, the courts and the American people, precisely what the NIH is primarily intending to fund for the first time pursuant to these *Guidelines --terminal experimentation on certain human beings for the speculative scientific benefit of other human beings.*

CLS futher notes that by exclusively using the term "pluripotent," the *Guidelines* are completely silent on the important issue of the use of totipotent human embryonic stem cells. Totipotent stem cells if separated from an embryo would be embryos (human beings) themselves, due to the fact that they "repair" themselves, as

is well known to NIH. The same mechanism takes place in fission during the natural twinning process. Therefore, CLS also objects to the use of totipotent stem cells in any research, and NIH should make it clear in any proposed guidelines that it would not fund either thederivation or use of totipotent stem cells for any purpose-- whether "donated" or otherwise.

In sum, only the derivation or use of *adult* stem cells or stem cells duly derived from fetal tissue pursuant to federal regulations is acceptable for federally-funded research under current law. Human embryonic stem cells, whether defined as "totipotent" or "pluripotent", are not a proper subject of federally funded research.

*2.* CLS is a signatory to the attached **STATEMENT ON HUMAN EMBRYOS AND STEM CELL RESEARCH: An Appeal for Legally and Ethically Responsible Science and Public Policy (July 1, 1999)**. The Statement, which has been signed by a still growing group of several hundred doctors, medical researchers, nurses, bio-ethicists, law professors, attorneys, and theologians makes the following points, all of which support CLS' request to withdraw the *Guidelines:*[8]

> *Stem cell research promises great good and is a worthy scientific priority as long as we pursue it ethically. Obtaining stem cells from people without seriously harming people in the process can be ethical. However, obtaining stem cells from human embryos cannot be ethical because it necessarily involves destroying those embryos.*
>
> ***A. Human embryonic stem cell research violates existing law and policy:***
>
> - ***States:*** *Homicide laws of all 50 states protect human life and the dignity of every human being--especially the vulnerable; laws of many states already specifically protect vulnerable embryonic human beings outside the womb; most prohibit destructive human embryo and human fetal research.*[9]
> - ***National:*** *The present Congressional ban on federally-funded human embryo research explicitly excludes "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death"; existing laws requiring separation between the death of an unborn child in abortion and research objectives using the unborn child's tissues preclude the destruction of human embryos as a means of achieving research objectives.*
> - ***International:*** *Documents such as the Nuremberg Code, the World Medical Association's Declaration of Helsinki, and the United Nations Declaration of Human Rights reject the use of human beings in experimental research without their informed consent and permit research on incompetent subjects only if there is a legal surrogate, minimal risk, and*

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[8] For Statement signatories and other information, *see* DO NO HARM-THE COALITION OF AMERICANS FOR RESEARCH ETHICS web site at http://www.stemcellresearch.org/signers.htm.

[9] *See* attached **Appendix A**, *The Legal Consensus on the Beginning of Life.*

*therapeutic benefit for the human subject.*

**B. *Human embryonic stem cell research is unethical:***

- *Recent history provides tragic examples of attempts to justify gross violations of the rights of human beings in medical research on the utilitarian basis of "social and medical benefit": the Tuskegee experiments on African Americans, U.S. government-sponsored radiation research, the Nazi medical war crimes, etc.*
- *Good ends (e.g., health) do not justify the use of unethical means (e.g., killing human beings).*
- *Scientifically, the international consensus of embryologists is that human beings begin at fertilization (or cloning)--i.e., when their genetic code is complete and operative; even before implantation they are far more than a "bunch of cells" or merely "potential human beings."*

**C. *Human embryonic stem cell research is scientifically unnecessary:***

- *Other research methods which use stem cells from adults to develop treatments for many diseases have recently been shown to be quite promising; in fact, the accompanying British Medical Journal (1999) has concluded that, in medical research, human embryonic stem cells "may soon be eclipsed by the more readily available and less controversial adult stem cells."* [10]
- *The use of a patient's own stem cells is even preferable to using embryonic stem cells because it avoids the problem of the body rejecting cells other than its own.*
- *Other new methods such as somatic cell gene therapy are increasingly successful in tissue regeneration and otherwise treating disease.*

3. The *Guidelines* are not designed to implement current laws and regulations protecting the human embryo from harmful experiments at federal expense -- they are designed to undermine that protection at federal expense. Such a purpose is contrary to the clear intention of Congress to maintain the *status quo* when enacting the current ban on federal funding for destructive human embryonic research. As one legal commentator has explained that legislative history (**emphasis added**):

> ***The history behind federal funding of human embryo research evinces uneasy disapproval of this type of experimentation.*** *Since 1980, the federal government has withheld funding for human embryo research by de facto*

[10] In Volume 286 of *Science* Magazine (December 17, 1999), in an article entitled *Capturing the Promise of Youth*, it is reported: *"Another astonishing development that occurred in 1999 may ease the ethical dilemma [of using stem cells derived from human embryos]. In defiance of decades of accepted wisdom, researchers in 1999 found that stem cells from adults retain the youthful ability to become several different kinds of tissues: Brain cells can become blood cells, and cells from bone marrow can become liver. Scientists are now speeding ahead with work on adult stem cells, hoping to discover whether their promise will rival that of embryonic stem (ES) cells."*

*moratorium. Until 1993, [45 C.F.R. § 46.204(d)] authorized federal funding of embryo research subject to approval of such projects by a Department of Health and Human Services Ethical Advisory Board ("EAB"). The first--and only--EAB appointed to evaluate embryo research concluded that it was ethical as a theoretical matter for the purpose of developing IVF techniques. Despite this approval, the NIH neither took action on a specific project nor appointed additional EAB's, and funding was never allocated for projects involving embryo research.*

*The National Institutes of Health Revitalization Act of 1993 eliminated the EAB approval requirements of. 45 C.F.R. § 46.204(d). ....*

*Before allocating any funds, however, the NIH convened the Human Embryo Research Panel. The Panel gathered nineteen participants with expertise in clinical research, ethics, law, social science, public health, and public policy to consider the moral and ethical implications of human embryo research, and to develop funding guidelines for that research.*

*After listening to testimony from more than forty witnesses and reviewing correspondence from 30,000 individuals,* ***the Panel [affirmed the NIH's prior recommendation] that embryo research should be funded by the federal government.*** *The members found that human embryo experimentation would generate significant advances in scientific research--particularly in the areas of infertility, genetic defects, and disease therapy. The Panel struggled, however, with the ethical implications of research conducted with deliberately fertilized embryos. While they did not define the precise moral or legal status of the embryo, they attempted to design their recommendations with "respect" for the embryo as a symbol of human life. The Panel believed that their guidelines and corresponding public funding would also stimulate ethical and scientific review of privately funded embryo research.*

....

*The Advisory Committee to the Director of the NIH ("ACD") approved all of the Panel's recommendations--including the one permitting deliberate creation of research embryos--and passed the recommendations on to the NIH Director, Harold Varmus, for the ultimate funding decision. Within hours of that vote, however, President Clinton stated: "I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that the NIH not allocate any resources for such research." William Galston, deputy director of Clinton's Domestic Policy Council, later confirmed that the Clinton administration had decided even before the ACD's meeting that deliberate creation of human embryos for experimentation exceeded the public's tolerance for "exotic" research.*

*The President's announcement did not prevent Varmus from implementing the NIH Panel's other recommendations--such as ... funding for experimentation on "surplus" embryos.* ***Congress, however, has since passed broader restrictions. Under Public Law 105-78 [continued under P.L.106-133], federal funds are presently unavailable not only for the creation of research embryos, but also for any type of research in which human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death. In effect, the***

***moratorium on federally-funded embryo research continues. No federal legislation, however, exists to regulate embryo research conducted in the private sector.***[11]

The foregoing legislative history makes clear that the purpose of the Federal Funding Ban (see footnote 2 *supra*) was to prevent NIH from implementing the very strategy the *Guidelines* are now being proposed to implement -- funding for experimentation on "surplus" human embryos. This congressional intent is absolutely frustrated by NIH's immaterial, hair-splitting distinction asserted in the *Guidelines* that a human embryo stem cell is not a human embryo. (*Guidelines*, Part I.) Moreover, given the nature of the living human embryo, *any* human stem cell research is, in the words of the Federal Funding Ban, a type of *"research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death...."* It is patently impossible for NIH in good conscience to promulgate these *Guidelines* and begin funding human embryo research without *knowing* that such funding means that human embryos are being *"knowingly subjected to risk of injury or death"* in patent violation of the Federal Funding Ban.[12] The funding proposed in the *Guidelines* can only serve to create the very "risk of ..death" prohibited by the Federal Funding Ban. Moreover, such funding plainly contradicts NIH's prior pronouncement that the early human embryo *"warrants serious moral consideration as developing form of human life."* NIH, *Final Report of the Human Embryo Research Panel*, Page 2 (1994). Killing a defenseless human being, then asking every taxpayer to pay for research on that human being's body parts, is the exact opposite of "moral consideration" --it is callous inhumanity.

*4.* The *Guidelines* tell researchers to assure parents that their *"early human embryos...will not survive"* the experiment, but *"will be handled respectfully, as is*

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[11] *See* Christine L. Feiler, *"Note: Human Embryo Experimentation: Regulation and Relative Rights,"* 66 Fordham Law Review 2435,2459-2461(1998). Pub. L. No. 105-277, Sec. 511(a) (1998), the current appropriations rider restricting the Department of Health and Human Services and its subordinates, provides that *"none of the funds made available in this Act may be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. [§] 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. [§] 289g(b))."* The standard of risk referenced in 45 C.F.R. § 46.208(a)(2) conditions *in utero* fetal research activity on the requirement that "risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means." The term "minimal risk" is defined at 45 C.F.R. § 46.102(i) as "mean[ing] that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." The standard of risk referenced in section 498(b) of the Public Health Service Act (42 U.S.C. § 289g(b)) provides that "in administering the regulations for the protection of human subjects research [at 45 C.F.R. 46] ... the Secretary [of Health and Human Services] shall require that the risk standard ... be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term."

[12] The Federal Funding Ban (*see* fn. 2 supra) defines an embryo as "any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means...." This provision proceeds to require that this embryo be treated exactly *like* protected human subjects, by extending to the embryo in the laboratory the protective standard already in effect for all fetuses *in utero*.

*appropriate for all human tissue used in research", Guidelines,* II.A.2.a.(vii). In short, *living* human embryos are to be dismissed under the *Guidelines* as mere "tissue" to be destroyed to harvest their stem cells for research. This destruction is said to be justified by, among other things, the prospect that such cells may be used reduce the need to use "laboratory animals" for drug testing (*Guidelines, 64 Fed. Reg.67576*). Such an inhumane purpose wherein the human embryo is deemed to rank lower in status than a laboratory rat only serves to reveal the inhumanity and ethical bankruptcy of the *Guidelines*. On September 7, 1999 Dr. Harold Shapiro, Chairman of the National Bioethics Advisory Commission wrote to President Clinton: "wide agreement exists that human embryos deserve respect as a form of human life." Are we to now presume that the respect due "human life" rises no higher than a lab rat?

The *Guidelines* further demean the humanity and ignore the life of the human embryo by suggesting that "early human embryos" are to be "donated" for research; and that the living human embryo's parents are only to think of themselves as "donors." *Guidelines,* Part II.A.1.c. It is quite unseemly for the NIH at all of the taxpayers expense to state in federal regulations that living human beings can and ought to "donated" by their legal guardians "for research" in this country. Human embryos are not tissue, nor are they personal property. Under the terms of the Federal Funding Ban, they are living human beings deserving of the same respect due to other protected *human* subjects under 45 C.F.R. 46

5. Since 1975, embryos in the womb at this same stage of development (about a week old) have been seen by the federal government as "human subjects" to be protected from harmful research (*see* 45 CFR §46.201 *et seq.*). Yet the NIH now decides that the same embryo outside the womb can be exploited and killed as mere "tissue." Even the NIH's own Human Embryo Research Panel in 1994, and President Clinton's National Bioethics Advisory Commission in 1999, admitted that a human embryo is a developing form of human life that deserves considerably more respect than is accorded the human embryo in the *Guidelines*.

6. Since January 1996, federal law has banned federal funding of *"research in which a human embryo or human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for fetuses in utero"* under federal human subjects regulations. Relying on a single deeply flawed legal analysis by the General Counsel of the Department of Health and Human Services, the *Guidelines* mangle the plain meaning of the law, narrowing it to ban only funding of the specific act of destroying the human embryo. This strained administrative agency interpretation, which is the *only* stated legal basis for the *Guidelines*, should also be rejected because it is no better an excuse than the misplaced distinction between derivation and use given by the complicit German residents adjacent Auschwitz in 1945 that sought to excuse their inhumanity towards the Jews by arguing "*we* didn't kill the Jews, we just used their shoes."[13]

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[13] In a letter dated February 11, 1999, about 75 members of Congress requested Secretary Shalala to correct DHHS General Counsel's misinterpretation of the federal funding ban on destructive human embryo research. The Secretary ignored the request.

7. By virtue of these *Guidelines* NIH directs how embryos are obtained for destruction, regulates the process for obtaining consent from the parents, and determines which categories of embryos may be destroyed for the federally funded research project. The *Guidelines* clearly establish that the process of destroying the embryo for its stem cells is an integral and federally regulated part of the research project receiving federal funds. The person or organization destroying the embryos can even be the same as the person who then uses the stem cells thus obtained -- simply using different funds for the two activities. Indeed, so long as the *"attending physician responsible for the fertility treatment and the researcher or investigator deriving and/or proposing to utilize human pluripotent stem cells should not have been one and the same person,"* nothing prevents an IVF facility from also being the human embryo killer and the human embryo stem cell researcher. (See *Guidelines*, Part II.A.1.b.) Thus, the Guidelines are too vague to even avoid the unacceptable "conflicts of interest" the proponents of these *Guidelines* state they were trying to achieve.

8. Embryos are deemed eligible for destructive research under the *Guidelines* if they were originally created for reproductive purposes but are now seen as being "in excess of clinical need"(i.e., are unwanted by the parents). But current federal law on embryo research was clearly designed to extend the same protection to these embryos that is now provided for the unborn child in the womb.[14]That law prohibits any effort to select an unborn child for risky or lethal research because he or she is "unwanted" and slated for a future abortion. Because that principle is ignored here, the *Guidelines* should be deemed to be contrary to the plain meaning and intent of the statutory ban on the federal funding of human embryo research.

9. A year ago it was claimed that embryonic cells were necessary for stem cell research because they were unique in their ability to self-renew for long periods and to create tissues and cells of widely differing types. But this claim is already well on its way to being discredited. For example, see the December 7 Proceedings of the National Academy of Sciences (muscle tissue producing a wide array of blood cells), July 6 issue of the same journal (long-term culturing and growth of adult stem cells), May 14 issue of *Science* (bone marrow stem cells producing liver and other tissue) and January 22, 1998 issue of that journal (neural stem cells producing blood cells). Even the NIH Human Embryo Research Panel and the National Bioethics Advisory Commission said human embryos should not be exploited except for vitally important research that cannot otherwise be done. Because the *Guidelines* fail to make any showing that human embryonic stem cell research is currently necessary and sufficient to accomplish vitally important research that cannot otherwise be accomplished through the use of adult stem cells, the *Guidelines* should be withdrawn as premature and unnecessary at this time.

Until the publication of these proposed *Guidelines*, it has been NIH's position that human embryos are to be used for research only if " the research goals cannot otherwise be accomplished" by other means. NIH, *Final Report of the Human Embryo Research Panel (1994)*, at page 3. More recently, the National Bioethics Advisory Commission has said that the derivation of stem cells from embryos is justifiable *"only*

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[14] *See* footnote 12 supra.

*if no less morally problematic alternatives are available for advancing the research."* NBAC, *Ethical Issues in Human Stem Cell Research* (Rockville, MD: September 1999, Volume I, at page 53.) Given what we know about the progress of adult stem cell research, NIH ought to withdraw the Guidelines and continue to fund adult stem cell research only as the "less morally problematic" alternative.

**10.** These *Guidelines* only set the stage for further abuses - No embryos *"created for research purposes"* are to be used (*64 Fed. Reg.67579*). But the distinction between *"spare"* embryos that are in *"excess of clinical use"* and those specially created for research is easy to evade: Infertility clinics can simply create more embryos at the outset, ostensibly for fertility treatment, so they will have more "spares" left for research. Ironically, the funding separation attempted by these guidelines, requiring the NIH to accept at face value the assurances researchers provide as to how they used private funds to obtain and destroy embryos, make it even less likely that such abuses will be detected or stopped. Thus, the *Guidelines* tend to encourage, not avoid, the very sort of abuses that will degrade public trust in the entire enterprise. The *Guidelines* also forbid funding of "research in which" stem cells are used to create a new embryo, as well as "research in which" human stem cells are combined with an animal embryo, etc. (*64 Fed. Reg.67579*). But now that the NIH erroneously interprets the phrase "research in which" in the Federal Funding Ban to apply only to funding the specific act itself, the NIH has left itself wide open to federal support for projects involving such abuses. Since the *Guidelines* are too vague and imprecise even to prevent the abuses which the proponents seem to agree would be abusive they should be withdrawn.[15]

**11.** The *Guidelines* erroneously presuppose without explanation that the parents of the human embryos are legally and morally empowered to substitute their judgment for the judgment of the human embryo in consenting to the killing of the human embryo due to the obvious incompetence of the human embryo to speak for itself.

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[15] The NIH is no stranger to the damage to public confidence such abuses engender. In January, 1997, media controversy erupted when NIH-supported geneticist and former HERP panelist Mark Hughes from Georgetown University was found to have violated the restrictions governing the use of human embryos. Hughes had included Federal equipment and personnel in lab experiments on prenatal embryo diagnosis, violating strict segregation rules designed to implement the ban. NIH Director Harold Varmus severed ties with the scientist and told a Congressional committee investigating the incident that NIH had taken "several steps to further diminish the risk of subsequent violations." See Rick Weiss, *"Georgetown Geneticist Admits Disobeying Test Ban on Embryos,"* Washington Post, 15 January 1997: 3; Testimony of Harold E. Varmus, M.D., Director, NIH, Before the Subcommittee on Oversight and Investigations Committee on Commerce, United States House of Representatives, June 19, 1997 (Serial No. 105-26; ISBN 0-16-055330-X). At that time, Dr. Varmus testified that Dr. Hughes' pre-implantation genetic diagnostic research of human embryos using federal equipment and funds violated "[federal] appropriations laws prohibited the use of federal resources for human embryo research." *Id. at 3-4;* Congressional Statement at 2; and Letter from John J. Callahan, Assistant Secretary for Management and Budget, DHHS, to DHHS Institutional Officials (February 1997) (reinforcing the legal requirements of the Congressional human embryo research ban). If the Hughes incident which did not even result in the deaths of any human embryos violated the Federal Funding Ban, how can the NIH consistently argue that the *Guidelines* which depend on the uniform destruction of human embryos not also violate the Federal Funding Ban?

(*Guidelines*, Part II.A.2.) In recent years, courts have encountered, with increasing frequency, requests for permission to withhold life-supporting medical treatment from incompetent individuals. Some courts have employed this so-called doctrine of substituted judgment to decide cases where the surrogate decision-maker's motives are not self-interested and can be further shown to reflect the true intentions of the incompetent patient, particularly where the imminent terminal outcome for the patient can be shown or safely presumed regardless of the medical care provided. However, any application of this doctrine in the instant situation to be regulated by the *Guidelines* suffers from theoretical incoherence and practical un-workability where a terminal outcome for the human embryo can be readily avoided by cyropreservation and implantation, and the surrogate decision-makers must be presumed to have an exclusively self-interested motive to always destroy the human embryo because the *Guidelines* presume the parents will only be asked to "donate" human embryos "in excess" of *their* clinical need." (*Guidelines*, Part II.A.1.)

Given the legal and moral uncertainty that the parents of a human embryo *ex utero* can or ought to be so authorized to speak for the human embryo under these circumstances, CLS suggests that such authority should only be legally recognized after a judicial proceeding and a court order, where the human embryos interests are represented by a court-appointed attorney, rather than his or her parents. Surely, if the interests of science are as great as the *Guidelines* suggest, the cost of requiring these judicial proceedings would be a small price to pay for the certainty that the decision to kill the human embryos was made by a neutral third party in conformance with applicable state law, untainted by conflicts of interest, and in a fully informed fashion.

CLS further submits that the *Guidelines* should not presume that the parents of the human embryo *ex utero* can legally and morally substitute their judgment for their incompetent human embryos who find themselves in the unfortunate position of being "in excess of clinical need." As one commentator has suggested under these circumstances:

> *[P]erhaps the best way to preclude the exploitation of the relative defenselessness of incompetents would be to set up a standard whereby incompetents would be treated as if they were competent individuals desiring life. Such a standard would not require the application of useless treatments, since these are irrelevant to a human embryos desire and ability to live. Nor would this standard mandate a life-at-all-costs approach: if a given treatment option would not be open to a competent individual (whether because of expense or impracticability, or because the requisite resources are already occupied elsewhere), it would also not be available to the incompetent. But his approach would require that an incompetent not be denied beneficial treatments solely on the basis of his incompetence to choose them.*
>
> *This approach, which might be denominated the 'presumptions approach,' seeks to strain out improper decisional bases. The notion that some classes of humans have less value before the law, for example, might otherwise serve as an implicit or explicit basis for decision-making.*

> *The presumptions approach also serves to check motivations originating in third-party selfishness. The strong presumption against the wishes of parental "donors" provides a stronger safeguard for the incompetent than does a standard which too readily accedes to the [donor's] requests. Those who seek the court's aid often want desperately to believe that they are acting for the incompetent's good, and not just their own convenience. Presumptions to the contrary test this belief and force its reexamination by both the court and, ideally, the parties seeking relief.* [16]

**12.** The *Guidelines* fail to require that parents receive sufficient information to be able to give a truly *informed* consent. By referring to the human embryo as mere "tissue" and then telling the parents that this tissue "will not survive" the stem cell harvesting process, the Guidelines are too evasive and euphemistic to withstand legal challenge as an inadequate consent. The National Bioethics Advisory Commission has recommended that such information *"make clear that the research will involve the destruction of the embryos."* NBAC, *Ethical Issues in Human Stem Cell Research* (Rockville, MD: September 1999, Volume I, at page 72.) Such clarity in this case will only serve to more clearly show how patently violative of the current Federal Funding Ban these proposed Guidelines are.

*CHRISTIAN LEGAL SOCIETY*

*By:* _____
*Samuel B. Casey, Executive Director*

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[16] Walter Weber, *Substituted Judgment Doctrine: A Critical Analysis*, 1 Issues L & Med. 131, 154-54 (1985).

# STATEMENT

## ON HUMAN EMBRYOS AND STEM CELL RESEARCH:

### AN APPEAL FOR LEGALLY AND ETHICALLY RESPONSIBLE SCIENCE AND PUBLIC POLICY

Released July 1, 1999

Recent scientific advances in human stem cell research have brought into fresh focus the dignity and status of the human embryo. These advances have prompted a decision by the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) to fund stem cell research which is dependent upon the destruction of human embryos. Moreover, the National Bioethics Advisory Commission (NBAC) is calling for a modification of the current ban against federally funded human embryo research in order to permit direct federal funding for the destructive harvesting of stem cells from human embryos. These developments require that the legal, ethical, and scientific issues associated with this research be critically addressed and articulated. Our careful consideration of these issues leads to the conclusion that human stem cell research requiring the destruction of human embryos is objectionable on legal, ethical, and scientific grounds. Moreover, destruction of human embryonic life is unnecessary for medical progress, as alternative methods of obtaining human stem cells and of repairing and regenerating human tissue exist and continue to be developed.

#### Human Embryonic Stem Cell Research Violates Existing Law and Policy

In November 1998, two independent teams of U.S. scientists reported that they had succeeded in isolating and culturing stem cells obtained from human embryos and fetuses. Stem cells are the cells from which all 210 different kinds of tissue in the human body originate. Because many diseases result from the death or dysfunction of a single cell type, scientists believe that the introduction of healthy cells of this type into a patient may restore lost or compromised function. Now that human embryonic stem cells can be isolated and multiplied in the laboratory, some scientists believe that treatments for a variety of diseases–such as diabetes, heart disease, Alzheimer's, and Parkinson's–may be within reach. While we in no way dispute the fact that the ability to treat or heal suffering persons is a great good, we also recognize that not all methods of achieving a desired good are morally or legally justifiable. If this were not so, the medically accepted and legally required practices of informed consent and of seeking to do no harm to the patient could be ignored whenever some "greater good" seems achievable.

One of the great hallmarks of American law has been its solicitous protection of the lives of individuals, especially the vulnerable. Our nation's traditional protection of human life and human rights derives from an affirmation of the essential dignity of every human being. Likewise, the

international structure of human rights law–one of the great achievements of the modern world–is founded on the conviction that when the dignity of one human being is assaulted, all of us are threatened. The duty to protect human life is specifically reflected in the homicide laws of all 50 states. Furthermore, federal law and the laws of many states specifically protect vulnerable human embryos from harmful experimentation. Yet in recently publicized experiments, stem cells have been harvested from human embryos in ways which destroy the embryos.

Despite an existing congressional ban on federally-funded human embryo research, the Department of Health and Human Services (HHS) determined on January 15, 1999 that the government may fund human embryonic stem cell research. The stated rationales behind this decision are that stem cells are not embryos (which itself may be a debatable point) and that research using cells obtained by destroying human embryos can be divorced from the destruction itself. However, even NBAC denies this latter claim, as is evident by the following statement in its May 6, 1999 Draft Report on Stem Cell Research:

> Whereas researchers using fetal tissue are not responsible for the death of the fetus, researchers using stem cells derived from embryos will typically be implicated in the destruction of the embryo. This is true whether or not researchers participate in the derivation of embryonic stem cells. As long as embryos are destroyed as part of the research enterprise, researchers using embryonic stem cells (and those who fund them) will be complicit in the death of embryos.

If the flawed rationales of HHS are accepted, federally-funded researchers may soon be able to experiment on stem cells obtained by destroying embryonic human beings, so long as the act of destruction does not itself receive federal funds. However, the very language of the existing ban prohibits the use of federal funds to support "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death...." (Sec. 511(a)(2)). Obviously, Congress' intent here was not merely to prohibit the use of federal funds for embryo destruction, but to prohibit the use of such funds for research dependent in any way upon such destruction. Therefore, the opinion of HHS that human embryonic stem cell research may receive federal funding clearly violates both the language of and intention behind the existing law. Congress and the courts should ensure that the law is properly interpreted and enforced to ban federal funding for research which harms, destroys, or is dependent upon the destruction of human embryos.

It is important to recognize also that research involving human embryos outside the womb–such as embryos produced in the laboratory by *in vitro* fertilization (IVF) or cloning–has never received federal funding. Initially, this was because a federal regulation of 1975 prevented government funding of IVF experiments unless such experiments were deemed acceptable by an Ethics Advisory Board. Following the failure of the first advisory board to reach a consensus on the matter, no administration chose to appoint a new board. After this regulation was rescinded by Congress in 1993, the Human Embryo Research Panel recommended to the National Institutes of Health (NIH) that certain kinds of harmful nontherapeutic experiments using human embryos receive federal funding. However, these recommendations were rejected in part by President Clinton and then rejected in their entirety by Congress.

Further, it is instructive to note that the existing law which permits researchers to use fetal tissue obtained from elective abortions requires that the abortions are performed for reasons which are entirely unrelated to the research objectives. This law thus prohibits HHS from promoting the destruction of human life in the name of medical progress, yet medical progress is precisely the

motivation and justification offered for the destruction of human life that occurs when stem cells are obtained from human embryos.

Current law against funding research in which human embryos are harmed and destroyed reflects well-established national and international legal and ethical norms against the misuse of any human being for research purposes. Since 1975, those norms have been applied to unborn children at every stage of development in the womb, and since 1995 they have been applied to the human embryo outside the womb as well. The existing law on human embryonic research is a reflection of universally accepted principles governing experiments on human subjects–principles reflected in the Nuremberg Code, the World Medical Association's Declaration of Helsinki, the United Nations Declaration of Human Rights, and many other statements. Accordingly, members of the human species who cannot give informed consent for research should not be the subjects of an experiment unless they personally may benefit from it or the experiment carries no significant risk of harming them. Only by upholding such research principles do we prevent treating people as things–as mere means to obtaining knowledge or benefits for others.

It may strike some as surprising that legal protection of embryonic human beings can co-exist with the U.S. Supreme Court's 1973 legalization of abortion. However, the Supreme Court has never prevented the government from protecting prenatal life outside the abortion context, and public sentiment also seems even more opposed to government funding of embryo experimentation than to the funding of abortion. The laws of a number of states–including Louisiana, Maine, Massachusetts, Michigan, Minnesota, Pennsylvania, Rhode Island, and Utah–specifically protect embryonic human beings outside the womb. Most of these provisions prohibit experiments on embryos outside the womb. We believe that the above legally acknowledged protections against assaults on human dignity must be extended to all human beings–irrespective of gender, race, religion, health, disability, or age. Consequently, the human embryo must not be subject to willful destruction even if the stated motivation is to help others. Therefore, on existing legal grounds alone, research using stem cells derived from the destruction of early human embryos is proscribed.

## Human Embryonic Stem Cell Research Is Unethical

The HHS decision and the recommendations of NBAC to federally fund research involving the destruction of human embryos would be profoundly disturbing even if this research could result in great scientific and medical gain. The prospect of government-sponsored experiments to manipulate and destroy human embryos should make us all lie awake at night. That some individuals would be destroyed in the name of medical science constitutes a threat to us all. Recent statements such as "stem cell research is too promising to be slowed, impeded, or stopped" underscore the sort of utopianism and hubris that could blind us to the truth of what we are doing and the harm we could cause to ourselves and others. Human embryos are not mere biological tissues or clusters of cells; they are the tiniest of human beings. Thus, we have a moral responsibility not to deliberately harm them.

An international scientific consensus now recognizes that human embryos are biologically human beings beginning at fertilization, and acknowledges the physical continuity of human growth and development from the one-cell stage forward. In the 1970s and 1980s, some frog and mouse embryologists referred to the human embryo in its first week or two of development as a "pre-

embryo," claiming that it deserved less respect than embryos in later stages of development. However, some embryology textbooks now openly refer to the term "pre-embryo" as a scientifically invalid and "inaccurate" term which has been "discarded" and others which once used the term have quietly dropped it from new editions. Both the Human Embryo Research Panel and the National Bioethics Advisory Commission have also rejected the term, describing the human embryo from its earliest stages as a living organism and a "developing form of human life." The claim that an early human embryo becomes a human being only after 14 days or implantation in the womb is therefore a scientific myth. Finally, the historic and well-respected 1995 Ramsey Colloquium statement on embryo research acknowledges that:

> The [embryo] is human; it will not articulate itself into some other kind of animal. Any being that is human is a human being. If it is objected that, at five days or fifteen days, the embryo does not look like a human being, it must be pointed out that this is precisely what a human being looks like—and what each of us looked like—at five or fifteen days of development.

Therefore, the term "pre-embryo," and all that it implies, is scientifically invalid.

The last century and a half has been marred by numerous atrocities against vulnerable human beings in the name of progress and medical benefit. In the 19th century, vulnerable human beings were bought and sold in the town square as slaves and bred as though they were animals. In this century, the vulnerable were executed mercilessly and subjected to demeaning experimentation at Dachau and Auschwitz. At mid-century, the vulnerable were subjects of our own government's radiation experiments without their knowledge or consent. Likewise, vulnerable African-Americans in Tuskegee, Alabama were victimized as subjects of a government-sponsored research project to study the effects of syphilis. Currently, we are witness to the gross abuse of mental patients used as subjects in purely experimental research. These experiments were and are driven by a crass utilitarian ethos which results in the creation of a "sub-class" of human beings, allowing the rights of the few to be sacrificed for the sake of potential benefit to the many. These unspeakably cruel and inherently wrong acts against human beings have resulted in the enactment of laws and policies which require the protection of human rights and liberties, including the right to be protected from the tyranny of the quest for scientific progress. The painful lessons of the past should have taught us that human beings must not be conscripted for research without their permission–no matter what the alleged justification–especially when that research means the forfeiture of their health or lives. Even if an individual's death is believed to be otherwise imminent, we still do not have a license to engage in lethal experimentation–just as we may not experiment on death row prisoners or harvest their organs without their consent.

We are aware that a number of Nobel scientists endorse human embryonic stem cell research on the basis that it may offer a great good to those who are suffering. While we acknowledge that the desire to heal people is certainly a laudable goal and understand that many have invested their lives in realizing this goal, we also recognize that we are simply not free to pursue good ends via unethical means. Of all human beings, embryos are the most defenseless against abuse. A policy promoting the use and destruction of human embryos would repeat the failures of the past. The intentional destruction of some human beings for the alleged good of other human beings is wrong. Therefore, on ethical grounds alone, research using stem cells obtained by destroying human embryos is ethically proscribed.

## Human Embryonic Stem Cell Research is Scientifically Questionable

Integral to the decision to use federal funds for research on human embryonic stem cells is the distinction between stem cells and embryos. HHS has stated that federal funds may be used to support human embryonic stem cell research because stem cells are not embryos. A statement issued by the National Institutes of Health (NIH) regarding this decision asserts that "The congressional prohibition on the use of [government] funds for...embryo research does not apply to research utilizing human pluripotent stem cells because such cells are not an embryo as defined by statute. Moreover, because pluripotent stem cells do not have the capacity to develop into a human being, they cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term."

It is important to note that the materials used in an experiment, as well as the methods of experimentation, are considered to be part of scientific research. When a scientific study is published, the first part of the article details the methods and materials used to conduct the research. Ethical and scientific evaluation of an experiment takes into account both the methods and materials used in the research process. Therefore, the source of stem cells obtained for research is both a scientifically and ethically relevant consideration.

Research on human embryonic stem cells is objectionable due to the fact that such research necessitates the prior destruction of human embryos; however, the HHS's claim that stem cells are not, and cannot develop into, embryos may itself be subject to dispute. Some evidence suggests that stem cells cultured in the laboratory may have a tendency to recongregate and form an aggregate of cells capable of beginning to develop as an embryo. In 1993, Canadian scientists reported that they successfully produced a live-born mouse from a cluster of mouse stem cells. While it is true that these stem cells had to be wrapped in placenta-like cells in order to implant in a female mouse, it seems that at least some doubt has been cast on the claim that a cluster of stem cells is not embryonic in nature. If embryonic stem cells do indeed possess the ability to form or develop as a human embryo (without any process of activation which affects the transformation of the cell into a human embryo), research on such stem cells could itself involve the creation and/or destruction of human life and would thereby certainly fall under the existing ban on federally-funded embryo research. It would be irresponsible for the HHS to conduct and condone human embryonic stem cell research without first discerning the status of these cells. Their use in any research in which they could be converted into human embryos should likewise be banned.

## Methods of Repairing and Regenerating Human Tissue Exist Which Do Not Require the Destruction of Human Embryos

While proponents of human embryonic stem cell research lobby aggressively for government funding of research requiring the destruction of human embryos, alternative methods for repairing and regenerating human tissue render such an approach unnecessary for medical progress.

For instance, a promising source of more mature stem cells for the treatment of disease is hematopoietic (blood cell-producing) stem cells from bone marrow or even from the placenta or umbilical cord blood in live births. These cells are already widely used in cancer treatment and in research on treating leukemia and other diseases. Recent experiments have indicated that their

versatility is even greater than once thought. For example, given the right environment, bone marrow cells can be used to regenerate muscle tissue, opening up a whole new avenue of potential therapies for muscular dystrophies. In April 1999, new advances were announced in isolating mesenchymal cells from bone marrow and directing them to form fat, cartilage, and bone tissue. Experts in stem cell research believe that these cells may allow for tissue replacement in patients suffering from cancer, osteoporosis, dental disease, or injury.

An enormously promising new source of more mature stem cells is fetal bone marrow, is many times more effective than adult bone marrow and umbilical cord blood. It appears that fetal bone marrow cells do not provoke immune reactions to the same degree as adult or even newborn infant cells. This is true whether the unborn child is the donor or the recipient–that is, fetal cells can be used to treat adults, or adult bone marrow cells can be used to treat a child in the womb without the usual risk of harmful immune reactions. Such cells would not need to be derived from fetuses who were intentionally aborted, but could instead be obtained from spontaneously aborted fetuses or stillborn infants.

In 1999, unprecedented advances were also made in isolating and culturing neural stem cells from living human nerve tissue and even from adult cadavers. Such advances render it quite possible that treatment of neural diseases such as Parkinson's and Alzheimer's, as well as spinal cord injuries, will not depend upon destructive embryo research.

Earlier claims that embryonic stem cells are uniquely capable of "self-renewal" and indefinite growth can also now be seen as premature. For example, scientists have isolated an enzyme, telomerase, which may allow human tissues to grow almost indefinitely. Although this enzyme has been linked to the development of cancer, researchers have been able to use it in a controlled way to "immortalize" useful tissue without producing cancerous growths or other harmful side effects. Thus, cultures of non-embryonic stem cells may be induced to grow and develop almost indefinitely for clinical use.

One of the most exciting new advances in stem cell research is the January 1999 announcement that Canadian and Italian researchers succeeded in producing new blood cells from neural stem cells taken from an adult mouse. Until recently, it was believed that adult stem cells were capable of producing only a particular type of cell: for example, a neural stem cell could develop only into cells belonging to the nervous system. Researchers believed that only embryonic stem cells retained the capacity to form all kinds of tissue in the human body. However, if stem cells taken from adult patients can produce cells and tissues capable of functioning within entirely different systems, new brain tissue needed to treat a patient with Parkinson's disease, for example, might be generated from blood stem cells derived from the patient's bone marrow. Conversely, neural stem cells might be used to produce needed blood and bone marrow. Use of a patient's own stem cells would circumvent one of the major obstacles posed by the use of embryonic stem cells–namely, the danger that tissue taken from another individual would be rejected when transplanted into a patient. Thus, in commenting on this finding, the *British Medical Journal* remarked on January 30, 1999 that the use of embryonic stem cells "may soon be eclipsed by the more readily available and less controversial adult stem cells." Given that the function of the adult stem cells was converted without the cells first having to pass through an embryonic stage, the use of such cells would not be subject to the ethical and legal objections raised by the use of human embryonic stem cells. The Director of the NIH has pointed out that evidence that adult stem cells can take on different functions has emerged only from studies on mice. However, his own claim that human embryonic stem cell research can produce treatments for

diabetes and other diseases is also based solely on experimental success in mice.

One approach to tissue regeneration that does not rely on stem cells at all, but on somatic cell gene therapy, is already in use as an experimental treatment. A gene that controls production of growth factors can be injected directly into a patient's own cells, with the result that new blood vessels will develop. In early trials, this type of therapy saved the legs of patients who would have otherwise undergone amputation. It was reported in January 1999 that the technique has generated new blood vessels in the human heart and improved the condition of 19 out of 20 patients with blocked cardiac blood vessels. Such growth factors are now being explored as a means for growing new organs and tissues of many kinds.

The above recent advances suggest that it is not even necessary to obtain stem cells by destroying human embryos in order to treat disease. A growing number of researchers believe that adult stem cells may soon be used to develop treatments for afflictions such as cancer, immune disorders, orthopedic injuries, congestive heart failure, and degenerative diseases. Such researchers are working to further research on adult, rather than embryonic, stem cells. In light of these promising new scientific advances, we urge Congress to provide federal funding for the development of methods to repair and regenerate human tissue which do not require the destruction of embryonic human life. However, even if such methods do not prove to be as valuable in treating disease as are human embryonic stem cells, use of the latter in the name of medical progress is still neither legally nor ethically justifiable for the reasons stated in this document.

## Conclusion

We believe that an examination of the legal, ethical, and scientific issues associated with human embryonic stem cell research leads to the conclusion that the use of federal funds to support any such research that necessitates the destruction of human embryos is, and should remain, prohibited by law. Therefore, we call on Congress to (1) maintain the existing ban against harmful federally-funded human embryo research and make explicit its application to stem cell research requiring the destruction of human embryos and (2) provide federal funding for the development of alternative treatments which do not require the destruction of human embryonic life. If anything is to be gained from the cruel atrocities committed against human beings in the last century and a half, it is the lesson that the utilitarian devaluation of one group of human beings for the alleged benefit of others is a price we simply cannot afford to pay.

For more information visit http://www.stemcellresearch.org

A referenced version is available upon request. If desired, contact The Center for Bioethics and Human Dignity at 847-317-8180.

# Doctors may report violence to police

Roger Dobson, *Abergavenny*

Doctors and nurses in Wales's biggest accident and emergency unit are being given the go-ahead to report cases of violence to the police on behalf of patients.

The move is part of a crackdown on violence launched by the Cardiff Violence Prevention Group chaired by John Shepherd, professor of oral and maxillofacial surgery at the University of Wales College of Medicine.

The innovative Cardiff project, visited by the home secretary, Jack Straw, and the Welsh secretary, Alun Michael, last week, also includes a strategy to name and shame the pubs and clubs that provide the unit with the most patients.

Free phone lines are provided for patients in the unit who want to report their injuries to the police.

Victims of violence also have access to an on-call psychological service.

Professor Shepherd says research shows that only one in nine assaults in licensed premises (and only one in three assaults in the community) that result in accident and emergency treatment for the victim are recorded by the police. He says that this suggests that patients who have been victims of violence need access to the criminal justice system while they are in hospital.

"But patients are passively prevented from reporting offences because when they come they spend some hours here and don't have any ready access to the police. To improve access we have put free phone lines to the police in the waiting rooms."

He and his team have also been in contract with the General Medical Council about the idea of doctors and nurses making complaints directly to the police at the request of patients.

"The GMC has now told us by letter that it cannot see any objections to doctors reporting offences to the police on behalf of patients, so we will be starting that pretty soon," he says. □

# GPs criticised by ombudsman

John Warden, *parliamentary correspondent, BMJ*

The first GPs in Britain to experience the rigours of the health service ombudsman's jurisdiction were called to account last week by MPs on the Commons select committee on public administration.

Dr William Cuthbert, a GP in Wolverhampton, was criticised by the ombudsman, Michael Buckley, for failing to respond to an out of hours call to arrange a syringe driver to administer morphine to a terminally ill patient when he was shopping on a Saturday morning.

He advised the relatives to call again on Monday morning, but by then the woman had died. The ombudsman upheld a daughter's complaint and found that Dr Cuthbert's actions fell well short of the professional service the patient and her family had a right to expect.

Dr Cuthbert told the committee that at the time he felt there was little he could do for the patient except send her to hospital, but the family were against that. With hindsight, he now felt he should have visited and had apologised to the family.

"I feel guilty. I feel I could have done better. There was a lack of communication," Dr Cuthbert said. He was now more cautious and looked for possible pitfalls. Asked what lessons there were for other doctors, Dr Cuthbert replied: "Short of visiting every patient who calls—if in doubt, go and have a look."

Dr Deepak Trevidi, a Wigan GP, was criticised by the ombudsman for acting with undue haste in removing three households—a mother, daughter, and son—from his list when only one removal was justified.

Dr Trevidi should have made more effort to preserve the doctor-patient relationship, the ombudsman said.

Dr Trevidi admitted to the MPs that at the time he was not aware of General Medical Service Committee's guidance of some six months earlier that as a matter of courtesy GPs should inform patients of a removal and briefly outline the reasons.

Dr Trevidi now accepted that he should have explained his reasons to the families. In his experience, however, if there was a disagreement with one unit of a family it was better to remove all of them. Since 1996 the ombudsman has had powers to investigate the actions of GPs. □

# Adult stem cells may be redefi nable

Deborah Josefson, *San Francisco*

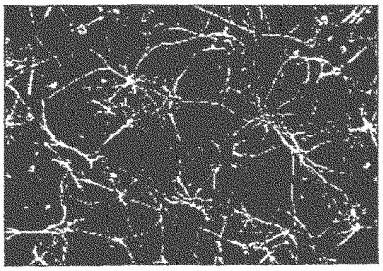
New research indicates that adult neural stem cells—previously thought to be committed to becoming either neurones, astrocytes, or oligodendrocytes—can de-differentiate and reinvent themselves as haemopoietic precursors (*Science* 1999;283:471, 534-7).

This finding raises the possibility that adult human stem cells may some day be coached to grow into organs, regenerate damaged tissue, or reconstitute the immune system.

The problem of immune rejection may also be circumvented if an individual's own cells can be used.

It also means that the need for fetal cells as a source of stem cells for medical research may soon be eclipsed by the more readily available and less controversial adult stem cells.

Christopher Bjornson, of the University of Washington in Seattle, and Angelo Vescovi, of the National Neurological Institute in Milan, Italy, showed that both adult and embryonic murine neural stem cells can adopt a haemopoietic identity when transplanted into mice whose bone marrow has been destroyed by radiation.



Astrocytes: can they reinvent themselves?

The scientists irradiated BALB/c mice to destroy their bone marrow and then injected them with neural stem cells derived from another strain of mice known as ROSA26.

The donor ROSA26 mice were transgenic for the *Escherichia coli* lacZ gene, which encodes the enzyme B-galactosidase. The presence of this gene product served as a marker to identify which cells took up the injected neural precursors.

The scientists injected mice with both adult and embryonic neural stem cells. Five to 12 months later they detected strong lacZ signals in the irradiated BALB/c mice, indicating that the donated cells had taken up residence in the mice.

B-galactosidase was found in the bone marrow of mice that had received adult neural stem cells, indicating that some of the donated cells had redeveloped into haemopoietic cells.

The researchers found that adult stem cells were as effective in reconstituting the immune system as fetal neural stem cells. However, both fetal and adult neural stem cells took longer to repopulate the bone marrow than did a control group with injected foreign hemopoetic cells.

The difference may reflect the time it takes for neural stem cells to redefine themselves. □

**APPENDIX A**
CLS Comments on Draft NIH Guidelines for Research
Involving Human Pluripotent Stem Cells,
64 Federal Register 67576-67579 (December 2, 1999)

(*International Journal of Sociology and Social Policy* 1999, 19:3/4:22-36 (in press)

# WHEN DO HUMAN BEINGS BEGIN? "SCIENTIFIC" MYTHS AND SCIENTIFIC FACTS

Dianne N. Irving, M.A., Ph.D.
(copyright February 1999)

## I. Introduction

The question as to when the physical material dimension of a human *being* begins is strictly a scientific question, and fundamentally should be answered by human embryologists—not by philosophers, bioethicists, theologians, politicians, x-ray technicians, movie stars, or obstetricians and gynecologists. The question as to when a human *person* begins is a philosophical question. Current discussions on abortion, human embryo research (including cloning, stem cell research, and the formation of mixed-species chimeras), and the use of abortifacients involve specific claims as to when the life of every human being begins. If the "science" used to ground these various discussions is incorrect, then any conclusions will be rendered groundless and invalid. The purpose of this article is to focus primarily on a sampling of the "scientific" myths, and on the objective scientific facts that ought to ground these discussions. At least it will clarify what the actual international consensus of human embryologists is with regard to this relatively simple scientific question. In the final section, I will also address some "scientific" myths that have caused much confusion within the philosophical discussions on "personhood."

## II. When does a human *being* begin?

Getting a handle on just a few basic human embryological terms accurately can considerably clarify the drastic difference between the "scientific" myths that are currently circulating, and the actual objective scientific facts. This would include such basic terms as: "gametogenesis," "oogenesis," "spermatogenesis," "fertilization," "zygote," "embryo," and "blastocyst." Only brief scientific descriptions will be given here for these terms. Further, more complicated, details can be obtained by investigating any well-established human embryology textbook in the library, such as some of those referenced below. Please note that the scientific facts presented here are not simply a matter of my own opinion. They are direct quotes and references from some of the most highly respected human embryology textbooks, and represent a consensus of human embryologists internationally.

**CLS Comments on NIH Guidelines**
**Appendix A (Cont.)**

**A. Basic human embryological facts**

To begin with, scientifically something very radical occurs between the processes of gametogenesis and fertilization—the change from a simple *part* of one human being (i.e., a sperm) and a simple *part* of another human being (i.e., an oocyte—usually referred to as an "ovum" or "egg"), which simply possess "human life", to a new, genetically unique, newly existing, individual, whole living human *being* (a single-cell embryonic human zygote). That is, upon fertilization, parts of human beings have actually been transformed into something very different from what they were before; they have been changed into a single, whole human being. During the process of fertilization, the sperm and the oocyte cease to exist as such, and a new human being is produced.

To understand this, it should be remembered that each kind of living organism has a specific number and quality of chromosomes that are characteristic for each member of a species. (The number can vary only slightly if the organism is to survive.) For example, the characteristic number of chromosomes for a member of the human species is 46 (plus or minus, e.g., in human beings with Down's or Turner's syndromes). Every somatic (or, body) cell in a human being has this characteristic number of chromosomes. Even the early germ cells contain 46 chromosomes; it is only their mature forms - the sex gametes, or sperms and oocytes - which will later contain only 23 chromosomes each..[1] Sperms and oocytes are derived from primitive germ cells in the developing fetus by means of the process known as "gametogenesis." Because each germ cell normally has 46 chromosomes, the process of "fertilization" can not take place until the total number of chromosomes in each germ cell are cut in half. This is necessary so that after their fusion at fertilization the characteristic number of chromosomes in a single individual member of the human species (46) can be maintained—otherwise we would end up with a monster of some sort.

To accurately see why a sperm or an oocyte are considered as only possessing human life, and not as living human beings themselves, one needs to look at the basic scientific facts involved in the processes of **gametogenesis** and of **fertilization**. It may help to keep in mind that the products of gametogenesis and fertilization are very different. The products of gametogenesis are mature sex gametes with only 23 instead of 46 chromosomes. The product of fertilization is a living human being with 46 chromosomes. Gametogenesis refers to the maturation of germ cells, resulting in gametes. Fertilization refers to the initiation of a new human being.

**1) Gametogenesis**

As the human embryologist Larsen[2] states it, **gametogenesis** is the process that converts primordial germ cells (primitive sex cells) into mature sex gametes—in the male (spermatozoa, or sperms), and in the female (definitive oocytes). The timing of gametogenesis is different in males and in females. The later stages of spermatogenesis in males occur at puberty, and continue throughout adult life. The process involves the production of spermatogonia from the primitive germ cells, which in turn become primary spermatocytes, and finally spermatids—or mature spermatozoa (sperms). These mature sperms will have only half of the number of their original chromosomes—i.e., the

number of chromosomes has been cut from 46 to 23, and therefore they are ready to take part in fertilization.[3]

**Oogenesis** begins in the female during fetal life. The total number of primary oocytes—about 7 million—is produced in the female fetus' ovaries by 5 months of gestation in the mother's uterus. By birth, only about 700,000 - 2 million remain. By puberty, only about 400,000 remain. The process includes several stages of maturation—the production of oogonia from primitive germ cells, which in turn become primary oocytes, which become definitive oocytes only at puberty. This definitive oocyte is what is released each month during the female's menstrual period, but it still has 46 chromosomes. In fact, it does not reduce its number of chromosomes until and unless it is fertilized by the sperm, during which process the definitive oocyte becomes a secondary oocyte with only 23 chromosomes.[4]

This halving of the number of chromosomes in the oocytes takes place by the process known as **meiosis**. Many people confuse meiosis with a different process known as mitosis, but there is an important difference. **Mitosis** refers to the normal division of a somatic or of a germ cell in order to increase the number of those cells during growth and development. The resulting cells contain the same number of chromosomes as the previous cells—in human beings, 46. **Meiosis** refers to the halving of the number of chromosomes that are normally present in a germ cell - the precursor of a sperm or a definitive oocyte - in order for fertilization to take place. The resulting gamete cells have only half of the number of chromosomes as the previous cells—in human beings, 23.

One of the best and most technically accurate explanations for this critical process of gametogenesis is by Ronan O'Rahilly,[5] the human embryologist who developed the classic Carnegie stages of human embryological development. He also sits on the international board of *Nomina Embryologica* (which determines the correct terminology to be used in human embryology textbooks internationally):

"**Gametogenesis** is the production of [gametes], i.e., spermatozoa and oocytes. These cells are produced in the gonads, i.e., the testes and ovaries respectively. ... During the differentiation of gametes, diploid cells (those with a double set of chromosomes, as found in somatic cells [46 chromosomes]) are termed primary, and haploid cells (those with a single set of chromosomes [23 chromosomes]) are called secondary. The reduction of chromosomal number ... from 46 (the diploid number or 2n) to 23 (the haploid number or n) is accomplished by a cellular division termed meiosis. ... **Spermatogenesis**, the production of spermatozoa, continues from immediately after puberty until old age. It takes place in the testis, which is also an endocrine gland, the interstitial cells of which secrete testosterone. Previous to puberty, spermatogonia in the simiferous tubules of the testis remain relatively inactive. After puberty, under stimulation from the interstitial cells, spermatogonia proliferate ... and some become primary spermatocytes. When these undergo their first maturation division (meiosis 1), they become secondary spermatocytes. The second maturation division (meiosis 2) results in spermatids, which become converted into spermatozoa."[6]

"**Oogenesis** is the production and maturation of oocytes, i.e.; the female gametes derived from oogonia. Oogonia (derived from primordial germ cells) multiply by mitosis

and become primary oocytes. The number of oogonia increases to nearly seven million by the middle of prenatal life, after which it diminishes to about two million at birth. From these, several thousand oocytes are derived, several hundred of which mature and are liberated (ovulated) during a reproductive period of some thirty years. Prophase of meiosis 1 begins during fetal life but ceases at the diplotene state, which persists during childhood. ... After puberty, meiosis 1 is resumed and a secondary oocyte ... is formed, together with polar body 1, which can be regarded as an oocyte having a reduced share of cytoplasm. The secondary oocyte is a female gamete in which the first meiotic division is completed and the second has begun. From oogonium to secondary oocyte takes from about 12 to 50 years to be completed. *Meiosis 2 is terminated after rupture of the follicle (ovulation) but only if a spermatozoon penetrates.* ... The term 'ovum' implies that polar body 2 has been given off, which event is usually delayed *until the oocyte has been penetrated by a spermatozoon (i.e., has been fertilized).* Hence a human ovum does not [really] exist. Moreover the term has been used for such disparate structures as an oocyte and a three-week embryo, and therefore should be discarded, as *a fortiori* should 'egg'."[7] (Emphasis added.)

Thus, for fertilization to be accomplished, a mature sperm and a mature human oocyte are needed. Before fertilization,[8] each has only 23 chromosomes. They each possess "human life," since they are parts of a *living* human being; but they are not each whole living human beings themselves. They each have only 23 chromosomes, not 46 chromosomes—the number of chromosomes necessary and characteristic for a single individual member of the human species. Furthermore, a sperm can produce only "sperm" proteins and enzymes; an oocyte can produce only "oocyte" proteins and enzymes; neither alone is or can produce a human being with 46 chromosomes.

Also, note O'Rahilly's statement that the use of terms such as "ovum" and "egg"—which would include the term "fertilized egg"—is scientifically incorrect, has no objective correlate in reality, and is therefore very misleading—especially in these present discussions. Thus these terms themselves would qualify as "scientific" myths. The commonly used term, "fertilized egg," is especially very misleading, since there is really no longer an egg (or oocyte) once fertilization has begun. What is being called a "fertilized egg" is not an egg of any sort; it is a human being.

**2) Fertilization**

Now that we have looked at the formation of the mature *haploid* sex gametes, the next important process to consider is fertilization. O'Rahilly defines **fertilization** as:

"... the procession of events that begins when a spermatozoon *makes contact* with a secondary oocyte or its investments, and ends with the intermingling of maternal and paternal chromosomes at metaphase of the first mitotic division of the *zygote*. The zygote is characteristic of the last phase of fertilization and is identified by the first cleavage spindle. It is a unicellular *embryo*."[9] (Emphasis added.)

The fusion of the sperm (with 23 chromosomes) and the oocyte (with 23 chromosomes) at fertilization results in a live human being, a single-cell human zygote.

with 46 chromosomes—the number of chromosomes characteristic of an individual member of the human species. Quoting Moore:

"**Zygote:** This cell results from the union of an oocyte and a sperm. *A zygote is the beginning of a new human being (i.e., an embryo).* The expression *fertilized ovum* refers to a secondary oocyte that is impregnated by a sperm; when fertilization is complete, the oocyte becomes a zygote."[10] (Emphasis added.)

This new single-cell human being immediately produces specifically human proteins and enzymes[11] (not carrot or frog enzymes and proteins), and genetically directs his/her own growth and development. (In fact, this genetic growth and development has been proven *not* to be directed by the mother.)[12] Finally, this new human being—the single-cell human zygote—is biologically an *individual*, a living organism—an individual member of the human species. Quoting Larsen:

"... [W]e begin our description of the developing human with the formation and differentiation of the male and female sex cells or gametes, which will unite at fertilization to initiate the embryonic development of *a new individual*."[13] (Emphasis added.)

In sum, *a mature human sperm and a mature human oocyte are products of gametogenesis—each has only 23 chromosomes.* They each have only half of the required number of chromosomes for a human being. They cannot singly develop further into human beings. They produce only "gamete" proteins and enzymes. They do not direct their own growth and development. And they are not individuals, i.e., members of the human species. They are only parts—each one a part *of* a human being. On the other hand, *a human being is the immediate product of fertilization.* As such he/she is a single-cell embryonic zygote, an organism *with 46 chromosomes*, the number required of a member of the human species. This human being immediately produces specifically human proteins and enzymes, directs his/her own further growth and development *as human*, and is a new, genetically unique, newly existing, live human *individual*.

After fertilization the single-cell human embryo doesn't become another *kind* of thing. It simply divides and grows bigger and bigger, developing through several stages as an embryo over an 8-week period. Several of these developmental stages of the growing embryo are given special names, e.g., a morula (about 4 days), a blastocyst (5-7 days), a bilaminar (two layer) embryo (during the second week), and a trilaminar (3-layer) embryo (during the third week).[14]

**B. "Scientific" myths and scientific fact:**

Given these basic facts of human embryology, it is easier to recognize the many scientifically inaccurate claims that have been advanced in the discussions about abortion, human embryo research, cloning, stem cell research, the formation of chimeras, and the use of abortifacients—and why these discussions obfuscate the objective scientific facts. The following is just a sampling of these current "scientific" myths.

**Myth 1:** "Prolifers claim that the abortion of a human embryo or a human fetus is wrong because it destroys human life. But human sperms and human ova are human life,

too. So prolifers would also have to agree that the destruction of human sperms and human ova are no different from abortions—and that is ridiculous!"

**Fact 1:** As pointed out above in the background section, there is a radical difference, scientifically, between parts of a human being that only possess "human life" and a human embryo or human fetus that is an actual "human being." Abortion is the destruction of a human being. Destroying a human sperm or a human oocyte would not constitute abortion, since neither are human beings. The issue is not when does human *life* begin, but rather when does the life of every human *being* begin. A human kidney or liver, a human skin cell, a sperm or an oocyte all possess human *life*, but they are not human *beings*—they are only parts of a human being. If a single sperm or a single oocyte were implanted into a woman's uterus, they would not grow; they would simply disintegrate.

**Myth 2:** "The product of fertilization is simply a 'blob,' a 'bunch of cells', a 'piece of the mother's tissues'."

**Fact 2:** As demonstrated above, the human embryonic organism formed at fertilization is a whole human being, and therefore it is not just a "blob" or a "bunch of cells." This new human individual also has a mixture of both the mother's and the father's chromosomes, and therefore it is not just a "piece of the *mother's* tissues". Quoting Carlson:

"... [T]hrough the mingling of maternal and paternal chromosomes, the zygote is *a genetically unique product of chromosomal reassortment*, which is important for the viability of any species."[15] (Emphasis added.)

**Myth 3:** "The immediate product of fertilization is just a 'potential' or a 'possible' human being—not a real existing human being."

**Fact 3:** As demonstrated above, scientifically there is absolutely no question whatsoever that the immediate product of fertilization is a newly existing human being. A human zygote *is* a human being. It is *not* a "potential" or a "possible" human being. It's an actual human being—with the potential to grow bigger and develop its capacities.

**Myth 4:** "A single-cell human zygote, or embryo, or fetus are not human beings, because they do not look like human beings."

**Fact 4:** As all human embryologists know, a single-cell human zygote, or a more developed human embryo, or human fetus is a human being—and that that's the way they are supposed to look at those particular periods of development.

**Myth 5:** "The immediate product of fertilization is just an 'it'—it is neither a girl nor a boy."

**Fact 5:** The immediate product of fertilization is genetically already a girl or a boy—determined by the kind of sperm that fertilizes the oocyte. Quoting Carlson again:

"...[T]he sex of the future embryo is determined by the chromosomal complement of the spermatozoon. (If the sperm contains 22 autosomes and 2 X chromosomes, the embryo will be a genetic female, and if it contains 22 autosomes and an X and a Y chromosome, the embryo will be a genetic male.)"[16]

**Myth 6:** "The embryo and the embryonic period begin at implantation." (Alternative myths claim 14 days, or 3 weeks.)

**Fact 6:** These are a few of the most common myths perpetuated sometimes even within quasi-scientific articles—especially within the bioethics literature. As demonstrated above, the human embryo, who is a human being, begins at fertilization—not at implantation (about 5-7 days), 14-days, or 3 weeks. Thus the embryonic period also begins at fertilization, and ends by the end of the eighth week, when the fetal period begins. Quoting O'Rahilly:

"Prenatal life is conveniently divided into two phases: the embryonic and the fetal. The *embryonic period proper* during which the vast majority of the named structures of the body appear, occupies the *first 8 postovulatory weeks*. ... [T]he fetal period extends from 8 weeks to birth ..."[17] (Emphasis added.)

**Myth 7:** "The product of fertilization, up to 14-days, is not an embryo; it is just a 'pre-embryo'—and therefore it can be used in experimental research, aborted, or donated."

**Fact 7:** This "scientific" myth is perhaps the most common error, which pervades the current literature. The term "pre-embryo" has quite a long and interesting history. (See Irving and Kischer, *The Human Development Hoax: Time To Tell The Truth!*, for extensive details and references.) But it roughly goes back to at least 1979 in the bioethics writings of Jesuit theologian Richard McCormick in his work with the Ethics Advisory Board to the United States Department of Health, Education and Welfare,[18] and those of frog developmental biologist Dr. Clifford Grobstein in a 1979 article in *Scientific American*,[19] and most notably in his classic book, *Science and the Unborn: Choosing Human Futures* (1988).[20] Both McCormick and Grobstein subsequently continued propagating this scientific myth as members of the Ethics Committee of the American Fertility Society, and in numerous influential bioethics articles, leading to its common use in bioethics, theological, and public policy literature to this day.

The term "pre-embryo" was also used as the rationale for permitting human embryo research in the British Warnock Committee Report (1984),[21] and then picked up by literally hundreds of writers internationally, including, e.g., Australian writers Michael Lockwood, Michael Tooley, Alan Trounson—and especially by Peter Singer (a philosopher), Pascal Kasimba (a lawyer), Helga Kuhse (an ethicist), Stephen Buckle (a philosopher) and Karen Dawson (a geneticist, not a human embryologist). Note that none of these is even a scientist, with the exception of Karen Dawson, who is just a geneticist.

Oddly, the influential book by Singer, Kuhse, Buckle, and Dawson, *Embryo Experimentation*,[22] (which uses the term "pre-embryo," and which contains no scientific references for its "human embryology" chart or its list of "scientific" terms), along with the work of theologian McCormick and frog developmental biologist Grobstein, was used in the United States as the *scientific* basis for the 1994 National Institutes of Heath (NIH) Human Embryo Research Report.[23] That Report concluded that the "preimplantation embryo" (they, too, originally used the term "pre-embryo") had only a "reduced moral status." (Both the Warnock Report and the NIH Report admitted that the 14-day limit for

human embryo research was arbitrary, and could and must be changed if necessary.) It is particularly in the writings of these and other bioethicists that so much incorrect science is claimed in order to "scientifically" ground the "pre-embryo" myth and therefore "scientifically" justify many of the issues noted at the beginning of this article. This would include abortion, as well as the use of donated or "made-for-research" early human embryos in destructive experimental human embryo research (such as infertility research, cloning, stem cell research, the formation of chimeras, etc.).

To begin with, it has been demonstrated above that the immediate product of fertilization is a human being with 46 chromosomes, a human embryo, an individual member of the human species, and that this is the beginning of the embryonic period. However, McCormick and Grobstein[24] claim that even though the product of fertilization is genetically human, it is not a "developmental individual" yet—and in turn, this "scientific fact" grounds their moral claim about this "pre-embryo." Quoting McCormick:

"I contend in this paper that *the moral status*—and specifically the controversial issue of personhood—*is related to the attainment of developmental individuality* (being the source of one individual) ... It should be noted that at the zygote stage the genetic individual is not yet developmentally single—a source of only one individual. As we will see, that does not occur until a single body axis has begun to form near the end of the second week post fertilization when implantation is underway."[25] (Emphasis added.)

Sounds very scientific. However, McCormick's embryology is already self-contradictory. Implantation takes place at 5-7 days. The "single body axis" to which he refers is the formation of the primitive streak, which takes place at 14 days. McCormick often confuses these different periods in his writings. But McCormick continues:

"This multicellular entity, called a blastocyst, has an outer cellular wall, a central fluid-filled cavity and a small gathering of cells at one end known as the inner cell mass. Developmental studies show that the cells of the outer wall become the trophoblast (feeding layer) and are precursors to the later placenta. Ultimately, *all* these cells are discarded at birth."[26] (Emphasis added.)

The clear implication is that there is absolutely no relationship or interaction between these two cell layers, and so the "entity" is not a "developmental individual" yet. However, quoting Larsen:

"These centrally placed blastomeres are now called the inner cell mass, while the blastomeres at the periphery constitute the outer cell mass. Some exchange occurs between these groups. ... The cells of this germ disc (the inner cell layer) develop into the embryo proper and also contribute to some of the extraembryonic membranes."[27] (Emphasis added.)

Similarly, it is not factually correct to state that *all* of the cells from the outer trophoblast layer are discarded after birth. Quoting Moore:

"The chorion, the amnion, the yolk sac, and the allantois constitute the fetal membranes. They develop from the zygote but do not participate in the formation of the embryo or fetus—*except for parts of the yolk sac and allantois. Part of the yolk sac is incorporated into the embryo as the primordium of the gut. The allantois forms a fibrous*

*cord that is known as the urachus in the fetus and the median umbilical ligament in the adult. It extends from the apex of the urinary bladder to the umbilicus.*"[28] (Emphasis added.)

Since scientists, in trying to "reach" young students in a more familiar language, sometimes use popularized (but scientifically inaccurate and misleading) terms themselves, the ever-vigilant O'Rahilly expresses concern in his classic text about the use of the term "fetal membranes":

"The developmental adnexa, commonly *but inaccurately* referred to as the 'fetal membranes,' include the trophoblast, amnion, chorion, umbilical vesicle (yolk sac), allantoic diverticulum, placenta and umbilical cord. *They are genetically a part of the* individual *and are composed of the same germ layers.*"[29] (Emphasis added.)

Consequently, it is also scientifically incorrect to claim that *only* the inner cell layer constitutes the "embryo proper." *The entire blastocyst—including both the inner and the outer cell layers—is the human embryo, the human being, the human individual.*

Finally, McCormick claims that this "pre-embryo" has not yet decided how many individuals it will become, since the cells are totipotent and twinning can still take place. Therefore, they argue, there is no "individual" present until 14-days and the formation of the primitive streak, after which twinning cannot take place.[30]

However, *twinning is possible after 14 days*, e.g., with fetus-in-fetu and Siamese twins. Quoting from O'Rahilly again:

"Partial duplication at an early stage and attempted duplication *from 2 weeks onward* (when bilateral symmetry has become manifest) would result in conjoined twins (e.g., 'Siamese twins')."[31] (Emphasis added.)

And even Karen Dawson acknowledges this as scientific fact in her article in *Embryo Experimentation*:

"*After the time of primitive streak formation*, other events are possible which indicate that the notion of 'irreversible individuality' may need some review if it is to be considered as an important criterion in human life coming to be the individual human being it is ever thereafter to be. There are two conditions which raise questions about the adequacy of this notion: conjoined twins, sometimes known as Siamese twins, and fetus-in-fetu. ... Conjoined twins arise from the twinning process *occurring after the primitive streak has begun to form, that is, beyond 14 days after fertilization*, or, in terms of the argument from segmentation, beyond the time at which irreversible individuality is said to exist. ... This situation weakens the possibility of seeing individuality as something irreversibly resolved by about 14 days after fertilization. This in turn raises questions about the adequacy of using the landmark of segmentation in development as the determinant of moral status."[32] (Emphasis added.)

It is unfortunate that the NIH Human Embryo Research Panel[33] did not read this particular portion of the Singer *et al.* book before making their recommendations about the moral status of the early human embryo.

**CLS Comments on NIH Guidelines**
**Appendix A (Cont.)**

The scientific fact is that there is no such thing as a "pre-embryo" in the real world. The term is a complete myth. It was fabricated out of thin air in order to justify a number of things that ordinarily would not be justifiable. Quoting O'Rahilly, who sits on the international board of *Nomina Embryologica*, again:

"The *ill-defined and inaccurate term 'pre-embryo,'* which includes the embryonic disk, is said either to end with the appearance of the primitive streak or to include neurulation. *The term is not used in this book.*[34] (Emphasis added.)

Unfortunately, the convenient but mythological term "pre-embryo" will be used to "scientifically" justify several of the other "scientific" myths to follow, which in turn will be used to justify public policy on abortion and human embryo research world-wide.

**Myth 8:** "Pregnancy begins with the implantation of the blastocyst (i.e., about 5-7 days)."

**Fact 8:** This definition of "pregnancy" was initiated to accommodate the introduction of the process of *in vitro* fertilization, where fertilization takes place artificially outside the mother in a petri dish, and then the embryo is artificially introduced into the woman's uterus so that implantation of the embryo can take place. Obviously, if the embryo is not within the woman's body, she is not "pregnant" in the literal, traditional sense of the term. However, this *artificial* situation cannot validly be substituted back to redefine "*normal* pregnancy," in which fertilization *does* take place within the woman's body in her fallopian tube, and subsequently the embryo itself moves along the tube to implant itself into her uterus. In normal situations, pregnancy begins at fertilization, not at implantation. Quoting Carlson:

"*Human pregnancy begins with the fusion of an egg and a sperm*, but a great deal of preparation precedes this event. First both male and female sex cells must pass through a long series of changes (gametogenesis) that converts them genetically and phenotypically into mature gametes, which are capable of participating in the process of fertilization. Next, the gametes must be released from the gonads and make their way to the upper part of the uterine tube, where fertilization *normally* takes place. Finally, *the fertilized egg, now properly called an embryo*, must make its way into the uterus, where it sinks into the uterine lining (implantation) to be nourished by the mother."[35] (Emphasis added.)

**Myth 9:** "The 'morning-after pill,' RU486, and the IUD are not abortifacient; they are only methods of contraception."

**Fact 9:** The "morning-after pill," RU486, and the IUD *can* be abortifacient, *if fertilization has taken place*. Then they would act to prevent the implantation of an already existing human embryo—the blastocyst—which is an existing human being. If the developing human blastocyst is prevented from implanting into the uterus, then obviously the embryo dies. In effect, these chemical and mechanical methods of contraception have become methods of abortion as well. Quoting Moore:

"The administration of relatively large doses of estrogens ('morning-after pill') for several days, beginning shortly after unprotected sexual intercourse, *usually does not prevent fertilization but often prevents implantation of the blastocyst*. Diethylstilbestrol, given daily in high dosage for 5-6 days, may also accelerate passage of the dividing

zygote along the uterine tube ... Normally, the endometrium progresses to the secretory phase of the menstrual cycle as the zygote forms, undergoes cleavage, and enters the uterus. The large amount of estrogen disturbs the normal balance between estrogen and progesterone that is necessary for preparation of the endometrium for implantation of the blastocyst. Postconception administration of hormones to prevent implantation of the blastocyst is sometimes used in cases of sexual assault or leakage of a condom, but this treatment is contraindicated for routine contraceptive use. *The 'abortion pill' RU486 also destroys the conceptus by interrupting implantation* because of interference with the hormonal environment of the implanting embryo. ... An intrauterine device (IUD) inserted into the uterus through the vagina and cervix usually interferes with implantation by causing a local inflammatory reaction. Some IUDs contain progesterone that is slowly released and interferes with the development of the endometrium so that implantation does not usually occur."[36] (Emphasis added.)

And since the *whole* human blastocyst is the embryonic human being—not *just* the inner cell layer—the use of chemical abortifacients that act "only" on the outer trophoblast layer of the blastocyst, e.g., methotrexate,[37] would be abortifacient as well.

**Myth 10:** "Human embryo research, human cloning, stem cell research, and the formation of chimeras are acceptable kinds of research because until implantation or 14 days there is only a 'pre-embryo', a 'potential' human embryo or human being present. A real human embryo and a human being (child) do not actually begin unless and until the 'pre-embryo' is implanted into the mother's uterus."

**Fact 10:** These claims are currently being made by bioethicists, research scientists, pharmaceutical companies, and other biotech research companies—even by some members of Congress. However, they too are "scientific" myths.

Scientifically it is perfectly clear that *there is no such thing as a "pre-embryo,"* as demonstrated in Fact 7. As demonstrated in the background material, the immediate product of fertilization is *a human being*, a human embryo, a human child—the zygote. This zygote is a newly existing, genetically unique, genetically male or female, individual human being—*it is not a "potential" or a "possible" human being*. And this developing human being is a human being, a human embryo, a human child *whether or not it is implanted artificially into the womb of the mother*.

Fertilization and cloning are different processes, but the immediate products of these processes are the same. The immediate product of human cloning would also be a human being—just as in human fertilization. It is not a "pre-embryo" or a "potential" human embryo or human being. Stem cell research obtains its "stem cells" by essentially exploding or otherwise destroying and killing a newly existing human blastocyst who is, scientifically, an existing human being. The formation of chimeras, i.e., the fertilization of a gamete of one species (e.g., a human oocyte) with the gamete of another species (e.g., a monkey sperm) also results in an embryo that is "half-human." All of these types of research have been banned by most countries in the world. *And all of these types of research are essentially human embryo research*—for which the use of federal funds has been banned.

**Myth 11:** "Certain early stages of the developing human embryo and fetus, e.g., during the formation of ancestral fish gills or tails, demonstrates that it is not yet a human being, but is only in the process of becoming one. It is simply 'recapitulating' the historical evolution of all of the species."

**Fact 11:** This "scientific" myth is yet another version of the "potential," "possible," "pre-embryo" myths. It is an attempt to deny the early human embryo its real identity as a human being and its real existence. But quoting once again from O'Rahilly:

"The theory that successive stages of individual development (ontogeny) correspond with ('recapitulate') successive adult ancestors in the line of evolutionary descent (phylogeny) became popular in the 19th century as the so-called biogenetic law. This theory of recapitulation, however, has had a 'regrettable influence in the progress of embryology' (citing de Beer). ... Furthermore, during its development an animal departs more and more from the form of other animals. Indeed, the early stages in the development of an animal are not like the adult stages of other forms, but resemble only the early stages of those animals."[38]

Hence, the developing human embryo or fetus is not a "fish" or a "frog," but is categorically a human being—as has been already demonstrated.

### III. When does a human *person* begin?

The question as to when a human *person* begins is a *philosophical* question—not a scientific question. I will not go into great detail here,[39] but "personhood" begins when the human being begins—at fertilization. But since many of the current popular "personhood" claims in bioethics are also based on mythological science, it would be useful to just look very briefly at these philosophical (or sometimes, theological) arguments simply for scientific accuracy as well.

Philosophically, virtually *any* claim for so-called "*delayed* personhood"—that is, "personhood" does not start until some point *after* fertilization—involves the theoretical disaster of accepting that the idea or concept of a mind/body split has any correlate or reflects the real world. Historically this problem was simply the consequence of wrong-headed thinking about reality, and was/is totally indefensible. It was abandoned with great embarrassment after Plato's time (even by Plato himself in his *Parmenides*!), but unfortunately resurfaces from time to time, e.g., as with Descartes in his *Meditations*, and now again with contemporary bioethics.[40] And as in the question of when a human being begins, if the *science* used to ground these philosophical "personhood" arguments is incorrect, the conclusions of these arguments (which are based on that incorrect science) are also incorrect and invalid.

**Myth 12:** "Maybe a human *being* begins at fertilization, but a human *person* does not begin until after 14-days, when twinning cannot take place."

**Fact 12:** The particular argument in Myth 12 is also made by McCormick and Grobstein (and their numerous followers). It is based on their biological claim that the "pre-embryo" is not a developmental individual, and therefore not a person, until after 14 days when twinning can no longer take place. However, it has already been scientifically

demonstrated here that there is no such thing as a "pre-embryo," and that in fact the embryo begins as a "developmental individual" at fertilization. Furthermore, twinning can take place after 14 days. Thus simply on the level of science, the philosophical claim of "personhood" advanced by these bioethicists is invalid and indefensible.

**Myth 13:** "A human *person* begins with 'brain birth,' the formation of the primitive nerve net, or the formation of the cortex—all physiological structures necessary to support thinking and feeling."

**Fact 13:** Such claims are all pure mental speculation, the product of imposing philosophical (or theological) concepts on the scientific data, and have no scientific evidence to back them up. As the well-known neurological researcher D. Gareth Jones has succinctly put it, the parallelism between "brain death" and "brain birth" is *scientifically invalid.* "Brain death" is the gradual or rapid cessation of the functions of a brain. "Brain birth" is the very gradual acquisition of the functions of a developing neural system. This developing neural system is not a brain. He questions, in fact, the entire assumption and asks what neurological reasons there might be for concluding that an incapacity for consciousness becomes a capacity for consciousness once this point is passed. Jones continues that the alleged symmetry is not as strong as is sometimes assumed, and *that it has yet to be provided with a firm biological base.*[41]

**Myth 14:** "A 'person' is defined in terms of the active exercising of 'rational attributes' (e.g., thinking, willing, choosing, self-consciousness, relating to the world around one, etc.), and/or the active exercising of 'sentience' (e.g., the feeling of pain and pleasure)."

**Fact 14:** Again, these are philosophical terms or concepts, which have been illegitimately imposed on the scientific data. The scientific fact is that the brain, which is supposed to be the physiological support for *both* "rational attributes" *and* "sentience," is not actually completely developed until young adulthood. Quoting Moore:

"Although it is customary to divide human development into prenatal (before birth) and postnatal (after birth) periods, birth is merely a dramatic event during development resulting in a change in environment. *Development does not stop at birth.* Important changes, in addition to growth, occur after birth (e.g., development of teeth and female breasts). The brain triples in weight between birth and 16 years; *most developmental changes are completed by the age of 25.*"[42] (Emphasis added.)

One should also consider simply the logical—and very real—consequences if a "person" is defined only in terms of the actual exercising of "rational attributes" or of "sentience." What would this mean for the following list of adult human beings with diminished "rational attributes": e.g., the mentally ill, the mentally retarded, the depressed elderly, Alzheimer's and Parkinson's patients, drug addicts, alcoholics—and for those with diminished "sentience," e.g., the comatose, patients in a "vegetative state," paraplegics, and other paralyzed and disabled patients, diabetics or other patients with nerve or brain damage, etc.? Would they then be considered as only human beings but not also as human persons? Would that mean that they would not have the same ethical and

legal rights and protections as those adult human beings who are considered as persons? Is there really such a "split" between a human being and a human person?

In fact, this is the position of bioethics writers such as the Australian animal rights philosopher Peter Singer,[43] the recently appointed Director of the Center for Human Values at Princeton University. Singer argues that the higher primates, e.g., dogs, pigs, apes, monkeys, *are* persons—but that some human beings, e.g., even normal human infants, and disabled human adults, are *not* persons. Fellow bioethicist Norman Fost actually considers "cognitively impaired" adult human beings as "brain dead." Philosopher/bioethicist R.G. Frey has also published that many of the adult human beings on the above list are not "persons," and suggests that they be substituted for the higher primates who are "persons" in purely destructive experimental research.[44] The list goes on.

## IV. Conclusions

Ideas do have concrete consequences—not only in one's personal life, but also in the formulation of public policies. And once a definition is accepted in one public policy, the logical extensions of it can then be applied, invalidly, in many other policies, even if they are not dealing with the same exact issue—as happens frequently in bioethics. Thus, the definitions of "human being" and of "person" that have been concretized in the abortion debates have been transferred to several other areas, e.g., human embryo research, cloning, stem cell research, the formation of chimeras, the use of abortifacients—even to the issues of brain death, brain birth, organ transplantation, the removal of food and hydration, and research with the mentally ill or the disabled. But both private choices and public policies should incorporate sound and accurate science whenever possible. What I have tried to indicate is that in these current discussions, individual choices and public policies have been based on "scientific" myth, rather than on objective scientific facts.

### Notes

1. B. Lewin, *Genes III* (New York: John Wiley and Sons, 1983), pp. 9-13; A. Emery, *Elements of Medical Genetics* (New York: Churchill Livingstone, 1983), pp. 19, 93.

2. William J. Larsen, *Human Embryology* (New York: Churchill Livingstone, 1997), pp. 4, 8, 11.

3. *Ibid.*

4. *Ibid.*

5. Ronan O'Rahilly and Fabiola Müller, *Human Embryology & Teratology* (New York: Wiley-Liss, 1994). See also, Bruce M. Carlson, *Human Embryology and Developmental Biology* (St. Louis, MO: Mosby, 1994), and Keith L. Moore and T.V.N. Persaud, *The Developing Human* (Philadelphia: W.B. Saunders Company, 1998).

6. O'Rahilly and Müller 1994, pp. 13-14.

7. *Ibid.*, p. 16. See also, Larsen, *op. cit.*, pp. 3-11; Moore and Persaud, *op. cit.*, pp. 18-34; Carlson, *op. cit.*, pp. 3-21.

8. *Note:* The number of chromosomes in the definitive oocyte are not halved unless and until it is penetrated by a sperm, which really does not take place *before* fertilization but is in fact

concurrent with and the beginning of the process of fertilization. However, for simplicity's sake, many writers (myself among them) will sometimes assume the reader clearly understands this timing, and simply say, "*before* fertilization the sperm and the oocyte each contain 23 chromosomes."

9. O'Rahilly and Müller, p. 19.

10. Moore and Persaud, p. 2.

11. E.g., as determined in extensive numbers of transgenic mice experiments as in Kollias *et al.*, "The human beta-globulin gene contains a downstream developmental specific enhancer," *Nucleic Acids Research* 15(14) (July, 1987), 5739-47; also similar work by, e.g., R.K. Humphries, A. Schnieke.

12. Holtzer *et al.*, "Induction-dependent and lineage-dependent models for cell-diversification are mutually exclusive," *Progress in Clinical Biological Research* 175:3-11 (1985); also similar work by, e.g., F. Mavilio, C. Hart.

13. Larsen, p. 1; also O'Rahilly and Müller, p. 20.

14. Larsen, p. 19, 33, 49.

15. Carlson, p. 31.

16. Carlson, p. 31.

17. O'Rahilly and Müller, p. 55; Carlson, p. 407.

18. Ethics Advisory Board, 1979, *Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer*, Washington, D.C.: United States Department of Health, Education and Welfare, p. 101.

19. Clifford Grobstein, "External human fertilization," *Scientific American* 240:57-67.

20. Clifford Grobstein, *Science and the Unborn: Choosing Human Futures* (New York: Basic Books, Inc., 1988).

21. Dame Mary Warnock, *Report of the Committee of Inquiry into Human Fertilization and Embryology* (London: Her Majesty's Stationary Office, 1984), pp. 27, 63. See also the writings of, e.g., H. Tristram Engelhardt, John Robertson (in legal writings), R.M. Hare, Bedate and Cefalo, William Wallace.

22. Peter Singer, Helga Kuhse, Stephen Buckle, Karen Dawson, and Pascal Kasimba, *Embryo Experimentation* (Cambridge: Cambridge University Press, 1990).

23. *National Institutes of Health: Report of the Human Embryo Research Panel*, September 27, 1994 (National Institutes of Health, Division of Science Policy Analysis and Development, Bethesda, MD).

24. Clifford Grobstein, "The early development of human embryos," *Journal of Medicine and Philosophy* 1985:10:213-236; and Richard McCormick, "Who or what is the preembryo?" *Kennedy Institute of Ethics Journal* 1991:1:1-15.

25. Richard McCormick, *ibid.*, p. 3.

26. McCormick, *ibid.*, p. 3.

27. Larsen, p. 19, 33.

28. Moore and Persaud, p. 131.

29. O'Rahilly and Müller, p. 51.

30. McCormick, *op. cit.*, p. 4.

31. O'Rahilly and Müller, p. 32.

32. Karen Dawson, "Segmentation and moral status," in Peter Singer *et al.*, *Embryo Experimentation* (Cambridge: Cambridge University Press, 1990), p. 58. See also Moore and Persaud, p. 133.

33. For extensive comments on the make-up of the NIH Human Embryo Research Panel and on its Report, see several of my articles in my book, co-authored with human embryologist C. Ward Kischer, *The Human Development Hoax: Time to Tell The Truth!* (Clinton Township, MI: Gold Leaf Press, 1995) (1st ed.); (2nd. ed. published by authors 1997; distributed by the American Life League, Stafford, VA).

34. O'Rahilly and Müller, p. 55.

35. Carlson, p. 3.

36. Moore and Persaud, p. 58.

37. But see Albert Moraczewski, "Managing tubal pregnancies: Part I" (June 1996) and "Part II" (August 1996), in *Ethics and Medics* (Braintree, MA: Pope John Center).

38. O'Rahilly and Müller, p. 8-9.

39. The use of massive historically incorrect and theoretically indefensible philosophy in the "delayed personhood" arguments has been addressed in my doctoral dissertation, *A Philosophical and Scientific Analysis of the Nature of the Early Human Embryo* (Washington, D.C.: Georgetown University, Department of Philosophy, 1991); see also several of my previously published articles in my book, co-authored by C. Ward Kischer, *supra*, note 33, *The Human Development Hoax: Time To Tell The Truth!*, which gives extensive references pro and con these bioethics arguments.

40. For an excellent and easy to read analysis of the problem of a mind/body split as one of the fundamental theoretical problems in contemporary bioethics theory, see Gilbert C. Meilaender, *Body, Soul, and Bioethics* (Notre Dame, IN: University of Notre Dame Press, 1995); see also many of the excellent articles about this problem in bioethics theory in Raanan Gillon (ed.), *Principles of Health Care Ethics* (New York: John Wiley & Sons, 1994); also Edwin R. DuBose, Ronald P. Hamel and Laurence J. O'Connell (eds.), *A Matter of Principles? Ferment in U.S. Bioethics* (Valley Forge, PA: Trinity Press International, 1994)—especially the "Preface" by Albert Jonsen. Even Daniel Callahan has admitted that the bioethics principles don't work, in "Bioethics: Private choice and common good," in *The Hastings Center Report* (May/June 1994), pp. 28-31.

41. D. Gareth Jones, "Brain birth and personal identity," *Journal of Medical Ethics* 15:4, 1989, p. 178.

42. Moore and Persaud, p. 2; see also Jones, p. 177.

43. Peter Singer, "Taking life: Abortion," in *Practical Ethics* (London: Cambridge University Press, 1981), p. 118; Helga Kuhse and Peter Singer, "For sometimes letting—and helping—die," *Law, Medicine and Health Care*, 1986, 3:4:149-153; Kuhse and Singer, *Should the Baby Live? The Problem of Handicapped Infants* (Oxford: Oxford University Press, 1985), p. 138; Singer and Kuhse, "The ethics of embryo research," *Law, Medicine and Health Care*, 1987, 14:13-14; Michael Tooley, "Abortion and infanticide," in Marshall Cohen (ed.) *et al.*, *The Rights and Wrongs of Abortions*, (New Jersey: Princeton University Press, 1974), pp. 59, 64; H. Tristram Engelhardt, *The Foundations of Bioethics* (New York: Oxford University Press, 1986), p. 111.

44. R.G. Frey, "The ethics of the search for benefits: Animal experimentation in medicine," in Raanan Gillon (ed.), *Principles of Health Care Ethics* (New York: John Wiley & Sons, 1994), pp. 1067-1075.

**APPENDIX B**

CLS Comments on Draft NIH Guidelines for Research Involving Human Pluripotent Stem Cells, 64 *Federal Register* 67576-67579 (December 2, 1999)

## The Legal Consensus on the Beginning of Life

[*See generally* Elizabeth Spahn and Barbara Andrade, *Mis-Conceptions: The Moment of Conception in Religion, Science and Law*, 32 U.S.F.L.Rev. 261 (1998); Paul B. Linton, *PLANNED PARENTHOOD v. CASEY: The Flight From Reason in the Supreme Court* 13 St. Louis U. Pub. L. Rev. 15 9 (1993)]

**Alabama:**

Trent v. State, 73 So. 834, 836 (Ala. Civ. App. 1916) (interpreting state abortion law) ("'does not the new being, from the first day of its uterine life, acquire a legal and moral status that entitles it to the same protection as that guaranteed to human beings in extra-uterine life?'") (quoting from the 1911 Transactions of the Medical Association of Alabama).

Wolfe v. Isbell, 280 So.2d 758, 761 (Ala. 1973) (rejecting viability requirement in wrongful death action where death occurs after live birth):

[T]he more recent authorities emphasize that there is no valid medical basis for a distinction based on viability, especially where the child has been born alive. These [decisions] proceed on the premise that the fetus is just as much an independent being prior to viability as it is afterwards, and that from the moment of conception, the fetus or embryo is not a part of the mother, but rather has a separate existence within the body of the mother.

Alabama Constitutional Convention Call (S.J. Res. 9, 1980 Ala. Acts 396):

[A]pplies to the Congress . . . to call a convention for the sole and exclusive purpose of proposing an amendment to the Constitution that would protect the lives of all human beings including unborn children at every stage of their biological development and providing that neither the United States nor any state shall deprive any human being, from the moment of fertilization, of the right to life without due process of law, nor shall any state deny any human being, from the moment of fertilization, the equal protection of the laws, except where pregnancy results from rape or incest; or where abortion is necessary to save the life of the mother; or where testing revealed abnormality or deformity of the fetus.

**Arizona:**

Nelson v. Planned Parenthood Ctr. of Tucson, 505 P.2d 580, 586 (Ariz. Ct. App. 1973) (construing state abortion law):

One cannot gainsay a legislative determination that an embryonic or fetal organism is "life." Once begun, the inevitable result is a human being, barring prior termination of the pregnancy.

ARIZ. REV. STAT. ANN., § 13-1103(A)(5) (1989) (defining offense of manslaughter to include "[k]nowingly or recklessly causing the death of an unborn child at any stage of

its development by any physical injury to the mother of such child which would be murder ***121** if the death of the mother had occurred").

**Arkansas:**

ARK. CONST. amend. 68, § 2 ("[t]he policy of Arkansas is to protect the life of every unborn child from conception until birth, . . . .").

Arkansas Constitutional Convention Call (Res. of Feb. 17, 1977, H.R.J. Res. 2):
Requests Congress to call a convention to propose a constitutional amendment which would provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled to the right of life; provides that Congress and the states shall have concurrent powers to enforce such an amendment.

**California:**

CAL. PENAL CODE, § 187(a) (West 1988) ("[m]urder is the unlawful killing of a human being, or a fetus, with malice aforethought").

CAL. CIV. CODE, § 29 (West 1982) ("[a] child conceived, but not yet born, is to be deemed an existing person, so far as may be necessary for its interests in the event of its subsequent birth")

Scott v. McPheeters, 92 P.2d 678, 681 (Cal. App. 1939) (it is "an established and recognized fact by science and by everyone of understanding" that "an unborn child is a human being separate and distinct from its mother").

**Connecticut:**

CONN. GEN. STAT. ANN. § 53-31(a) (West 1985) ("[t]he public policy of the state and the intent of the legislature is to protect and preserve human life from the moment of conception") (rep. by P.A. 90-113, §4 (1990)).

Simon v. Mullin, 380 A.2d 1353, 1357 (Conn. Supp.1977) (rejecting viability requirement in wrongful death action where death occurs after live birth) ("[t]he development of the principle of law that now permits recovery by or on behalf of a child born alive for prenatal injuries suffered at any time after conception, without regard to the viability of the fetus, is a notable illustration of the viability of our common law").

**CLS Comments on NIH Guidelines**
**APPENDIX B (Cont.)**

**Delaware:**

Scott v. State, 117 A.2d 831, 835-36 (Del. 1955) (characterizing abortion law as one that defines an offense against the lives and persons of individuals).

Delaware Constitutional Convention Call (Res. of May 23, 1978, H.R. Con. Res. 9):
Requests Congress to call a convention to propose a constitutional amendment that would protect the lives of all human beings, including unborn children at every stage of their biological development.

**District of Columbia:**

Bonbrest v. Kotz, 65 F.Supp. 138, 140 (D.D.C. 1946) (recognizing cause of action for prenatal injuries) ("[f]rom the viewpoint of the civil law and the law of property, a child en ventre sa mere is not only regarded as [a] human being, but as such from the moment of conception--which it is in fact").

**Florida:**

Day v. Nationwide Mut. Ins. Co., 328 So.2d 560, 561 (Fla. Dist. Ct. App.2d Dist. 1976) (rejecting viability requirement in case of prenatal injuries) (quoting with approval WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS §55, at 336 (4th ed. 1971)):
Viability of course does not affect the question of the legal existence of the foetus, and therefore of the defendant's duty; and it is a most unsatisfactory criterion, since it is a relative matter, depending on the health of mother and child and many other matters in addition to the stage of development. Certainly the infant may be no less injured; and all logic is in favor of ignoring the stage at which it occurs.

**Georgia:**

Hornbuckle v. Plantation Pipe Line Co., 93 S.E.2d 727, 728 (Ga. 1956) (rejecting viability requirement in case of prenatal injuries) ("[i]f a child born after an injury sustained at any period of its prenatal life can prove the effect on it of a tort, it would have a right to recover") (a dissent characterized majority opinion as holding, in effect, "that an infant becomes a 'person' from the moment of conception, with the right to sue for a tortious injury after its birth"); id. at 729.

Morrow v. Scott, 7 Ga. 535, 537 (1849) ("[i]n . . . general, a child is to be considered as in being, from the time of its conception, where it will be for the benefit of such child to be so considered").

**Idaho:**

Nash v. Meyer, 31 P.2d 273, 280 (Idaho 1934) (construing state abortion law) (criminal abortion statute intended "to discourage abortions because thereby the life of a human

being, the unborn child, is taken").

Blake v. Cruz, 698 P.2d 315, 323 (Idah 1984) (Bistline, J., concurring in part and dissenting in part) ("[t]his Court recently committed itself to the proposition that an unborn child is a person in being," citing Volk v. Baldazo, 651 P.2d 11 (Idaho 1982) (rejecting live birth requirement in wrongful death action where death occurs after viability)).

Idaho Constitutional Convention Call (S. Con. Res. 132, 45th Legis. 2d Sess., 1980 Idaho Sess. Laws 1005):

[R]equest[s] that the Congress . . . call a constitutional convention for the specific and exclusive purpose of proposing an amendment . . . [to provide that]:

(a) From the moment of conception a person shall be guaranteed all personal rights extended to all individuals under the constitution and laws of the United States of America and the state or states of residence and only under extreme circumstances shall it be otherwise; namely, to save the life of the mother, or other extenuating circumstances where at least two consulting physicians, one not having previously been involved in the case, and after due and thorough consultation with all persons having the legal right to be involved, find it is necessary and just that the life of the unborn shall be terminated.

(b) Provide that the several states shall have the power to enforce such an amendment, and establish priority of life by appropriate legislation.

**Illinois:**

720 ILL. COMP. STAT. ANN. § 510/1 (Smith-Hurd 1993) (preamble to Illinois Abortion Law of 1975):

[T]he General Assembly of the State of Illinois do solemnly declare and find in reaffirmation of the longstanding policy of this State, that the unborn child is a human being from the time of conception and is, therefore, a legal person for purposes of the unborn child's right to life and is entitled to the right to life from conception under the laws and Constitution of this State.

740 ILL. COMP. STAT. ANN. § 180/2.2 (Smith-Hurd 1993) (amending wrongful death statute to allow wrongful death action to be brought on behalf of an unborn child without regard to the stage of pregnancy when the child is injured or whether there is a live birth).

720 ILL. COMP. STAT. ANN. § 5/9-1.2(b)(1) (Smith-Hurd 1993) (defining "unborn child" as "any individual of the human species from fertilization until birth").

720 ILL. COMP. STAT. ANN. §§ 5/9-1.2, 5/9-2.1, 519-3.2, 5/12- 3.2, 5/12-4.4 (Smith-Hurd 1993) (amending criminal code to define broad range of crimes, including homicide, that can be committed against unborn child, regardless of gestational age).

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**Indiana:**

*124 Cheaney v. State, 285 N.E.2d 265, 268 (1972) cert. denied, 410 U.S. 991 (1973) (construing state abortion law) ("[i]t is now established that some sort of independent life begins at conception," rejecting quickening and viability as outdated and arbitrary distinctions).

**Kansas:**

City of Wichita v. Tilson, Case No. 91 MC 108 (Sedgwick County Court, July 21, 1991) (accepting necessity defense) (slip op. at 22) ("the medical and scientific communities . . . are of the opinion that life in homo sapiens begins at conception"), appeal sustained without discussion of this point, 855 P.2d 911, 918 (Kan. 1993), cert. denied, Nov. 16, 1993, 62 U.S. L. W. 3348 (Docket 93-467).

State v. Harris, 136 P. 264, 267 (Kan. 1913) (construing state abortion law):

The arbitrary refusal of the common law to regard the foetus as alive . . . until quick[ening] was based on no sound physiological principle . . . . [T]he movement recognized by the mother, and which is supposed to prove that her unborn child is alive, is merely one evidence of life, whereas unless life had existed long before the most disastrous consequences to the mother must have already been suffered . . . .

For many purposes the law regards the infant as alive from its conception.

**Kentucky:**

KY. REV. STAT. ANN. § 311.710(5) (Michie/Bobbs-Merrill 1990):

If . . . the United States constitution is amended or relevant judicial decisions are reversed or modified, the declared policy of this Commonwealth to recognize and to protect the lives of all human beings regardless of their degree of biological development shall be fully restored.

KY. REV. STAT. ANN. §§ 311.720(5), (6) (Michie/Bobbs-Merrill 1990) (abortion regulations) (defining "fetus" as "a human being from fertilization until birth" and "human being" as "any member of the species homo sapiens from fertilization until death").

Hollis v. Commonwealth, 652 S.W.2d 61, 66-67 (Ky. 1983) (Wintersheimer, J., dissenting) (noting that "[b]iologically speaking, human life begins at the moment of conception" and that "[m]edical authority has long recognized that the child is in existence from the moment of conception").

Kentucky Constitutional Convention Call (H.R. Res. 7, 1978 Gen. Assembly, Reg. Sess., 1978 Ky. Acts 1401):

[R]equest[s] the Congress . . . to call a convention for the sole purpose of proposing the following article as an amendment to the Constitution . . .:

Section 1. With respect to the right to life, the word person as used in this article and in

the Fifth and Fourteenth Articles of Amendment to this Constitution applies to all human beings irrespective of age, health, function, or condition of dependency, including their unborn offspring at every stage of their biological development.

Section 2. No unborn person shall be deprived of life by any person, provided, however, that nothing in this article shall prohibit a law permitting only those medical procedures required to prevent the death of the mother.

Section 3. The Congress and the several states shall have the power to enforce this article by appropriate legislation.

**Louisiana:**

LA. REV. STAT. ANN. § 14:2(7) (West 1986) (defining "person" for purposes of criminal code to include "a human being from the moment of fertilization and implantation").

LA. REV. STAT. ANN. §§ 14:32.5-32.8 (West 1992 Supp.) (defining fetal homicide offenses).

Danos v. St. Pierre, 383 So. 2d 1019, 1027 (La. Ct. App. 1980), aff'd, 402 So. 2d 633 (La. 1981) (Lottinger, J., concurring):

This definition [LA. REV. STAT. ANN. § 14:2(7) (West 1986)] added to the Criminal Code in 1976, reflects a legislative intent to classify an unborn child as a "person" for purposes of violent criminal conduct like homicide and battery. The definition reveals an express recognition by the legislature that life begins at the moment of conception and that this form of life can indeed be the victim of a harm, i.e., a murder or battery.

1991 La. Acts. § 1, No. 26 (amending state abortion law):

It is declared to be the public policy of the state of Louisiana that it has a legitimate compelling interest in protecting, to the greatest extent possible, the life of the unborn from the time of conception until birth. We also affirm our belief that life begins at conception and that life thereafter is a continuum until the time of death.

Johnson v. New Orleans Light and Traction Co., Docket 9048 (La. App. Orl. Dec. 10, 1923) (rejecting live birth and viability requirements in cause of action for wrongful death) (quoted with approval in Danos v. St. Pierre, 402 So. 2d 633, 639 (La. 1981)):

The argument of the defendant is that the infant before it is born is not a child, not a human being, that it is only a thing, a part of the anatomy of the mother, as are her organs. We cannot accept that theory. We believe the infant is a child from the moment of conception although life may be in a state of suspended animation, the subject of love, affection and hope and that the injury or killing of it in its mother's womb is covered by the [wrongful death statute] and gives its bereaved parents to a right of action against the guilty parties for their grief and mental anguish.

Danos v. St. Pierre, 383 So. 2d 1019, 1029 (La. Ct. App. 1980), aff'd, 402 So. 2d 633 (La. 1981) (rejecting live birth requirement in action for wrongful death of a viable unborn child) (Lottinger, J., concurring):

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Viability has not been the controlling factor in some previous Louisiana cases allowing recovery [for wrongful death of a stillborn child], and there is no need to make it a controlling factor in this decision. Just as live birth is an arbitrary cutoff point for wrongful death purposes, viability is equally arbitrary in deciding whether the fetus is a "person" whose wrongful killing is compensable.

Louisiana Constitutional Convention Call (Res. of July 16, 1976, S. Con Res. 70):
Requests Congress to call a convention to propose a constitutional amendment extending the term "person" in the Fifth and Fourteenth amendments to apply to all human beings "irrespective of age, health, function or condition of dependency, including unborn offspring at every stage of their biological development;" permits states to adopt laws necessary to preserve the woman's life; requests state legislative bodies to apply to Congress to call a convention to propose this constitutional amendment; grants Congress and the states the power to enforce the amendment.

**Maryland:**

Damasiewicz v. Gorsuch, 79 A.2d 550, 559 (Md. 1951) (recognizing cause of action for prenatal injuries) ("from a medical point of view, a child is alive within the mother before the time arrives when it can live apart from her"), Id. at 560 (theory that "an unborn child is a part of the mother" is "an outworn point of view, now rejected by modern medicine").

Group Health Ass'n v. Blumenthal, 453 A.2d 1198, 1207 (Md. 1983) ("a cause of action lies for the wrongful death of a child born alive who dies as a result of injuries sustained while en ventre sa mere") (rejecting viability requirement).

**Massachusetts:**

Commonwealth v. Cass, 467 N.E.2d 1324, 1325 (Mass. 1984) (viable fetus is a "person" within meaning of vehicular homicide statute):
In keeping with approved usage, and giving terms their ordinary meaning, the word "person" is synonymous with the term "human being." An offspring of human parents cannot reasonably be considered to be other than a human being, and therefore a person, first within, and then in the normal course outside, the womb . . . . By the use of the term[] "person" . . . the Legislature has given no hint of a contemplated distinction between pre-born and born human beings.

Torigian v. Watertown News Co., 225 N.E.2d 926, 927 (Mass. 1967) (rejecting viability requirement in wrongful death action where death follows live birth).

MASS. GEN. LAWS ANN.ch.112 §12K (West 1996)[for purposes of physician registration statute the following definition is given for the "Unborn child, the individual human life in existence and developing from fertilization until birth."

Massachusetts Constitutional Convention Call (Act of June 8, 1977, H.R. 5984):
Requests Congress to call a convention to propose a constitutional amendment

extending the term "person" in the Fifth and Fourteenth amendments to apply to all human beings "irrespective of age, health, function or condition of dependency, including unborn offspring at every stage of their biological development;" permits states to adopt laws necessary to preserve the woman's life; grants Congress and the states the power to enforce the amendment.

**Michigan:**

Womack v. Buchhorn, 187 N.W.2d 218, 222 (Mich. 1971) (recognizing cause of action for prental injuries and rejecting viability requirement because "a child has a legal right to begin life with a sound mind and body").

O'Neill v. Morse, 188 N.W.2d 785 (Mich. 1971) (recognizing cause of action for wrongful death of a viable stillborn child).

Larkin v. Cahalan, 208 N.W.2d 176, 179 (Mich. 1973) (construing state abortion law) ("statutes proscribing manslaughter by abortion are designed to protect human life and carry the necessary implication that that life, the destruction of which is punishable as manslaughter, is human life").

**Minnesota:**

MINN. STAT. ANN. §§ 609.266, 609.2661 through 609.2665, 609.267, 609.2671, 609.2672, 609.268 (West 1987 & 1992 Supp.) (amending criminal code to include a broad range of crimes, including homicide, that can be committed against an unborn child, regardless of gestational age).

Verkennes v. Corniea, 38 N.W.2d 838, 840 (Minn. 1949) (rejecting live birth requirement in wrongful death action) (quoting with approval federal district court opinion in Bonbrest v. Kotz, 65 F.Supp. 138, 140 (D.D.C. 1946), where court said "[f]rom the viewpoint of the civil law and the law of property, a child en ventre sa mere is not only regarded as [a] human being, but as such from the moment of conception--which it is in fact").

**Missouri:**

MO. ANN. STAT. § 1.205.1(1) (Vernon Supp.1992) (preamble to Missouri Abortion Law) ("[t]he life of each human being begins at conception").

MO. ANN. STAT. § 188.015(6) (Vernon Supp.1992) (abortion regulations) (defining "unborn child" as "the offspring of human beings from the moment of conception until birth and at every stage of its biological development").

Rodgers v. Danforth, 486 S.W.2d 258, 259 (Mo. 1972) (construing criminal abortion law) (accepting stipulation that "unborn children have all the qualities and attributes of adult human persons differing only in age or maturity" and that "[m]edically, human life

is a continuum from conception to death").

Missouri Constitutional Convention Call (Res. of Apr. 24, 1975, S. Con. Res. 7):
Requests Congress to call a convention to propose a constitutional amendment extending the term "person" in the Fifth and Fourteenth amendments to apply to all human beings "irrespective of age, health, function, or condition of dependency, including unborn offspring at every stage of their biological development;" permits states to adopt laws necessary to preserve the woman's life; grants Congress and the states the power to enforce the amendment.

**Montana:**

MONT. CODE ANN. § 50-20-102 (1993) (statement of legislative purpose and intent--abortion regulations):
The legislature reaffirms the tradition of the state of Montana to protect every human life, whether unborn or aged, healthy or sick. In keeping with this tradition and in the spirit of our constitution, we reaffirm the intent to extend the protection of the laws of Montana in favor of all human life.

MONT. CODE ANN. § 41-1-103 (1993) ("[a] child conceived but not yet born is to be deemed an existing person, so far as may be necessary for its interests in the event of its subsequent birth").

**Nebraska:**

NEB. REV. STAT. § 28-326(5) (1995) (legislative findings in statutes regulating abortion) (legislators "deplore the destruction of the unborn human lives which has and will occur . . . as a consequence of the United States Supreme Court's decision," and lament their inability "to protect the life, health, and welfare of pregnant women and unborn human life").

Hans v. State, 22 N.W.2d 385, 389, (Neb. 1946) vacated on reh'g 25 N.W.2d 35 (Neb. 1946) (statute defining offense of "foeticide" meant "the unlawful destruction of an unborn child, in ventre sa mere, at any stage of gestation").

Nebraska Constitutional Convention Call (Res. of Apr. 21, 1978, Legis. Res. 152):
Legislature . . . petition[s] . . . Congress . . . to call a convention for the sole purpose of proposing the following article as an amendment to the Constitution of the United States . . . .

ARTICLE

Section 1. With respect to the right to life, the word person as used in this article and in the Fifth and Fourteenth Articles of Amendment to this Constitution applies to all human beings irrespective of age, health, function, or condition of dependency, including their unborn offspring at every stage of their biological development.
Section 2. No unborn child shall be deprived of life by any person, provided, however,

that nothing in this article shall prohibit a law permitting only those medical procedures required to prevent the death of the mother.

Section 3. The Congress and the several states shall have the power to enforce this article by appropriate legislation.

**Nevada:**

White v. Yup, 458 P.2d 617, 623 (Nev. 1969) (recognizing cause of action for prenatal injuries and for the wrongful death of a viable, stillborn child) (proposition that "[a]n unborn child is a part of its mother until birth and thus has no juridical existence" "has no scientific or medical basis in fact").

Nevada Constitutional Convention Call (S.J. Res. 27, 60th Legis., 1979 Nev. Stat. 2014):

[L]egislature requests . . . Congress . . . to call a convention limited to proposing an amendment to the Constitution . . . to protect human life by restricting abortion [subject to exceptions in cases where the pregnancy results from rape or incest and where continuation of the pregnancy would seriously endanger the life of the mother].

**New Hampshire:**

Bennett v. Hymers, 147 A.2d 108, 110 (N.H. 1958) (rejecting viability requirement in cause of action for prenatal injuries) ("[w]e adopt the opinion that the fetus from the time of conception becomes a separate organism and remains so throughout its life").

Wallace v. Wallace, 421 A.2d 134, 136 (N.H. 1980) (wrongful death action) ("[t]o deny a nonviable fetus a [wrongful death] cause of action is not to deny that life begins with conception").

**New Jersey:**

Smith v. Brennan, 157 A.2d 497, 502 (N.J. 1960) (rejecting viability requirement in cause of action for prenatal injuries) ("[m]edical authorities have long recognized that a child is in existence from the moment of conception, and not merely a part of its mother's body"):

We see no reason for denying recovery for a prenatal injury because it occurred before the infant was capable of separate existence. In the first place, age is not the sole measure of viability, and there is no real way of determining in a borderline case whether or not a fetus was viable at the time of the injury, unless it was immediately born. Therefore, the viability rule is impossible of practical application . . . . In addition, . . . medical authority recognizes that an unborn child is a distinct biological entity from the time of conception, and many branches of the law afford the unborn child protection throughout the period of gestation. The most important consideration, however, is that the viability distinction has no relevance to the injustice of denying recovery for harm which can be proved to have resulted from the wrongful act of another. Whether viable or not at the time of the injury, the child sustains the same harm after birth, and therefore, should be given the same

opportunity for redress.

Id. at 504.

Gleitman v. Cosgrove, 227 A.2d 689, 696 n.3 (1967) (Francis, J., concurring) (rejecting cause of action for wrongful life) ("[i]t was noted 30 years ago that the increase in knowledge of embryology had revealed that the child has separate existence from the moment of conception"), overruled, Bermarr v. Allan, 404 A.2d 8 (N.J. 1979) (reorganizing action).

New Jersey Constitutional Convention Call (Act of Apr. 21, 1977, S. 1271):

Requests Congress to call a convention to propose a constitutional amendment which would provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled to the right to life; provides that Congress and the states shall have concurrent powers to enforce such an amendment.

**New York:**

New York City Health and Hosp. Corp., 286 N.E.2d 887, 888 (N.Y. 1972), appeal dismissed, 410 U.S. 949 (1973) (rejecting challenge to pre-Roe abortion law which allowed abortion on demand through the twenty-fourth week of gestation but recognizing that human life begins at conception):

It is not effectively contradicted, if it is contradicted at all, that modern biological disciplines accept that upon conception a fetus has an independent genetic "package" with potential to become a full-fledged human being and that it has an autonomy of development and character although it is for the period of gestation dependent upon the mother. It is human, if only because it may not be characterized as not human, and it is unquestionably alive.

Kelly v. Gregory, 125 N.Y.S.2d 696, 697 (N.Y. App. Div. 1953) (rejecting viability requirement in cause of action for prenatal injuries) ("legal separability should begin where there is biological separability" and "separability begins at conception"):

The mother's biological contribution from conception on is nourishment and protection; but the foetus has become a separate organism and remains so throughout its life. That it may not live if its protection and nourishment are cut off earlier than the viable stage of its development is not to destroy its separability; it is rather to describe conditions under which life will not continue. Succeeding conditions exist, of course, that have that result at every stage of its life, postnatal as well as prenatal. Id. at 697.

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**North Carolina:**

DiDonato v. Wortman, 358 S.E.2d 489, 496 (N.C. 1987) (recognizing cause of action for wrongful death of a viable unborn child) ("[t]he public policy of this state as expressed by the legislature in our statutes recognizes that an unborn infant is a person") (Martin, J., concurring in part and dissenting in part).

Corkey v. Edwards, 322 F.Supp. 1248, 1252 (W.D.N.C. 1971), vacated and remanded, 410 U.S. 950 (1973) (construing criminal abortion statute):

Apart, the sperm and the unfertilized egg will die; neither has the capacity to grow and develop independently as does the fertilized egg. During fertilization, sperm and egg pool their nucleii and chromosones. Biologically, a living organism belonging to the species homo sapiens is created out of this organization. Genetically, the adult man was from such a beginning all that the essentially has become in every cell and human attribute.

**North Dakota:**

N.D. CENT. CODE §§ 12.1-17.1-02 through 12.1-17.1-06 (Supp.1991) (amending criminal code to define broad range of crimes, including homicide, that can be committed against unborn child, regardless of gestational age).

Statute providing that "[a] child conceived but not born is to be deemed an existing person so far as may be necessary for its interests in the event of its subsequent birth" was intended "to ensure and to protect the interests of a child subsequent to its conception but prior to its birth," Hopkins v. McBane, 359 N.W.2d 862, 864 (N.D. 1984).

**Ohio:**

Steinberg v. Brown, 321 F.Supp. 741, 746 (N.D. Ohio 1970) (construing criminal abortion law) (holding that human life is entitled to federal constitutional protection from conception) ("a new life comes into being with the union of human egg and sperm cells" and "[s]uch terms as 'quick' or 'viable', which are frequently encountered in legal discussion, are scientifically imprecise and without recognized medical meaning").

Williams v. Marion Rapid Transit, 87 N.E.2d 334, 340 (Ohio 1949) (recognizing cause of action for prenatal injuries):

To hold that the plaintiff in the instant case [a viable unborn child] did not suffer an injury in her person would require this court to announce that as a matter of law the infant is part of the mother until birth and has no existence in law until that time. In our view such a ruling would deprive the infant of the right [to a remedy] conferred by the [Ohio] Constitution upon all persons, by the application of a time worn fiction not founded on fact and within common knowledge untrue and unjustified.

The court also quoted with approval WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS § 31, 189 (1941). Professor Prosser stated, "So far as duty is concerned, if existence at the time [of injury] is necessary, medical authority has

recognized long since that the child is in existence from the moment of conception, and for many purposes its existence is recognized by the law." Id. at 339.

**Oklahoma:**

OKLA. STAT. ANN. tit. 63, § 1-730(2) (West 1997) (abortion regulations) (defining "unborn child" as "the unborn offspring of human beings from the moment of conception, through pregnancy, and until live birth . . . .").

Evans v. Olson, 550 P.2d 924, 926 (Okla. 1976) (rejecting viability requirement in cause of action for prenatal injuries and live birth requirement in wrongful death actions) ("there is no medical or scientific basis" for the proposition that "an unborn child has no judicial existence apart from its mother").

**Oregon:**

State v. Ausplund, 167 P. 1019, 1022-23 (Or. 1917) (construing criminal abortion law):

The statute refers to "any woman pregnant with a child" without reference to the stage of pregnancy. When a virile spermatozoon unites with a fertile ovum in the uterus, conception is accomplished. Pregnancy at once ensues, and under normal circumstances continues until parturition. During all this time the woman is "pregnant with a child" within the meaning of the statute. She cannot be pregnant with anything else than a child. From the moment of conception a new life has begun, and is protected by the enactment. The product of conception during its entire course is imbued with life, and is capable of being destroyed as contemplated by the law. By such destruction the death of a child is produced and often that of its mother as well.

Mallison v. Pomeroy, 291 P.2d 225, 228 (Or. 1955) (recognizing cause of action for prenatal injuries) ("[i]n Oregon we have recognized by statute the separate entity of an unborn child by protecting him in his property rights and against criminal conduct . . . .").

Libbee v. Permanente Clinic, 518 P.2d 636 (Or. 1974) (recognizing cause of action for the wrongful death of a viable stillborn child).

**Pennsylvania:**

18 PA. CONS. STAT. ANN. § 3203 (1995) (abortion regulations) (defining "unborn child" and "fetus" as "an individual organism of the species homo sapiens from fertilization until live birth").

Amadio v. Levin, 501 A.2d 1085, 1087 (Pa. 1985) (rejecting live birth requirement in wrongful death actions) ("a child en ventre sa mere is a separate individual from the moment of conception").

Sinkler v. Kneale, 164 A.2d 93, 96 (Pa. 1960) (rejecting viability requirement in cause of action for prenatal injuries) (viability has "little to do with the basic right to recover,

when the foetus is regarded as having existence as a separate creature from the moment of conception").

Pennsylvania Constitutional Convention Call (H.R. 71, 1978 Gen. Assembly, 1978 Pa. Laws 1431):

[A]pplication to the Congress . . . to call a convention for drafting and proposing an amendment to the Constitution . . . to guarantee the right to life to the unborn fetus by doing the following:

(a) With respect to the right to life guaranteed in the United States Constitution, provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled to the right to life.

(b) Provide that Congress and the several states shall have concurrent powers to enforce such an amendment by appropriate legislation.

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(d) Nothing in this article shall prohibit a law permitting only those medical procedures required to prevent the death of the mother.

**Rhode Island:**

R.I. GEN. LAWS § 11-3-4 (1981) (1973 R.I. Pub. Laws 68-70, ch. 15, §2) (criminal abortion statute):

It shall be conclusively presumed in any action concerning the construction, application or validity of sec. 11-3-1 [prohibiting abortion], that human life commences at the instant of conception and that said human life at said instant of conception is a person within the language and meaning of the fourteenth amendment of the Constitution . . . .

Sylvia v. Gobeille, 220 A.2d 222, 223-24 (R.I. 1966) (rejecting viability requirement in cause of action for prenatal injuries) (noting "the medical fact that a fetus becomes a living human being from the moment of conception" and rejecting viability as a "decisive criterion" because "there is no sound reason for drawing a line at the precise moment of the fetal development when the child attains the capability of an independent existence").

Presley v. Newport Hosp., 365 A.2d 748, 751 (R.I. 1976) (rejecting live birth requirement in wrongful death of a viable unborn child) (citing with approval the civil law proposition that "from the moment of conception a separate organism with its own identity comes into existence" and the medical proposition that "an ovum, once it is fertilized, is a separate living entity"):

[V]iability is a concept bearing no relation to the attempts of the law to provide remedies for civil wrongs. If we profess allegiance to reason, it would be seditious to adopt so arbitrary and uncertain a concept as viability as a dividing line between those persons who shall enjoy the protection of our remedial laws and those who shall become, for most intents and purposes, nonentities. It seems that if live birth is to be characterized, as it so frequently has been, as an arbitrary line of demarcation, then viability, when enlisted to serve that same purpose, is a veritable non sequitur.

Id. at 753-54 (dicta in plurality opinion) (disapproved Miccolis v. Amica Mutual Ins. Co., 587 A.2d 611 (R.I. 1991)).

Rhode Island Constitutional Convention Call (Act. of Apr. 21, 1977, H.R. 5150):
Requests Congress to call a convention to propose a constitutional amendment which would provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled to the right to life; provides that Congress and the states shall have concurrent power to enforce such an amendment.

**South Dakota:**

State v. Munson, 201 N.W.2d 123, 126 (S.D. 1972), vacated and remanded, 410 U.S. 950 (1973) (construing criminal abortion law) (citing with approval holding in Steinberg v. Brown, 321 F.Supp. 741 (N.D. Ohio 1970), that human life is entitled to federal constitutional protection from conception).

S.D. CODIFIED LAWS ANN. § 21-5-1 (1987) (amending wrongful death statute to include "an unborn child" without regard to gestational age).

S.D. CODIFIED LAWS ANN. § 22-17-6 (1988) ("[a]ny person who intentionally kills a human fetus by causing an injury to its mother . . . is guilty of a Class 4 felony").

S.D. CODIFIED LAWS ANN. § 26-1-2 (1992) ("[a] child conceived, but not born, is to be deemed an existing person so far as may be necessary for its interests in the event of its subsequent birth").

**Texas:**

Thompson v. State, 493 S.W.2d 913, 918 (Tex. Crim. App. 1971) vacated and remanded, 410 U.S. 950 (1973) (construing criminal abortion law):
The State of Texas is committed to preserving the lives of its citizens so that no citizen "shall be deprived of life, . . . except by the due course of the law of the land." [Citation omitted]. [The Texas abortion law] is designed to protect fetal life . . . and this justifies prohibiting termination of the life of the fetus or embryo except for the purpose of saving the life of the mother.

Leal v. C.C. Pitts Sand and Gravel, Inc., 419 S.W.2d 820, 822 (Tex. 1967) (recognizing cause of action for wrongful death for prenatal injuries where death occurs after live birth), rev'g 413 S.W.2d 825 (Tex. Civ. App. 1967) (denying cause of action) and app'g dissenting opinion of Justice Cadena, 413 S.W.2d at 828 ("medical science . . . consider[s] that life begins at conception"), id. at 829 ("legalistic concept that the unborn child is but a part of its mother" is "contrary to scientific fact and common sense").

Witty v. Am. Gen. Capital Distrib., Inc., 727 S.W.2d 503, 505 (Tex. 1987) (denying

cause of action for wrongful death of viable child who was stillborn but recognizing "the fetus as having an existence separate from its mother").

Delgado v. Yandell, 468 S.W.2d 475 (Tex. Civ. App. 1971), writ ref'd n.r.e. 471 S.W.2d 569 (Tex. 1971) (per curiam) (rejecting viability requirement in cause of action for prenatal injuries).

**Utah:**

UTAH CODE ANN. § 76-7-301.1(1) (1992) (preamble to Utah abortion law):
It is the finding and policy of the Legislature, reflecting and reasserting the provisions of Article I, Sections 1 and 7, Utah Constitution, which recognize that life founded on inherent and inalienable rights is entitled to protection of law and due process; and that unborn children have inherent and inalienable rights that are entitled to protection by the state of Utah pursuant to the provisions of the Utah Constitution.

§ 76-7-301.1(2):
The state of Utah has a compelling interest in the protection of the lives of unborn children.

§ 76-7-301.1(3):
It is the intent of the Legislature to protect and guarantee to unborn children their inherent and inalienable right to life as required by Article I, Sections 1 and 7, Utah Constitution.

UTAH CODE ANN. § 76-5-201(1) (1992 Supp.) (defining offense of criminal homicide as causing "the death of another human being, including an unborn child").

Utah Constitutional Convention Call (H.R.J. Res. 28, 42nd Legis., Reg. Sess., 1977 Utah Laws 1317, 1318):
[A]pplies to the Congress . . . to call a convention for the purpose of drafting and submitting for ratification by the states, . . . an amendment to the Constitution that will guarantee to every human life, from the moment of fertilization throughout its natural existence, in every state, territory, and possession of the United States, the full protection of all laws respecting life, excepting an unborn child whose mother's life would otherwise be lost.

**Virginia:**

Kalafut v. Gruver, 389 S.E.2d 681, 683-84 (Va. 1990) (rejecting viability rule in cause of action for prenatal injuries or for wrongful death following live birth) (noting "developments in medical science, especially in the field of embryology," court held that "an action may be maintained for recovery of damages for any injury occurring after conception, provided the tortious conduct and the proximate cause of the harm can be established").

**CLS Comments on NIH Guidelines**
**APPENDIX B (Cont.)**

**Wisconsin:**

WIS. STAT. ANN. § 940.04(6) (West 1982) (criminal abortion statute defining "unborn child" as "a human being from the time of conception until it is born alive")

Puhl v. Milwaukee Auto. Ins. Co., 99 N.W.2d 163, 170 (Wis. 1959) (rejecting viability requirement in cause of action for prenatal injuries), overruled on other grounds, In re Estate of Stromsted, 299 N.W.2d 226 (Wis. 1980):

The viability theory has been challenged as unrealistic in that it draws an arbitrary line between viability and nonviability, and fails to recognize the biological fact there is a living human being before viability. A child is no more a part of its mother before it becomes viable than it is after viability. It would be more accurate to say that the fetus from conception lives within its mother rather than as a part of her. The claim of a child injured before viability is just as meritorious as that of a child injured during the viable stage.

Kwaterski v. State Farm Mut. Auto. Ins. Co., 148 N.W.2d 107, 111 (Wis. 1967) (rejecting born alive requirement in wrongful death actions) (assertion that "[a] child has no juridical existence apart from its mother" has "no scientific or medical basis in fact").

**APPENDIX C**

CLS Comments on Draft NIH Guidelines for Research Involving Human Pluripotent Stem Cells, 64 *Federal Register* 67576-67579 (December 2, 1999)

# *Frozen Embryos:*
## The Adoption Solution

RONALD L. STODDART, ESQ.© (November 5, 1999)

**THE BACKGROUND**

The increase in the use of "reproductive technology" has resulted in the birth of children through an alphabet soup of conception techniques. For those families who have gone through infertility treatment, terms such as IVF, GIFT, ZIFT, AHA, etc. sometimes obscure the fact that achieving a pregnancy and having a family is the goal. But while pursuing the goal, families find themselves creating new issues as frequently as they resolve existing ones.

For example, one of the by-products of in-vitro fertilization of eggs is the creation of embryos which are not immediately implanted. Where economics and technology clash, the economy of scale has typically prevailed and left the "fertility challenged" parents with "extra" embryos that can be frozen and stored for later implantation. Whether the first implantations are unsuccessful or the parents desire additional children, the availability of stored embryos is an attractive service offered by the fertility physicians.

By some estimates, there are hundreds of thousands of frozen embryos currently in storage in the United States. A recent report indicated that there were over 25,000 frozen embryos being stored in Massachusetts, alone, due to their favorable health insurance coverage requirements for infertility procedures.

Eventually the genetic parents will be confronted with the need to make a decision on the future of their stored embryos when they have completed their own family. The three choices they are given are (1) to donate the embryos for implantation, (2) to donate the embryos for research or (3) to have the embryos destroyed. Physicians, bioethicists, social workers, clergy and other "experts" have weighed in on these choices with arguments reminiscent of the Pro-Life - Pro-Choice debate. Although I am strongly Pro-Life, this issue is largely irrelevant when dealing with the focus of this article, the adoption of frozen embryos.

For the record, however, I would like to state the fundamental argument for "adopting" frozen embryos rather than transferring them through some other contractual means. A frozen embryo is a pre-born child with the potential for development into a viable fetus and ultimately a new born baby. Regardless of the debate surrounding the creation of the embryos that are now frozen and stored, the movement to offer the genetic parents the full rights of birth parents in an adoption proceeding recognizes the deep emotional bonds that exist between genetic parents and their children - regardless of how they come to be born.

## THE LAW

As one might imagine, the law has lagged far behind reproductive technology and generally responds to disputes that test the wisdom of Solomon. In California, the Penal Code has brought the transfer of embryos under the common law Statue of Frauds by requiring a written agreement. The further regulation of such transfers, however, are woefully lacking any specifics or protections for either party to the written agreement, other than those provided by the Health & Safety Code sections dealing with tissue transfer and health issues.

California Penal Code Section 367(b) provides the legal basis for the formalities required in an embryo transfer as follows:

"It shall be unlawful for anyone to knowingly implant sperm, ova, or embryos, through the use of assisted reproduction technology, into a recipient who is not the sperm, ova, or embryo provider, without the signed written consent of the sperm, ova, or embryo provider and recipient."

There are certainly clinics and physicians that are transferring embryos with the most abbreviated consent forms imaginable. To those families who are comfortable with the designation "provider" and "recipient", perhaps such informality is sufficient. But the law has always treated the adoption of human beings with a bit more respect.

## ADOPTION LAW

The basic elements of an adoption, even ignoring the considerable evidence supporting the importance of "open adoption", include:

1. Complete and thorough advisement of legal rights to the birth parent(s), generally accompanied by psychological counseling.
2. Complete and thorough screening and education of the adopting parent(s), generally through the home study process.
3. Formal execution of consent documents by both birth parents and adopting parents.
4. Court decree recognizing the sufficiency of the process and the protection of the best interests of the child.
5. Promulgation of a new birth certificate reflecting the legal status of adopting parents and child.

When dealing with embryo adoptions, the first three elements of an adoption can be satisfied, and should be satisfied for the protection of the child and the adult parties to the adoption. As will be shown below, the need for a new birth

certificate is obviated in an embryo adoption and there is no statutory basis for an adoption decree (although some courts may be willing to issue ceremonial decrees).

## DEFINING THE ROLES

As with any new area of the law, defining the roles of the participants - and the terminology applied to them - is often the first hurdle to overcome. To ease the understanding of the roles - both emotionally and legally - of the parties we have adopted the following definitions.

**Genetic Parents:** The genetic parents fill the role most commonly associated with "birth parents" in adoptions. The frozen embryo is the pre-born child of the genetic parents. The genetic parents have the legal right to custody and control of the frozen embryos, which custody has generally been assigned temporarily to a fertility clinic or cryobank laboratory. With some exceptions, the law recognizes this right of custody more as an ownership interest than parental rights and obligations.

For purposes of this article, the genetic parents are assumed to have been the source of the eggs and sperm used to create the embryos. In the case where donor eggs or donor sperm were used, the genetic parents are the individuals with the legal right to determine the future of the frozen embryos.

**Pre-born Child:** A frozen embryo is a pre-born child, subject to many of the same risks of survival as any pre-born child. Our purpose in emphasizing the personhood of the frozen embryo is not to subject the genetic parents to a moral and religious argument for not destroying the embryo - although certainly that is our unequivocal position. Rather, it is easier to understand and plan for the future emotional needs of the "adopted" embryo by recognizing its identity at the earliest possible time.

**Adopting Parents:** The adopting parents are the recipients of the frozen embryo and therefore the child's "birth parents" under the law. The frozen embryo would be implanted in the adopting mother after it has been legally "relinquished" or transferred to the adopting parents. No additional legal proceedings would be necessary for the adopting parents/birth parents to secure full legal and physical custody to the child.

**Relinquishment:** The term relinquishment, rather than donation, legal transfer or gift, is used to describe the procedure for the genetic parents to terminate their legal rights to the frozen embryo. It is important that this be accomplished with the same safeguards as are found in a more traditional adoption in order to best prepare and educate all of the parties involved. It is also important that the relinquishment be accomplished prior to the implantation of the frozen embryo into the adopting mother so that there is no later dispute as to the legal roles of the parties.

**Genetic Siblings:** One of the little noticed, but important factors in treating the transfer of a frozen embryo to another family as an "adoption" is to safeguard the later needs of the genetic family, including genetic siblings. Unlike other

forms of in-vitro fertilization used in infertility cases, the placement of frozen embryos for adoption generally involves genetic parents who have already been successful in giving birth to children using the contemporaneously created embryos.

## ADVANTAGES OF EMBRYO ADOPTION

There are a number of advantages to embryo adoption to all of the parties involved. Let's review what some of those advantages might be.

1. *Advantages to Genetic Parents*

   As was discussed earlier, once genetic parents have completed their families and have no further desire to give birth to additional children, the decision as to the future of any remaining frozen embryos must be made. Regardless of the medical status of the embryo, which may be as few as 4 cells, the genetic parents are frequently emotionally invested in the future of "all" of their children, even those that carry the label "potential" children. For those genetic parents who believe that the embryos are more than tissue, and who would like to give each embryo a fair chance at life, adoption is the most satisfying answer.

   Mere release of the embryos for implantation in unknown parents is similar to the old "closed adoption" system that left birth mothers grieving for far too long when simple information as to the child's welfare would have been a healing balm. Like birth mothers in an open adoption, genetic parents can be as involved or uninvolved in the selection of adopting parents as they choose. In addition, they can maintain the security of knowing that the genetic siblings of their own children will always be known in the event of medical emergencies or to later answer imponderable questions.

2. *Advantages to Adopting Parents*

   For infertile couples, it was thought that the closest experience to giving birth was adopting a new born baby and taking the baby home directly from the hospital. Although some women who have experienced labor and delivery may disagree, the opportunity to become pregnant with your adopted child, carry the child to term and then give birth to your adopted child truly maximizes the parenting experience. For those experts who extol the virtues of "pre-natal bonding", frozen embryo adoption is the great equalizer.

## MODEL EMBRYO ADOPTION PROGRAM

I. *Services to the Genetic Parents*

Similar to traditional adoptions, genetic parents should be offered counseling as to all of the options available to them. Adoption of the frozen embryos should be described as a lifelong commitment to the children who may be born from the implantation of the embryos in an adopting mother. As with open adoption, genetic parents should be encouraged to participate in the establishment of criteria for the adopting parents and even in the actual selection of parents.

Genetic parents will provide complete medical information, including recent HIV test results. Such information must be disclosed to the adopting parents and the physician assisting with the embryo implantation.

Post-adoption services, including counseling must also be made available to genetic parents. Every effort should be made to maintain contact through the agency involved with the genetic parents.

*II. Services to Adopting Parents*

Potential adopting parents should complete a home study as would any other adopting parents. It is important that the family be counseled as to the life long issues of adoption, even though they will be giving birth to their adopted child. To try to ignore the fact that the child is adopted could result in emotional upheaval for the child later in life. Although the way of explaining to a birthed child that the child is adopted may seem bizarre to us now, children will soon find the realities of reproductive technology very common place. Education and support will be as important in frozen embryo adoptions as they are in other more traditional adoptions.

Potential adopting mothers must also show, through recommendations from her physician, that she is capable of carrying a child to term even though she may suffer from other infertility problems. It is also highly desirable that the adopting parents have the willingness to provide continuing information on their child(ren) to the agency and genetic parents. It should be remembered that the tie between genetic parents and adopting parents is particularly strong when the presence of genetic siblings are recognized.

*III. The Role of the Adoption Agency*

The role of the adoption agency is critical to the future of frozen embryo adoptions. Without the recognition that adoptions of frozen embryos are entitled to the same safeguards and protections as other adoptions, the potential for a "market" in frozen embryos being created is very real. Just as the law regulates who may act as an intermediary in traditional adoptions (either the birth parent(s) directly or a licensed adoption agency), it is equally important to regulate who may act as an intermediary in a frozen embryo adoption. It should also be noted that

even when birth parent(s) place a child directly with adopting parents, the law still requires a home study and court approval of the adoption.

In the case of frozen embryo adoption, until the law catches up with the science, the appropriate adoption expertise to apply to frozen embryo adoption will come from licensed agencies. The agency can offer the counseling, screening, education and formal relinquishment services that should be the hallmarks of a frozen embryo adoption. Until the legislature or courts provide for other formalities or protections, the adoption community should encourage, even advocate, for the necessity of such an adoption model.

**CONCLUSIONS**

Although many physicians and facilitators may point to the success of their myriad varieties of egg, sperm and embryo transfers, at some point the treatment of embryos must conform to that afforded children rather than property. To wait until we have a generation of displaced children, with little knowledge or understanding of their roots, crying for "open records" and their "right to know" their history, would reflect too little appreciation for the past errors of adoption practice. The time to develop a progressive and thoughtful approach to dealing with the futures of the hundreds of thousands of stored frozen embryos is now.

Although the program developed by Christian Adoption & Family Services (called Snowflakes) is certainly a "work in progress", it does recognize the unique nature of each embryo and the real needs of the genetic parents in planning for their future. It is hoped that the dialogue that develops over the coming months will add to the services that can be offered to genetic parents and infertile couples.

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September 6, 2001

Conn Carroll
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
B-373-Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Carroll:

We received a copy of the testimony Joan Samuelson provided at the hearing on July 17, "Opportunities and Advancements in Stem Cell Research." Due to some confusion in forwarding of mail to Ms. Samuelson's California office from our headquarters, the transcript was not received until recently. We realize that edits were due back to you by August 17, so we understand that the attached change may be too late for incorporation. In case it is possible to include it, we note only the one change to "deep brain" stimulation on page 145 attached.

We appreciate your assistance and apologize for our delay.

Sincerely,

Elfie Fassler
Executive Assistant to
Joan I. Samuelson

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

January 15, 1999

TO: Harold Varmus, M.D.
Director, NIH

FROM: Harriet S. Rabb

SUBJECT: Federal Funding for Research Involving Human Pluripotent Stem Cells

The Office of the General Counsel of the U.S. Department of Health and Human Services (HHS) has prepared the following in response to your request for a legal opinion on whether federal funds may be used for research conducted with human pluripotent stem cells derived from embryos created by *in vitro* fertilization or from primordial germ cells isolated from the tissue of non-living fetuses. This inquiry arises from the recently reported research of: (1) Dr. James A. Thomson of the University of Wisconsin-Madison, who isolated pluripotent stem cells from embryos donated for research by persons undergoing fertility treatment[1]; and (2) Dr. Michael Shamblott of the Johns Hopkins University School of Medicine, who derived pluripotent stem cells from primordial germ cells from non-living fetuses.[2] The research described in these two published reports was not funded by HHS.

Summary Answer

The statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition. To the extent human pluripotent stem cells are considered human fetal tissue by law, they are subject to the statutory prohibition on sale for valuable consideration, the restrictions on fetal tissue transplantation research that is conducted or funded by HHS, as well as to the federal criminal prohibition on the directed donation of fetal

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[1] James A. Thomson et al., Embryonic Stem Cell Lines Derived from Human Blastocysts, Science, vol. 282, November 6, 1998, pp. 1145-1147.

[2] Michael J. Shamblott et al., Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells, 95 Proc. Nat'l. Acad. Sci. USA 13726 (Nov. 1998).

tissue. Research involving human pluripotent stem cells excised from a non-living fetus may be conducted only in accordance with any applicable state or local law. Finally, the Presidential Directive banning federal funding of human cloning would apply to pluripotent stem cells, only if they were to be used for that purpose.

Analysis

I. Prohibition on Federal Funding for Human Embryo Research

In the appropriations provision for the Departments of Labor, Health and Human Services, and Education, and Related Agencies in the Omnibus Consolidated and Emergency Supplemental Appropriations Act, Fiscal Year 1999, Public Law 105-277, section 511 provides that none of the funds made available in that appropriation may be used for:

> (1) the creation of a human embryo or embryos for research purposes; or
> (2) research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g (b)).

The term "human embryo or embryos" is defined in the statute to include "any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

Pluripotent stem cells are not a human "organism" as that term is used in the definition of human embryo provided by statute. The term "organism" is not itself defined by law, and the question of what is an organism calls for a science-based answer. According to the McGraw-Hill Dictionary of Scientific and Technical Terms (hereinafter McGraw-Hill), an organism is "[a]n individual constituted to carry out all life functions."[3] Pluripotent stem cells are not organisms

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[3] McGraw-Hill Dictionary of Scientific and Technical Terms 1408 ( 5th edition 1994). See also N. Campbell, Biology, (4th edition 1996) pp. 8-9, which defines organism as follows:

> While cells are the units of organisms, it is organisms that are the units of life. It's an important distinction. Except for unicellular life, 'cell' does not equal 'organism.' A single-celled organism such as an amoeba is analogous not to one of your cells, but to your whole body. What the amoeba accomplishes with a single cell -- the uptake and processing of nutrients, excretion of wastes, response to environmental stimuli, reproduction, and other functions -- a human or other multicellular organism accomplishes with a division of labor among specialized tissues, organs, and organ systems. Unlike the amoeba, none of your cells could live for long on its own. The organism we recognize as an animal or plant is not a

and do not have the capacity to develop into an organism that could perform all the life functions of a human being -- in this sense they are not even precursors to human organisms.[4] They are, rather, human cells that have the potential to evolve into different types of cells such as blood cells or insulin producing cells.

Moreover, a human embryo, as that term is virtually universally understood, has the potential to develop in the normal course of events into a living human being. The scientific definition of embryo, as described in McGraw-Hill, is "[t]he product of conception up to the third month of human pregnancy."[5] Pluripotent stem cells do not have the capacity to develop into a human being, even if transferred to a uterus.[6] Therefore, in addition to falling outside of the legal definition provided by statute, pluripotent stem cells cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term. Thus, based on

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collection of unicells, but a multicellular cooperative with the emergent properties of 'whole organism.'

[4] At a December 2, 1998, stem cell research hearing before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee, Senator Tom Harkin asked five scientists, two bioethicists, and a theologian testifying before the committee if, in their view, stem cells were organisms. All of the experts who responded concluded that human pluripotent stem cells are not organisms. Use of Fetal Tissue in Brain Stem Cell Research; Hearing Before the Subcomm. on Labor, Health and Human Services, and Education of the Senate Appropriations Comm., 105th Cong. (December 2, 1998) available in LEGI-SLATE, Transcript No. 983360015 [hereinafter Stem Cell Hearing] (statement of Dr. Harold Varmus, Director, National Institutes of Health; Dr. John Gearhart, Johns Hopkins University School of Medicine; Dr. James Thomson, Wisconsin Primate Research Center, University of Wisconsin; Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System; and Mr. Richard Doerflinger, Associate Director for Policy Development, Secretariat of Pro-Life Activities, National Conference of Catholic Bishops). One expert, Dr. Eric Meslin, Executive Director of the National Bioethics Advisory Commission, stated that he could not speak on behalf of the Commission because it had not considered the question. Stem Cell Hearing, supra, (statement of Dr. Eric Meslin).

[5] McGraw-Hill Dictionary, supra note 3, at 673.

[6] See Letter from the Chair of the National Bioethics Advisory Commission, to the President of the United States, response to question no. 2, November 20, 1998; National Institutes of Health, Report of the Human Embryo Research Panel, Sept. 1994, p. 26. See also Stem Cell Hearing, supra note 4, (statements of Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; and Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System).

an analysis of the relevant law and scientific facts, federally funded research that utilizes human pluripotent stem cells would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such stem cells are not human embryos.

II. Restrictions on the Use of Human Fetal Tissue

There are a number of potential sources of human pluripotent stem cells; some of these stem cells may fall within the legal definition of human fetal tissue and would, therefore, be subject to federal regulations. Section 498A of the Public Health Service Act specifies that fetal tissue "means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." 42 U.S.C. 289g-1(g). Some stem cells, for example those derived from the primordial germ cells of non-living fetuses, would be considered human fetal tissue for purposes of Section 498A.

The Public Health Service Act (hereinafter "The Act") contains three relevant provisions governing the use and transfer of human fetal tissue: (1) a criminal prohibition against the sale of human fetal tissue for valuable consideration; (2) restrictions on fetal tissue transplantation research supported by federal funds; and (3) a prohibition on the directed donation of fetal tissue for transplantation. We explore each of these restrictions in turn.

Section 498B(a) of the Act states that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration,[7] if the transfer affects interstate commerce.[8] 42 U.S.C. 289g-2(a). It is common practice for scientists throughout the United States to share research materials through transactions that result in such materials crossing state boundaries. Such exchanges, as well as transactions within the District of Columbia, or exchanges within a state that "affect interstate commerce" would meet the statutory criterion of affecting interstate commerce, but would not fall within the scope of the criminal

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[7] The term "valuable consideration" encompasses both monetary and non-monetary payments. Section 498B (d)(3) provides that the term does not include "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

[8] The statute adopts the definition of interstate commerce in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b): ". . . commerce between any State or Territory and any place outside thereof, and . . . commerce within the District of Columbia or within any other Territory not organized with a legislative body." The statute does not define what "affects" interstate commerce, but, in interpreting similar language in another criminal statute the Supreme Court found that "affecting interstate commerce" is an expression of Congress' intent to broadly exercise its Commerce Clause power under the Constitution. Scarborough v. United States, 431 U.S. 563, 571-72 (1977).

prohibition unless the scientist providing the materials sought payment in excess of the expenses included in the statutory definition of "valuable consideration."

In addition, the law places some restrictions on federal support for research on the transplantation of fetal tissue. Section 498A of the Act provides that the Secretary may conduct or support research on the "transplantation of fetal tissue for therapeutic purposes," only if certain statutory requirements are met. 42 U.S.C. 289g-1. These requirements include obtaining: (1) the informed consent of the woman donating the tissue; (2) a statement by the attending physician regarding the woman's consent and the method of obtaining the tissue; (3) a statement by the researcher regarding his or her understanding of the source of the tissue, that such information has been conveyed to the donee, and that the researcher has not participated in any decision regarding termination of the pregnancy.

Finally, section 498B(b) of the Act provides that it shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation into another person if the tissue will be or is obtained pursuant to an induced abortion, and there is a promise to the donor: (1) to transplant the tissue into a person specified by the donor; (2) the tissue will be transplanted into a relative of the donor; or (3) the donee of the tissue has provided valuable consideration for the costs associated with the abortion. 42 U.S.C. 289g-2(b). The Act provides criminal penalties for violation of the prohibition on directed donations.

III. Federal Restrictions on Fetal Research

Federal regulation provides that activities involving cells, tissues, or organs excised from a non-living fetus shall be conducted only in accordance with any applicable state or local law. 45 CFR 46.210, Subpart B. This regulation would apply to certain human pluripotent stem cells, including those derived from the primordial germ cells of non-living fetuses.

IV. Prohibition on Federal Funding for Cloning of Human Beings

In a March 4, 1997, memorandum to the heads of executive departments and agencies, the President directed that no federal funds will be used for the cloning of human beings and that federal funds shall not be allocated for that purpose.[9] There are myriad uses for human pluripotent stem cells that are completely unrelated to cloning. However, to the extent such stem cells were to be used for human cloning, the prohibition on the use of federal funds for that purpose would apply.

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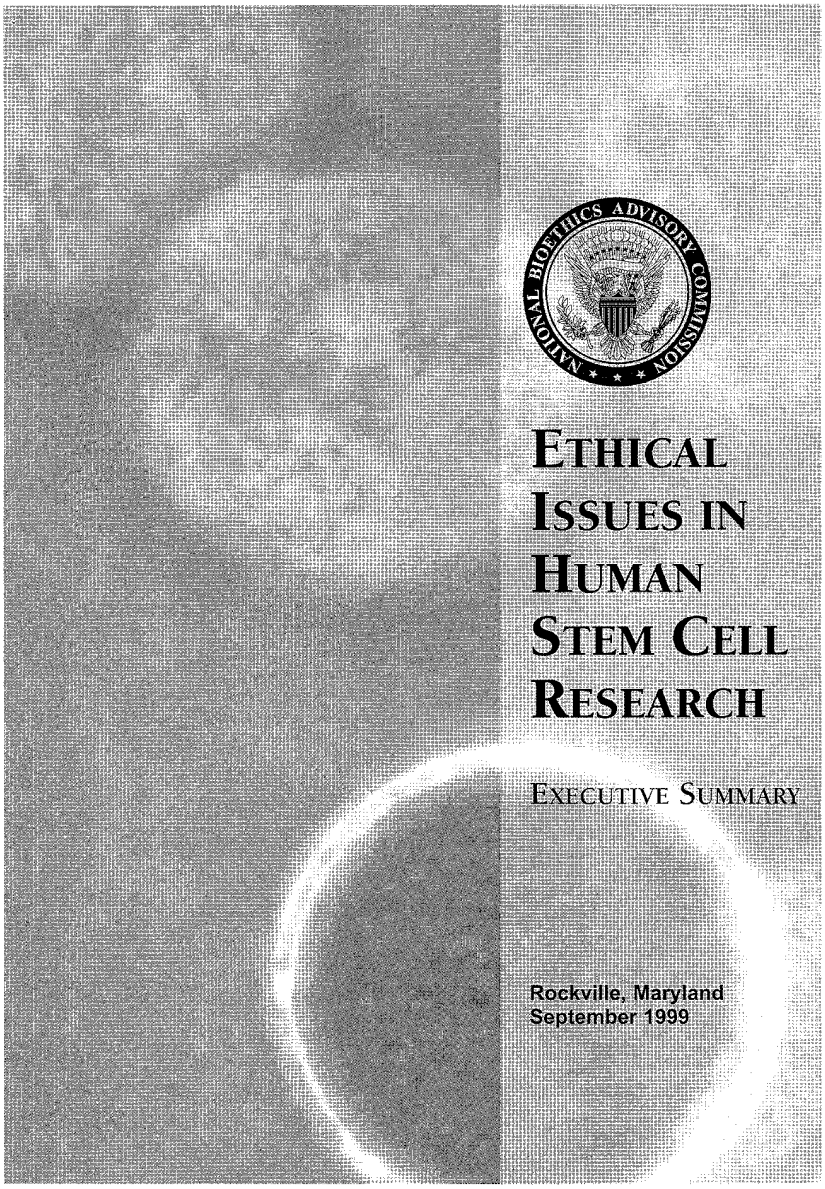
[9] Memorandum from the President of the United States to Heads of Executive Departments and Agencies (March 4, 1997).


NATIONAL BIOETHICS ADVISORY COMMISSION
ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH
EXECUTIVE SUMMARY
Rockville, Maryland
September 1999

The National Bioethics Advisory Commission (NBAC) was established by Executive Order 12975, signed by President Clinton on October 3, 1995. NBAC's functions are defined as follows:

a) NBAC shall provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

   1) the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and

   2) applications, including the clinical applications, of that research.

b) NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.

c) NBAC shall not be responsible for the review and approval of specific projects.

d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council.

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## National Bioethics Advisory Commission

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*To avoid the appearance of a conflict of interest, Commissioner Charo recused herself from all Commission deliberations as of February 1, 1999. She neither dissents from nor endorses this report and its recommendations.

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# Executive Summary

## Introduction

In November 1998, President Clinton charged the National Bioethics Advisory Commission with the task of conducting a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations. The President's request was made in response to three separate reports that brought to the fore the exciting scientific and clinical prospects of stem cell research while also raising a series of ethical controversies regarding federal sponsorship of scientific inquiry in this area. Scientific reports of the successful isolation and culture of these specialized cells have offered hope of new cures for debilitating and even fatal illness and at the same time have renewed an important national debate about the ethics of research involving human embryos and cadaveric fetal material.

## Scientific and Medical Considerations

The stem cell is a unique and essential cell type found in animals. Many kinds of stem cells are found in the body, with some more differentiated, or committed, to a particular function than others. In other words, when stem cells divide, some of the progeny mature into cells of a specific type (e.g., heart, muscle, blood, or brain cells), while others remain stem cells, ready to repair some of the everyday wear and tear undergone by our bodies. These stem cells are capable of continually reproducing themselves and serve to renew tissue throughout an individual's life. For example, they constantly regenerate the lining of the gut, revitalize skin, and produce a whole range of blood cells. Although the term *stem cell* commonly is used to refer to the cells within the adult organism that renew tissue (e.g., hematopoietic stem cells, a type of cell found in the blood), the most fundamental and extraordinary of the stem cells are found in the early stage embryo. These *embryonic stem (ES) cells*, unlike the more differentiated adult stem cells or other cell types, retain the special ability to develop into nearly any cell type. *Embryonic germ (EG) cells*, which originate from the primordial reproductive cells of the developing fetus, have properties similar to ES cells.

It is the potentially unique versatility of the ES and EG cells derived, respectively, from the early stage embryo and cadaveric fetal tissue that presents such unusual scientific and therapeutic promise. Indeed, scientists have long recognized the possibility of using such cells to generate more specialized cells or tissue, which could allow the generation of new cells to be used to treat injuries or diseases, such as Alzheimer's disease, Parkinson's disease, heart disease, and kidney failure. Likewise, scientists regard these cells as an important—perhaps essential—means for understanding the earliest stages of human development and as an important tool in the development of life-saving drugs and cell-replacement therapies to treat disorders caused by early cell death or impairment.

The techniques for deriving these cells have not been fully developed as standardized and readily available research tools, and the development of any therapeutic application remains some years away. Thus, ES and EG cells are still primarily a matter of intense research interest.

At this time, human stem cells can be derived from the following sources:

- human fetal tissue following elective abortion (EG cells),

- human embryos that are created by *in vitro* fertilization (IVF) and that are no longer needed by couples being treated for infertility (ES cells),
- human embryos that are created by IVF with gametes donated for the sole purpose of providing research material (ES cells), and
- potentially, human (or hybrid) embryos generated asexually by somatic cell nuclear transfer or similar cloning techniques in which the nucleus of an adult human cell is introduced into an enucleated human or animal ovum (ES cells).

In addition, although much promising research currently is being conducted with stem cells obtained from adult organisms, studies in animals suggest that this approach will be scientifically and technically limited, and in some cases the anatomic source of the cells might preclude easy or safe access. However, because there are no legal restrictions or new ethical considerations regarding research on adult stem cells (other than the usual concerns about consent and risks), important research can and should go forward in this area. Moreover, because important biological differences exist between embryonic and adult stem cells, this source of stem cells should not be considered an alternative to ES and EG cell research.

## Ethical and Policy Considerations

The scientific reports of the successful isolation and culture of ES and EG cells have renewed a longstanding controversy about the ethics of research involving human embryos and cadaveric fetal material. This controversy arises from sharply differing moral views regarding elective abortion or the use of embryos for research. Indeed, an earnest national and international debate continues over the ethical, legal, and medical issues that arise in this arena. This debate represents both a challenge and an opportunity: a challenge because it concerns important and morally contested questions regarding the beginning of life, and an opportunity because it provides another occasion for serious public discussion about important ethical issues. We are hopeful that this dialogue will foster public understanding about the relationships between the opportunities that biomedical science offers to improve human welfare and the limits set by important ethical obligations.

Although we believe most would agree that human embryos deserve respect as a form of human life, disagreements arise regarding both what form such respect should take and what level of protection is required at different stages of embryonic development. Therefore, embryo research that is not therapeutic to the embryo is bound to raise serious concerns and to heighten the tensions between two important ethical commitments: to cure disease and to protect human life. For those who believe that the embryo has the moral status of a person from the moment of conception, research (or any other activity) that would destroy the embryo is considered wrong and should not take place. For those who believe otherwise, arriving at an ethically acceptable policy in this arena involves a complex balancing of a number of important ethical concerns. Although many of the issues remain contested on moral grounds, they co-exist within a broad area of consensus upon which public policy can, at least in part, be constructed.

For most observers, the resolution of these ethical and scientific issues depends to some degree on the source of the stem cells. The use of cadaveric fetal tissue to derive EG cell lines—like other uses of tissues or organs from dead bodies—is generally the most accepted, provided that the research complies with the system of public safeguards and oversight already in place for such scientific inquiry. With respect to embryos and the ES cells from which they can be derived, some draw an ethical distinction between two types of embryos. One is referred to as the *research embryo*, an embryo created through IVF with gametes provided solely for research purposes. Many people, including the President, have expressed the view that the federal government should not fund research that involves creating such embryos. The second type of embryo is that which was created for infertility treatment, but is now intended to be discarded because it is unsuitable or no longer needed for such treatment. The use of these embryos raises fewer ethical questions because it does not alter their final disposition. Finally, the recent demonstration of cloning techniques (somatic cell nuclear transfer) in nonhuman animals suggests that transfer of a human somatic cell nucleus into an oocyte

might create an embryo that could be used as a source of ES cells. The creation of a human organism using this technique raises questions similar to those raised by the creation of research embryos through IVF, and at this time federal funds may not be used for such research. In addition, if the enucleated oocyte that was to be combined with a human somatic cell nucleus came from an animal other than a human being, other issues would arise about the nature of the embryo produced. Thus, each source of material raises ethical questions as well as scientific, medical, and legal ones.

Conscientious individuals have come to different conclusions regarding both public policy and private actions in the area of stem cell research. Their differing perspectives by their very nature cannot easily be bridged by any single public policy. But the development of public policy in a morally contested area is not a novel challenge for a pluralistic democracy such as that which exists in the United States. We are profoundly aware of the diverse and strongly held views on the subject of this report and have wrestled with the implications of these different views at each of our meetings devoted to this topic. Our aim throughout these deliberations has been to formulate a set of recommendations that fully reflects widely shared views and that, in our view, would serve the best interests of society.

Most states place no legal restrictions on any of the means of creating ES and EG cells that are described in this report. In addition, current Food and Drug Administration regulations do not apply to this type of early stage research. Therefore, because the public controversy surrounding such activities in the United States has revolved around whether it is appropriate for the federal government to sponsor such research, this report focuses on the question of whether the scientific merit and the substantial clinical promise of this research justify federal support, and, if so, with what restrictions and safeguards.

## Conclusions and Recommendations

This report presents the conclusions that the Commission has reached and the recommendations that the Commission has made in the following areas: the ethical acceptability of federal funding for research that either derives or uses ES or EG cells; the means of ensuring appropriate consent of women or couples who donate cadaveric fetal tissue or embryos remaining after infertility treatments; the need for restrictions on the sale of these materials and the designation of those who may benefit from their use; the need for ethical oversight and review of such research at the national and institutional level; and the appropriateness of voluntary compliance by the private sector with some of these recommendations.

### The Ethical Acceptability of Federal Funding of ES and EG Cell Research by the Source of the Material

A principal ethical justification for public sponsorship of research with human ES or EG cells is that this research has the potential to produce health benefits for individuals who are suffering from serious and often fatal diseases. We recognize that it is possible that the various sources of human ES or EG cells eventually could be important to research and clinical application because of, for example, their differing proliferation potential, differing availability and accessibility, and differing ability to be manipulated, as well as possibly significant differences in their cell biology. **At this time, therefore, the Commission believes that federal funding for the use and derivation of ES and EG cells should be limited to two sources of such material: cadaveric fetal tissue and embryos remaining after infertility treatments.** Specific recommendations and their justifications are provided below.

*Recommendation 1: EG Cells from Fetal Tissue*

**Research involving the derivation and use of human EG cells from cadaveric fetal tissue should continue to be eligible for federal funding. Relevant statutes and regulations should be amended to make clear that the ethical safeguards that exist for fetal tissue transplantation also apply to the derivation and use of human EG cells for research purposes.**

Considerable agreement exists, both in the United States and throughout the world, that the use of fetal tissue in therapy for people with serious disorders, such

as Parkinson's disease, is acceptable. Research that uses tissue from aborted fetuses is analogous to the use of fetal tissue in transplantation. The rationales for conducting EG research are equally strong, and the arguments against it are not persuasive. The removal of fetal germ cells does not occasion the destruction of a live fetus, nor is fetal tissue intentionally or purposefully created for human stem cell research. Although abortion itself doubtless will remain a contentious issue in our society, the procedures that have been developed to prevent fetal tissue donation for therapeutic transplantation from influencing the abortion decision offer a model for creating such separation in research to derive human EG cells. Because the existing statutes are written in terms of tissue transplantation, which is not a current feature of EG cell research, changes are needed to make it explicit that the relevant safeguards will apply to research to derive EG cells from aborted fetuses. At present, no legal prohibitions exist that would inhibit the use of such tissue for EG cell research.

*Recommendation 2: ES Cells from Embryos Remaining After Infertility Treatments*

**Research involving the derivation and use of human ES cells from embryos remaining after infertility treatments should be eligible for federal funding. An exception should be made to the present statutory ban on federal funding of embryo research to permit federal agencies to fund research involving the derivation of human ES cells from this source under appropriate regulations that include public oversight and review. (See Recommendations 5 through 9.)**

The current ban on embryo research is in the form of a rider to the appropriations bill for the Department of Health and Human Services (DHHS), of which the National Institutes of Health (NIH) is a part. The rider prohibits use of the appropriated funds to support any research "in which a human embryo [is] destroyed, discarded, or knowingly subjected to risk of injury greater than that allowed for research on fetuses *in utero*" (Pub. L. No. 105-78, 513(a)). The term "human embryo" in the statute is defined as "any organism . . . that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells." The ban is revisited each year when the language of the NIH appropriations bill is considered.

The ban, which concerns only federally sponsored research, reflects a moral point of view either that embryos deserve the full protection of society because of their moral status as persons or that there is sufficient public controversy to preclude the use of federal funds for this type of research. At the same time, however, some effects of the embryo research ban raise serious moral and public policy concerns for those who hold differing views regarding the ethics of embryo research. In our view, the ban conflicts with several of the ethical goals of medicine and related health disciplines, especially healing, prevention, and research. These goals are rightly characterized by the principles of beneficence and nonmaleficence, which jointly encourage pursuing social benefits and avoiding or ameliorating potential harm.

Although some may view the derivation and use of ES cells as ethically distinct activities, we do not believe that these differences are significant from the point of view of eligibility for federal funding. That is, we believe that it is ethically acceptable for the federal government to finance research that both derives cell lines from embryos remaining after infertility treatments and that uses those cell lines. Although one might argue that some important research could proceed in the absence of federal funding for research that derives stem cells from embryos remaining after infertility treatments (i.e., federally funded scientists merely using cells derived with private funds), we believe that it is important that federal funding be made available for protocols that also derive such cells. Relying on cell lines that might be derived exclusively by a subset of privately funded researchers who are interested in this area could severely limit scientific and clinical progress.

Trying to separate research in which human ES cells are used from the process of deriving those cells presents an ethical problem, because doing so diminishes the scientific value of the activities receiving federal support. This separation—under which neither biomedical researchers at NIH nor scientists at universities and other research institutions that rely on federal support could participate in some aspects of this research—rests on the

mistaken notion that the two areas of research are so distinct that participating in one need not mean participating in the other. We believe that this is a misrepresentation of the new field of human stem cell research, and this misrepresentation could adversely affect scientific progress for several reasons.

First, researchers using human ES cell lines will derive substantial scientific benefits from a detailed understanding of the process of ES cell derivation, because the properties of ES cells and the methods for sustaining the cell lines may differ depending on the conditions and methods that were used to derive them. Thus, scientists who conduct basic research and are interested in fundamental cellular processes are likely to make elemental discoveries about the nature of ES cells as they derive them in the laboratory. Second, significant basic research needs to be conducted regarding the process of ES cell derivation before cell-based therapies can be realized, and this work must be pursued in a wide variety of settings, including those exclusively devoted to basic academic research. Third, ES cells are not indefinitely stable in culture. As these cells are grown, irreversible changes occur in their genetic makeup. Thus, especially in the first few years of human ES cell research, it is important to be able to repeatedly derive ES cells in order to ensure that the properties of the cells that are being studied have not changed.

Thus, anyone who believes that federal support of this important new field of research should maximize its scientific and clinical value within a system of appropriate ethical oversight should be dissatisfied with a position that allows federal agencies to fund research using human ES cells but not research through which the cells are derived from embryos. Instead, recognizing the close connection in practical and ethical terms between derivation and use of the cells, it would be preferable to enact provisions applicable to funding by all federal agencies, provisions that would carve out a narrow exception for funding of research to use or to derive human ES cells from embryos that are being discarded by infertility treatment programs.

*Recommendation 3: ES Cells from Embryos Made Solely for Research Purposes Using IVF*

**Federal agencies should not fund research involving the derivation or use of human ES cells from embryos made solely for research purposes using IVF.**

ES cells can be obtained from human research embryos created from donor gametes through IVF for the sole purpose of deriving such cells for research. The primary objection to creating embryos specifically for research is that there is a morally relevant difference between generating an embryo for the sole purpose of creating a child and producing an embryo with no such goal. Those who object to creating embryos for research often appeal to arguments about respecting human dignity by avoiding instrumental use of human embryos (i.e., using embryos merely as a means to some other goal does not treat them with appropriate respect or concern as a form of human life).

In 1994, the NIH Human Embryo Research Panel argued in support of federal funding of the creation of embryos for research purposes in exceptional cases, such as the need to create banks of cell lines with different genetic make-ups that encoded various transplantation antigens—the better to respond, for example, to the transplant needs of groups with different genetic profiles. This would require the recruitment of embryos from genetically diverse donors.

In determining how to deal with this issue, a number of points are worth considering. First, it is possible that the creation of research embryos will provide the only way in which to conduct certain kinds of research, such as research into the process of human fertilization. Second, as IVF techniques improve, it is possible that the supply of embryos for research from this source will dwindle. Nevertheless, we have concluded that, either from a scientific or a clinical perspective, there is no compelling reason at this time to provide federal funds for the creation of embryos for research. At the current time, cadaveric fetal tissue and embryos remaining after infertility treatment provide an adequate supply of research resources for federal research projects.

*Recommendation 4: ES Cells from Embryos Made Using Somatic Cell Nuclear Transfer into Oocytes*

**Federal agencies should not fund research involving the derivation or use of human ES cells from embryos made using somatic cell nuclear transfer into oocytes.**

Somatic cell nuclear transfer of the nucleus of an adult somatic cell into an enucleated human egg likely

has the potential of creating a human embryo. To date, although little is known about these embryos as potential sources of human ES cells, there is significant reason to believe that their use may have therapeutic potential. For example, the potential use of matched tissue for autologous cell replacement therapy from ES cells may require the use of somatic cell nuclear transfer. The use of this technique to create an embryo arguably is different from all the other cases we considered—due to the asexual origin of the source of the ES cells—although oocyte donation is necessarily involved. The Commission concludes that, at this time, federal funding should not be provided to derive ES cells from this source. Nevertheless, scientific progress and the medical utility of this line of research should be monitored closely.

### Requirements for the Donation of Cadaveric Fetal Tissue and Embryos for Research

Potential donors of embryos for ES cell research must be able to make voluntary and informed choices about whether and how to dispose of their embryos. Because of concerns about coercion and exploitation of potential donors, as well as societal controversy about the moral status of embryos, it is important, whenever possible, to separate donors' decisions to dispose of their embryos from their decisions to donate them for research. Potential donors should be asked to provide embryos for research only if they have decided to have those embryos discarded instead of donating them to another couple or storing them. If the decision to discard the embryos precedes the decision to donate them for research purposes, then the research determines only how their destruction occurs, not whether it occurs.

*Recommendation 5: Requirements for Donation to Stem Cell Research of Embryos That Would Otherwise Be Discarded After Infertility Treatment*

**Prospective donors of embryos remaining after infertility treatments should receive timely, relevant, and appropriate information to make informed and voluntary choices regarding disposition of the embryos. Prior to considering the potential research use of the embryos, a prospective donor should have been presented with the option of storing the embryos, donating them to another woman, or discarding them. If a prospective donor chooses to discard embryos remaining after infertility treatment, the option of donating to research may then be presented. (At any point, the prospective donors' questions—including inquiries about possible research use of any embryos remaining after infertility treatment—should be answered truthfully, with all information that is relevant to the questions presented.)**

**During the presentation about potential research use of embryos that would otherwise be discarded, the person seeking the donation should**

a) **disclose that the ES cell research is not intended to provide medical benefit to embryo donors,**
b) **make clear that consenting or refusing to donate embryos to research will not affect the quality of any future care provided to prospective donors,**
c) **describe the general area of the research to be carried out with the embryos and the specific research protocol, if known,**
d) **disclose the source of funding and expected commercial benefits of the research with the embryos, if known,**
e) **make clear that embryos used in research will not be transferred to any woman's uterus, and**
f) **make clear that the research will involve the destruction of the embryos.**

To assure that inappropriate incentives do not enter into a woman's decision to have an abortion, we recommend that directed donation of cadaveric fetal tissue for EG cell derivation be prohibited. Although the ethical considerations supporting a prohibition of the directed donation of human fetal tissue are less acute for EG cell research than for transplantation, certain concerns remain. Potential donors of cadaveric fetal tissue for EG cell derivation would not receive a direct therapeutic incentive to create or abort tissue for research purposes in the same way that such personal interest might arise in a transplant context. However, we agree that the prohibition remains a prudent and appropriate way of assuring that inappropriate incentives, regardless of how remote they may be, are not introduced into a woman's decision to have an abortion. Any suggestion of personal benefit to the donor or to an individual known to the donor would be untenable and possibly coercive.

*Recommendation 6: No Promises to Embryo Donors That Stem Cells Will Be Provided to Particular Patient-Subjects*

**In federally funded research involving embryos remaining after infertility treatments, researchers may not promise donors that ES cells derived from their embryos will be used to treat patient-subjects specified by the donors.**

Existing rules prohibit the practice of designated donation, the provision of monetary inducements to women undergoing abortion, and the purchase or sale of fetal tissue. We concur in these restrictions and in the earlier recommendation of the 1988 Human Fetal Tissue Transplantation Research Panel that the sale of fetal tissue for research purposes should not be permitted under any circumstances. The potential for coercive pressure is greatest when financial incentives are present, and the treatment of the developing human embryo or fetus as an entity deserving of respect may be greatly undermined by the introduction of any commercial motive into the donation or solicitation of fetal or embryonic tissue for research purposes.

*Recommendation 7: Commerce in Embryos and Cadaveric Fetal Tissue*

**Embryos and cadaveric fetal tissue should not be bought or sold.**

If and when sufficient scientific evidence and societal agreement exist that the creation of embryos specifically for research or therapeutic purposes is justified (specifically through somatic cell nuclear transfer), prohibitions on directed donation should be revisited. For obvious reasons, the use of somatic cell nuclear transfer to develop ES cells for autologous transplantation might require that the recipient be specified.

### The Need for National Oversight and Review

The need for national as well as local oversight and review of human stem cell research is crucial. No such system currently exists in the United States. A national mechanism to review protocols for *deriving* human ES and EG cells and to monitor research using such cells would ensure strict adherence to guidelines and standards across the country. Thus, federal oversight can provide the public with the assurance that research involving stem cells is being undertaken appropriately. Given the ethical issues involved in human stem cell research—an area in which heightened sensitivity about the very research itself led the President to request that the Commission study the issue—the public and the Congress must be assured that oversight can be accomplished efficiently, constructively, and in a timely fashion, with sufficient attention to the relevant ethical considerations.

*Recommendation 8: Creation and Duties of an Oversight and Review Panel*

**DHHS should establish a National Stem Cell Oversight and Review Panel to ensure that all federally funded research involving the derivation and/or use of human ES or EG cells is conducted in conformance with the ethical principles and recommendations contained in this report. The panel should have a broad, multidisciplinary membership, including members of the general public, and should**

a) **review protocols for the derivation of ES and EG cells and approve those that meet the requirements described in this report,**
b) **certify ES and EG cells lines that result from approved protocols,**
c) **maintain a public registry of approved protocols and certified ES and EG cell lines,**
d) **establish a database—linked to the public registry—consisting of information submitted by federal research sponsors (and, on a voluntary basis, by private sponsors, whose proprietary information shall be appropriately protected) that includes all protocols that derive or use ES or EG cells (including any available data on research outcomes, including published papers),**
e) **use the database and other appropriate sources to track the history and ultimate use of certified cell lines as an aid to policy assessment and formulation,**
f) **establish requirements for and provide guidance to sponsoring agencies on the social and ethical issues that should be considered in the review of research protocols that derive or use ES or EG cells, and**

g) **report at least annually to the DHHS Secretary with an assessment of the current state of the science for both the derivation and use of human ES and EG cells, a review of recent developments in the broad category of stem cell research, a summary of any emerging ethical or social concerns associated with this research, and an analysis of the adequacy and continued appropriateness of the recommendations contained in this report.**

### The Need for Local Review of Derivation Protocols

For more than two decades, prospective review by an Institutional Review Board (IRB) has been the principal method for assuring that federally sponsored research involving human subjects will be conducted in compliance with guidelines, policies, and regulations designed to protect human beings from harm. This system of local review has been subject to criticism, and, indeed, in previous analyses we have identified a number of concerns regarding this system. In the course of preparing this report, we considered a number of proposals that would allow for the local review of research protocols involving human stem cell research, bearing in mind that a decision by the Commission to recommend a role for IRBs might be incorrectly interpreted as endorsing the view that human ES or EG cells or human embryos are human subjects and therefore would be under the purview of the Common Rule.

We adopted the principle, reflected in these recommendations, that for research to derive human ES and EG cells, a system of national oversight and review supplemented by local review would be necessary to ensure that important research could proceed—but only under specific conditions. We recognized that for research proposals involving the derivation of human ES or EG cells, many of the ethical issues associated with these protocols could be considered at the local level, that is, at the institutions at which the research would be taking place. For protocols using but not deriving ES cells (i.e., generating the cells elsewhere), a separate set of ethical deliberations would have occurred. In general, the IRB is an appropriate body to review protocols that aim to derive ES or EG cells. Although few review bodies (including IRBs) have extensive experience in reviewing protocols of this kind, they remain the most visible and expert entities available. It is for this reason, for example, that we make a number of recommendations (8, 9, 10, 11, and 12) that discuss the importance of developing additional guidance for the review of such protocols.

For proposals involving the derivation of human ES or EG cells, particular sensitivities require attention through a national review process. This process should, however, begin at the local level, because institutions that intend to conduct research involving the derivation of human ES cells or EG cells should continue to take responsibility for assuring the ethical conduct of that research. More importantly, however, IRBs can play an important role, particularly by reviewing consent documents and by assuring that collaborative research undertaken by investigators at foreign institutions has satisfied any regulatory requirements for sharing research materials.

*Recommendation 9: Institutional Review of Protocols to Derive Stem Cells*

**Protocols involving the *derivation* of human ES and EG cells should be reviewed and approved by an IRB or by another appropriately constituted and convened institutional review body prior to consideration by the National Stem Cell Oversight and Review Panel. (See Recommendation 8.) This review should ensure compliance with any requirements established by the panel, including confirming that individuals or organizations (in the United States or abroad) that supply embryos or cadaveric fetal tissue have obtained them in accordance with the requirements established by the panel.**

### Responsibilities of Federal Research Agencies

Federal research agencies have in place a comprehensive system for the submission, review, and approval of research proposals. This system includes the use of a peer review group—sometimes called a study section or initial review group—that is established to assess the scientific merit of the proposals. In addition, in some agencies, such as NIH, staff members review protocols prior to their transmittal to a national advisory council for final approval. These levels of review provide an opportunity to consider ethical issues that arise in the proposals.

When research proposals involve human subjects, federal agencies rely on local IRBs to review and approve the research in order to assure that it is ethically acceptable. (See Recommendation 9.) A grant application should not be funded until ethical issues that are associated with research involving human subjects have been resolved fully. Therefore, at every point in this continuum—from the first discussions that a prospective applicant may have with program staff within a particular institution to the final decision by the relevant national advisory council—ethical and scientific issues can be addressed by the sponsoring agency.

*Recommendation 10: Sponsoring Agency Review of Research Use of Stem Cells*

**All federal agencies should ensure that their review processes for protocols using human ES or EG cells comply with any requirements established by the National Stem Cell Oversight and Review Panel (see Recommendation 8), paying particular attention to the adequacy of the justification for using such cell lines.**

Research involving human ES and EG cells raises critical ethical issues, particularly when the proposals involve the derivation of ES cells from embryos remaining after infertility treatments. We recognize that these research proposals may not follow the paradigm usually associated with human subjects research. Nevertheless, research proposals being considered for funding by federal agencies must, in our view, meet the highest standards of scientific merit and ethical acceptability. To that end, the recommendations made in this report, including a proposed set of *Points to Consider in Evaluating Basic Research Involving Human ES Cells and EG Cells*, constitute a set of ethical and policy considerations that should be reflected in the respective policies of federal agencies conducting or sponsoring human ES or EG cell research.

### Attention to Issues for the Private Sector

Although this report primarily addresses the ethical issues associated with the use of federal funds for research to derive and use ES and EG cells, we recognize that considerable work in both of these areas will be conducted under private sponsorship. Thus, our recommendations may have implications for those working in the private sector. First, for cell lines to be eligible for use in federally funded research, they must be certified by the National Stem Cell Oversight and Review Panel described in Recommendation 8. Therefore, if a private company aims to make its cell lines available to publicly funded researchers, it must submit its derivation protocol(s) to the same oversight and review process recommended for the public sector, i.e., local review (see Recommendation 9) and for certification that the cells have been derived from embryos remaining after infertility treatments or from cadaveric fetal tissue.

Second, we hope that nonproprietary aspects of protocols developed under private sponsorship will be made available in the public registry, as described in Recommendation 8. The greater the participation of the private sector in providing information on stem cell research, the more comprehensive the development of the science and related public policies in this area.

Third, and perhaps most relevant, in an ethically sensitive area of emerging biomedical research it is important that all members of the research community, whether in the public or private sectors, conduct the research in a manner that is open to appropriate public scrutiny. The last two decades have witnessed an unprecedented level of cooperation between the public and private sectors in biomedical research, which has resulted in the international leadership position of the United States in this arena. Public bodies and other authorities, such as the Recombinant DNA Advisory Committee, have played a crucial role in enabling important medical advances in fields such as gene therapy by providing oversight of both publicly and privately funded research efforts. We believe that voluntary participation by the private sector in the review and certification procedures of the proposed national panel, as well as in its deliberations, can contribute equally to the socially responsible development of ES and EG cell technologies and accelerate their translation into biomedically important therapies that will benefit patients.

*Recommendation 11: Voluntary Actions by Private Sponsors of Research That Would Be Eligible for Federal Funding*

**For privately funded research projects that involve ES or EG cells that would be eligible for federal funding, private sponsors and researchers are**

**encouraged to adopt voluntarily the applicable recommendations of this report. This includes submitting protocols for the derivation of ES or EG cells to the National Stem Cell Oversight and Review Panel for review and cell line certification. (See Recommendations 8 and 9.)**

In this report, we recommend that federally funded research to derive ES cells be limited to those efforts that use embryos remaining after infertility treatment. Some of the recommendations made in this context—such as the requirement for separating the decision by a woman to cease such treatment when embryos still remain and her decision to donate those embryos to research—simply do not apply to efforts to derive ES cells from embryos created (whether by IVF or somatic cell nuclear transfer) solely for research purposes, activities that might be pursued in the private sector. Nevertheless, other ethical standards and safeguards embodied in the recommendations, such as provisions to prevent the coercion of women and the commodification of human reproduction, remain vitally important, even when embryos are created solely for research purposes.

*Recommendation 12: Voluntary Actions by Private Sponsors of Research That Would Not Be Eligible for Federal Funding*

**For privately funded research projects that involve deriving ES cells from embryos created solely for research purposes and that are therefore not eligible for federal funding (see Recommendations 3 and 4)**

**a) professional societies and trade associations should develop and promulgate ethical safeguards and standards consistent with the principles underlying this report, and**

**b) private sponsors and researchers involved in such research should voluntarily comply with these safeguards and standards.**

Professional societies and trade associations dedicated to reproductive medicine and technology play a central role in establishing policy and standards for clinical care, research, and education. We believe that these organizations can and should play a salutary role in ensuring that all stem cell and embryo research conducted in the United States, including that which is privately funded, conforms to the ethical principles underlying this report. Many of these organizations already have developed policy statements, ethics guidelines, or other directives addressing issues in this report, and the Commission has benefited from a careful review of these materials. These organizations are encouraged to review their professional standards to ensure not only that they keep pace with the evolving science of human ES and EG cell research, but also that their members are knowledgeable about and in compliance with them. For those organizations that conduct research in this area but that lack statements or guidelines addressing the topics of this report, we recommend strongly that they develop such statements or guidelines. No single institution or organization, whether in the public or the private sector, can provide all the necessary protections and safeguards.

### The Need for Ongoing Review and Assessment

No system of federal oversight and review of such a sensitive and important area of investigation should be established without simultaneously providing an evaluation of its effectiveness, value, and ongoing need. The pace of scientific development in human ES and EG cell research likely will increase. Although one cannot predict the direction of the science of human stem cell research, in order for the American public to realize the promise of this research and to be assured that it is being conducted responsibly, close attention to and monitoring of all the mechanisms established for oversight and review are required.

*Recommendation 13: Sunset Provision for National Panel*

**The National Stem Cell Oversight and Review Panel described in Recommendation 8 should be chartered for a fixed period of time, not to exceed five years. Prior to the expiration of this period, DHHS should commission an independent evaluation of the panel's activities to determine whether it has adequately fulfilled its functions and whether it should be continued.**

There are several reasons for allowing the national panel to function for a fixed period of time and for evaluating its activities before continuing. First, some of the hoped-for results will be available from research projects

that are using the two sources we consider to be ethically acceptable for federal funding. Five years is a reasonable period of time to allow some of this information to amass, offering the panel, researchers, members of Congress, and the public sufficient time to determine whether any of the knowledge or potential health benefits are being realized. The growing body of information in the public registry and database described above (particularly if privately funded researchers and sponsors voluntarily participate) will aid these considerations.

Second, within this period the panel may be able to determine whether additional sources of ES cells are necessary in order for important research to continue. Two arguments are evident for supporting research using embryos created specifically for research purposes: one is the concern that not enough embryos remain for this purpose from infertility treatments, and the other is the recognition that some research requires embryos that are generated particularly for research and/or medical purposes. The panel should assess whether additional sources of ES cells that we have judged to be ineligible for federal funding at this time (i.e., embryos created solely for research purposes) are needed.

Third, an opportunity to assess the relationship between local review of protocols using human ES and EG cells and the panel's review of protocols for the derivation of ES cells will be offered. It will, of course, take time for this national oversight and review mechanism to develop experience with the processes of review, certification, and approval described in this report. Fourth, we hope that the panel will contribute to the national dialogue on the ethical issues regarding research involving human embryos. A recurring theme of our deliberations, and in the testimony we heard, was the importance of encouraging this ongoing national conversation.

The criteria for determining whether the panel has adequately fulfilled its functions should be set forth by an independent body established by DHHS. However, it would be reasonable to expect that the evaluation would rely generally on the seven functions described above in Recommendation 8 and that this evaluation would be conducted by a group with expertise in these areas. In addition, some of the following questions might be considered when conducting this evaluation: Is there reason to believe that the private sector is voluntarily submitting descriptions of protocols involving the derivation of human ES cells to the panel for review? Is the panel reviewing projects in a timely manner? Do researchers find that the review process is substantively helpful? Is the public being provided with the assurance that social and ethical issues are being considered?

## Summary

Recent developments in human stem cell research have raised hopes that new therapies will become available that will serve to relieve human suffering. These developments also have served to remind society of the deep moral concerns that are related to research involving human embryos and cadaveric fetal tissue. Serious ethical discussion will (and should) continue on these issues. However, in light of public testimony, expert advice, and published writings, we have found substantial agreement among individuals with diverse perspectives that although the human embryo and fetus deserve respect as forms of human life, the scientific and clinical benefits of stem cell research should not be foregone. We were persuaded that carrying out human stem cell research under federal sponsorship is important, but only if it is conducted in an ethically responsible manner. And after extensive deliberation, the Commission believes that acceptable public policy can be forged, in part, on widely shared views. Through this report, we not only offer recommendations regarding federal funding and oversight of stem cell research, but also hope to further stimulate the important public debate about the profound ethical issues regarding this potentially beneficial research.

# Legislators See Opening on Stem Cell Studies

## *In a Divided Congress, Lawmakers Are Writing Bills, Scheduling Hearings and Lobbying President*

*By* CECI CONNOLLY
*Washington Post Staff Writer*

As President Bush struggles over whether to spend federal money on embryonic stem cell research, lawmakers on each side are attempting this week to seize upon what could be a pivotal moment in the impassioned debate.

Sensing an opening during Bush's period of indecision, several members of Congress have written bills, scheduled hearings, demanded White House meetings and taken to the airwaves to reassert themselves in the battle over cells smaller than the head of a pin.

"People see him [Bush] agonizing over the decision and see this as an opportunity to push him in one direction," one congressional Republican said of the increasingly aggressive maneuvers.

Pressure began mounting yesterday with an emotional news conference by Rep. Christopher H. Smith (R-N.J.), a leading antiabortion activist, and the families of children born from "adopted" frozen embryos.

"I presume the president will act in good faith and in accordance with his campaign promise not to promote federally funded research on human embryos," said Ken Connor, president of the conservative Family Research Council. "If he violates that campaign pledge, that would represent a serious issue about his integrity."

Regardless of how or when Bush decides, many on Capitol Hill say the battle will continue.

"I think this is an issue that should be worked out in the Congress, and the president should defer," said Sen. Rick Santorum (R-Pa.), who opposes research on embryonic stem cells.

Sen. Arlen Specter (R-Pa.) takes the opposite view on the question of stem cells, but agreed that Congress is poised to act—and potentially deliver Bush a defeat.

"If he [Bush] limits federal funding, the Senate will take it up," Specter said. "I believe there are more than 70 votes in the Senate to authorize federal funding for the research and possibly to extract the cells for experimentation.

Others were not as confident, but noted that Senate Majority Leader Thomas A. Daschle (D-S.D.) has promised to bring the issue to the floor if Bush rejects a request allowing the National Institutes of Health to use part of its $24.6 billion budget on stem cell experiments.

The political landscape is less clear in the House, where three leaders have vociferously opposed funding in the face of at least 50 rank-and-file Republicans who support it.

Bush's mailbox has been overflowing in recent weeks with a back-and-forth stream of letters from Capitol Hill. When a group of three dozen House Republicans wrote urging him to proceed, Majority Leader Richard K. Armey and Whip Tom DeLay, both of Texas, responded with a statement condemning those who "rely on an industry of death."

That sparked a second, sharper rebuke from members of the usually tame Main Street Partnership, who have been promised a meeting with senior administration officials this week.

"It is very important stem cell research be able to go forward in the future," said Rep. Michael N. Castle (R-Del.), who opposes any compromises on funding. "I would be concerned about any limitation placed on this research."

And Vice President Cheney called Armey and DeLay, urging them to tone down the rhetoric, said aides to both.

Supporters of the research argue that the cells, which may have the ability to grow into any type of tissue, could lead to treatments for many diseases. Opponents object to the work because to obtain the cells, researchers destroy embryos, mostly surplus embryos from fertility clinics.

For weeks, the administration has promised a decision was imminent. But according to several people who have spoken to Bush recently, the complicated science and ethical dimensions have thrust him into a period of great uncertainty.

Complicating Bush's decision is that the debate over stem cell research has transcended traditional partisan or abortion boundaries. Prominent antiabortion Republicans such as Sens. Orrin Hatch (Utah), Gordon Smith (Ore.) and Strom Thurmond (S.C.) support the work, saying the cells hold such promise it would be anti-life not to pursue it. A contingent of moderate Republicans, many of whom support abortion rights, is also lobbying for money to continue the research.

To cut off funding "is so profoundly hostile to the concept of intellectual freedom on which our humanity, as well as our prosperity and democracy rests, it would be a significant mistake to ban the use of embryonic tissue in stem cell research," said Rep. Nancy L. Johnson (R-Conn.).

Yesterday, the publicity machines cranked up as a prelude to hearings being convened today and Wednesday in Congress.

"We know he's met with other stakeholders in this debate, but I think you'll agree with me that no one has a bigger stake in the outcome of this debate than these children," said Connor of the Family Research Council.

Some lawmakers, such as Rep. Jim Ramstad (R-Minn.), have made intensely personal appeals to Bush.

"With my mother totally debilitated by Alzheimer's disease, a first cousin who died from diabetes and several close friends suffering from Parkinson's disease and spinal cord injuries, I plead with you to give hope to my loved ones who are suffering," he wrote in a July 6 letter.

Many politicians involved in the fight said a protracted discussion is not necessarily bad. Among them is Rep. David Joseph Weldon (R-Fla.), a physician, who opposes embryonic stem cell research but supports work on adult stem cells.

Lawmakers, he said, are engaged in a "legitimate debate" on the issue. And at the White House, "the longer they drag their feet, the more I become impressed they are truly internally conflicted on this."

*Staff writer Amy Goldstein contributed to this report.*

## Key Researcher to Move to England

A prominent American stem cell scientist announced yesterday that he was moving to England, where human embryo research is legal and publicly funded, spurring fears among some research proponents that the nation could suffer from a "brain drain" if President Bush refuses to fund the field.

Roger Pedersen, a professor at the University of California at San Francisco (UCSF), said he would join the faculty at the University of Cambridge this summer, where he will continue his research.

"I was faced with an irresistible career opportunity and the possibility of carrying out my . . . human embryonic stem cell research with public support," Pedersen said in a statement released by UCSF.

Pedersen's research has been supported by Geron Corp., a Menlo Park, Calif., biotechnology company. Two other Geron-supported researchers, James Thomson of the University of Wisconsin and John Gerhart of Johns Hopkins University, were the first to isolate human embryonic stem cells, in November 1998.

Pedersen has reported at recent scientific meetings that he believes he has established two new stem cell lines, or colonies, according to other scientists, but he has not yet published his results.

Pedersen will maintain some ties with UCSF, but the dean of the university's school of medicine warned yesterday that the nation could lose other top scientists if Bush opts not to fund the field.

"If federal support for stem cell research is not forthcoming, the risk exists that talented scientists will leave academic centers to seek opportunities in the private sector or even overseas," said Haile Debas, who is also the university's chancellor for medical affairs. "This would be a tragedy of the greatest proportion."

— Rick Weiss

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# Congress of the United States

Washington, DC 20515

July 30, 2001

President George W. Bush
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear Mr. President:

We are respectfully writing to ask you to support the current policy of allowing federal funding for embryonic stem cell research. We believe that funding of embryonic stem cell research will help scientists find new treatments for chronic diseases such as Parkinson's, diabetes, Alzheimer's, and will ultimately save lives. We also send this letter to show you that there is strong bipartisan support for this position.

We know that the question of whether or not to encourage medical scientists to pursue embryonic stem cell research presents you with a philosophical dilemma, and we greatly respect your need to take a studied, deliberate approach to making a decision on this weighty issue.

Mr. President, we urge you to support the NIH policy guidelines on human pluripotent stem cell research. This life-saving technology may make a world of difference for those suffering from Parkinson's, diabetes, Alzheimer's, spinal cord injuries and countless other medical conditions.

Diseases like ALS, Alzheimer's, Parkinson's, and juvenile diabetes afflict human beings with no concern for party lines, age, gender, income level, perspective on abortion, or geography. Individuals suffering from these various diseases, and their families, want nothing more than cures. These diverse voices are the voices of our constituencies. Mr. President, this letter is signed by Members of Congress from different parties and regions of the country and for several of us, this request is a deeply personal one as well. As signers of this letter, we urge you to support continued research that holds the potential to save and improve the lives of our wives, fathers, mothers, husbands, and children.

Mr. President, we thank you again for your attention to this matter. With the greatest degree of respect for the challenges you face in your decision making process, we once again urge you to support the existing policy of providing federal funds for embryonic stem cell research.

With best regards,

Carolyn B. Maloney
**CAROLYN B. MALONEY**
**Member of Congress**

Connie Morella
**CONSTANCE MORELLA**
**Member of Congress**

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Member of Congress

107TH CONGRESS
1ST SESSION

# H. CON. RES. 17

Expressing the sense of the Congress supporting Federal funding of pluripotent stem cell research.

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IN THE HOUSE OF REPRESENTATIVES

JANUARY 30, 2001

Mrs. MALONEY of New York (for herself and Mrs. MORELLA) submitted the following concurrent resolution; which was referred to the Committee on Energy and Commerce

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# CONCURRENT RESOLUTION

Expressing the sense of the Congress supporting Federal funding of pluripotent stem cell research.

Whereas Federal funds are crucial for researchers to proceed with stem cell research and technologies;

Whereas pluripotent stem cell research does not undermine the current ban on Federal funding of human embryo research because pluripotent stem cells are not embryos and cannot become embryos;

Whereas pluripotent stem cells are presursors of specialized cells which are destroyed or damaged in many incurable diseases and disabilities;

Whereas the ability to use pluripotent stem cells to generate specialized cells, such as the dopamine-producing cells that are degenerated in Parkinson's disease or the insu-

lin-producing cells that are impaired in diabetes, allows doctors to learn to generate the specialized cells that are destroyed or damaged in other diseases and disabilities;

Whereas pluripotent stem cell research could lead to vastly improved treatments or cures for Alzheimer's disease, anemia, AIDS, arthritis, blindness, brain injury, birth defects, cancer, deafness, diabetes, heart disease, kidney disease, liver disease, lung disease, Lou Gehrig's disease, multiple sclerosis, muscular dystrophy, Parkinson's disease, severe burns, sickle cell anemia, spinal cord injury, and stroke, and could also lead to improved success of organ transplantation; and

Whereas Federal funding through the National Institutes of Health ensures that sensitive research will be conducted in accordance with the highest scientific and ethical standards: Now, therefore, be it

1 *Resolved by the House of Representatives (the Senate*
2 *concurring),* That the Congress supports Federal funding
3 of pluripotent stem cell research.

○

EXPAND STORY

# Adult stem cells key in tissue repair

The Cincinnati Post, 03/07/02

Adult stem cells circulating in the blood are able to differentiate into a number of organ-specific cells, researchers have found, and they believe these floating repair kits play an active role in replacing normal tissue or repairing injured tissue of various organs.

"For years, the school of thought was that when tissue was injured, the repair came from the tissue itself. But we can prove the existence of a systemic supply of stem cells distributed via the blood that are capable of tissue repair," said Dr. Martin Korbling, a bone-marrow-transplant specialist at the M.D. Anderson Cancer Center in Houston.

He is the lead author of a study published today in The New England Journal of Medicine.

"The significance is that this leads us into new knowledge of what happens in the body without intervention," added Dr. Zeev Estrov, a professor of bioimmunotherapy at Anderson and another senior co- author of the study.

The finding is also certain to be heralded by foes of research on embryonic stem cells.

These critics contend that the potential of adult stem cells should be fully explored before work on cells derived from embryos is pursued.

Embryonic stem cells have the capacity to develop into any type of human tissue.

Those who support both this research and the use of cloning to create embryos for such purposes say that until more is known about both types of cells, research should continue in tandem.

"We don't know yet whether these adult blood stem cells have properties that are similar to embryonic stem cells," Korbling said. "There is no comparative study."

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