AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 108–160

PROMOTING ETHICAL REGENERATIVE MEDICINE RESEARCH AND PROHIBITING IMMORAL HUMAN REPRODUCTIVE CLONING

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

MARCH 19, 2003

Serial No. J–108–7

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

89–327 DTP WASHINGTON : 2003

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON THE JUDICIARY

ORRIN G. HATCH, Utah, *Chairman*

CHARLES E. GRASSLEY, Iowa
ARLEN SPECTER, Pennsylvania
JON KYL, Arizona
MIKE DEWINE, Ohio
JEFF SESSIONS, Alabama
LINDSEY O. GRAHAM, South Carolina
LARRY E. CRAIG, Idaho
SAXBY CHAMBLISS, Georgia
JOHN CORNYN, Texas

PATRICK J. LEAHY, Vermont
EDWARD M. KENNEDY, Massachusetts
JOSEPH R. BIDEN, JR., Delaware
HERBERT KOHL, Wisconsin
DIANNE FEINSTEIN, California
RUSSELL D. FEINGOLD, Wisconsin
CHARLES E. SCHUMER, New York
RICHARD J. DURBIN, Illinois
JOHN EDWARDS, North Carolina

MAKAN DELRAHIM, *Chief Counsel and Staff Director*
BRUCE A. COHEN, *Democratic Chief Counsel and Staff Director*

CONTENTS

STATEMENTS OF COMMITTEE MEMBERS

	Page
Craig, Hon. Larry E., a U.S. Senator from the State of Idaho	6
prepared statement	72
Feinstein, Hon. Dianne, a U.S. Senator from the State of California	4
prepared statement	76
Hatch, Hon. Orrin G., a U.S. Senator from the State of Utah	1
prepared statement	80
Kennedy, Hon. Edward M., a U.S. Senator from the State of Massachusetts, prepared statement	101
Kyl, Hon. Jon, a U.S. Senator from the State of Arizona, prepared statement	102
Leahy, Hon. Patrick J., a U.S. Senator from the State of Vermont, prepared statement	107

WITNESSES

Berg, Paul, Cahill Professor Emeritus of Cancer Research and Biochemistry, Stanford University Medical Center and Chair, Public Policy Committee, American Society for Cell Biology, Palo Alto, California	37
Brownback, Hon. Sam, a U.S. Senator from the State of Kansas	8
Kass, Leon, M.D., Hertog Fellow in Social Thought, American Enterprise Institute, Washington, D.C.	23
Kelly, James, Patient Advocate, Granbury, Texas	15
Langevin, Hon. Jim R., a Representative in Congress from the State of Rhode Island	11
Mathews-Roth, Micheline M., M.D., Associate Professor of Medicine, Harvard Medical School, Boston, Massachusetts	33
Murray, Thomas, President, Hastings Center, Garrison, New York	25
Usala, Anton Lewis, M.D., Clinical Professor and Medical/Administrative Director, Office for Regulatory Review of Clinical Trials, East Carolina University, Greenville, North Carolina	31
Varmus, Harold, M.D., President Memorial Sloan-Kettering Cancer Center, New York, New York	28
Wasson, Greg, Cotati, California	17

SUBMISSIONS FOR THE RECORD

Alliance for Aging Research, Daniel Perry, Executive Director, Washington, D.C., letter	54
Alpha-1 Foundation, John W. Walsh, President and CEO, Miami, Florida and Alpha-1 Association, John P. Morton, Chair, Board of Directors, Washington, D.C., joint letter and attachments	55
American Association for Cancer Research, Margaret Foti, Chief Executive Officer, Philadelphia, Pennsylvania, letter	58
American Society of Hematology, Ronald Hoffman, M.D., President, Washington, D.C., letter	59
Association of American Medical Colleges, Jordan J. Cohen, M.D., President, Washington, D.C., letter	60
Association of Reproductive Health Professionals, Felicia H. Stewart, M.D., Chair, Board of Directors and Wayne C. Shields, President and CEO, Washington, D.C., letter	61

Page

Berg, Paul, Cahill Professor Emeritus of Cancer Research and Biochemistry, Stanford University Medical Center and Chair, Public Policy Committee, American Society for Cell Biology, Palo Alto, California, prepared statement 62
Bledsoe, Rev. Michael, Pastor, Riverside Baptist Church, Washington, D.C., statement 69
Californians for Cure, Don C. Reed, Chair, Fremont, California, letter 70
Children's Neurobiological Solutions Foundation, Fia Richmond, President, Santa Barbara, California, letter 71
Christopher Reeve Paralysis Foundation, Michael Manganiello, Senior Vice President, Springfield, New Jersey, letter 74
Coalition for the Advancement of Medical Research, Michael Manganiello, President, Washington, D.C., letter 75
Hadassah, Bonnie Lipton, National President, New York, New York, letter 79
International Myeloma Foundation, Susie Novis, President, North Hollywood, California, letter 84
Kass, Leon, M.D., Hertog Fellow in Social Thought, American Enterprise Institute, Washington, D.C., prepared statement 85
Kelly, James, Patient Advocate, Granbury, Texas, prepared statement 93
Mathews-Roth, Micheline M., M.D., Associate Professor of Medicine, Harvard Medical School, Boston, Massachusetts, prepared statement 108
Members of the religious community, February 5, 2003, joint letter 111
Murray, Thomas, Hastings Center, Garrison, New York, prepared statement . 112
National Venture Capital Association, Mark G. Heesen, President, Arlington, Virginia, letter 116
Rett Syndrome Research Foundation, Monica Coenraads, VP of Research, Cincinnati, Ohio, letter 117
Society for Women's Health Research, Roberta Biegel, Director of Government Relations, Washington, D.C., letter 118
Steven and Michele Kirsch Foundation, Susan E. Frank, Director, Public Policy, San Jose, California, letter 119
Union of Orthodox Jewish Congregations of America and Rabbinical Council of America, joint statement 120
United Church of Christ, Justice and Witness Ministries, Pat Conover, Legislative Director, Washington, D.C., letter 122
University of California, Richard C. Atkinson, President, Oakland, California, letter 125
Usala, Anton-Lewis, M.D., Clinical Professor and Medical/Administrative Director, Office for Regulatory Review of Clinical Trials, East Carolina University, Greenville, North Carolina, prepared statement 127
Varmus, Harold, M.D., President, Memorial Sloan-Kettering Cancer Center, New York, New York, prepared statement 131
Wasson, Greg, Cotati, California, prepared statement 139
Wiley, John D., Chancellor, University of Wisconsin-Madison, Madison, Wisconsin, letter 146

PROMOTING ETHICAL REGENERATIVE MEDICINE RESEARCH AND PROHIBITING IMMORAL HUMAN REPRODUCTIVE CLONING

WEDNESDAY, MARCH 19, 2003

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Committee met, Pursuant to notice, at 10:34 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Orrin G. Hatch, Chairman of the Committee, presiding.

Present: Senators Hatch, Craig, Cornyn, Feinstein, and Durbin.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Chairman HATCH. Good morning. Today, the Judiciary Committee will explore whether and how it might be possible to draw a line between promoting ethical stem cell research and prohibiting immoral human reproductive cloning.

I am a cosponsor, along with Senators Feinstein, Specter, Kennedy, Harkin, Durbin and others, of bipartisan legislation, S. 303, the Human Cloning Ban and Stem Cell Research Protection Act of 2003.

Our bill has two goals: first, to stop any attempts to facilitate the birth of a cloned baby. Virtually everyone in Congress and among the American public agrees that reproductive cloning should be criminalized so this practice can be stopped before it even begins. At a minimum, the 108th Congress should pass legislation that bans reproductive cloning. That is the very least we should do.

Second, our legislation allows a promising form of stem cell research to go forward under strict ethical and moral guidelines. This research utilizes a cloning technique, and keep in mind that in biomedical science the term "cloning" merely means to make an exact copy of cells, proteins, molecules, viruses, DNA sequences, and other such entities.

In the cloning technique of somatic cell nuclear transfer, also called nuclear transplantation, an egg's normal component of 23 chromosomes is removed and replaced with a full set of 46 chromosomes from a somatic or body cell, such as the skin. This process does not involve a fertilized egg or any sperm cells.

There are two potential pathways for such engineered non-fertilized embryonic cells. If introduced into a womb, it is possible that a cloned human being could be born. Let me repeat my opposi-

tion to reproductive cloning and stress that our bill would impose severe criminal penalties on anyone participating in that activity.

It is the other pathway, using nuclear transplantation as a source to derive stem cells, that has generated so much excitement in the scientific community and has spawned so much discussion of the ethical dimensions of this type of research.

I am proud to hold a right-to-life philosophy. I believe that human life begins in the womb, not in a petri dish. While I recognize that not everyone agrees with me, I am heartened that so many of the people that I meet in Utah and throughout the country, including many fellow right-to-lifers, have supported me in my views. I believe that as the public studies and reflects upon these issues, support for the legislation we have drafted will grow.

Deciding where one stands on this matter is not easy. Among the difficult questions that must be carefully considered are: what does it mean to be human, when does life begin, and in our quest to improve the quality of human life, how can we best establish ethical safeguards to protect against doing harm to mankind?

These are not easy questions. Although some are calling for a moratorium on somatic cell nuclear transfer, I fail to see how a moratorium will help our society fully consider, debate, and attempt to resolve the ethical issues.

The cost of delay is real. Some 100 million Americans might 1 day benefit from embryonic stem cell research. We must not forget them. There is no way to impose a moratorium on their pain and their suffering. We must also understand that this avenue of inquiry is still in the very early stages, and we must conduct basic research before any new tests or treatments can be developed.

Some argue, including some of those you will hear today, that adult stem cell research is actually superior to embryonic stem cell research. I support a vigorous program of adult stem cell research. I just hope that my colleagues will listen carefully to our scientific witnesses today, because it appears that the consensus among most scientists is that embryonic stem cell research, including stem cells derived through nuclear transplantation, offers unique and perhaps revolutionary opportunities.

From my discussions with experts, including Dr. Irv Weissman, of Stanford, and University of Utah faculty Dr. Mario Capecchi, a leading mouse stem cell researcher, and Dr. Stephen Prescott, the Director of the Huntsman Cancer Institute, I conclude that this line of research merits further investigation and it merits our support.

At the least, we should all acknowledge that the progress that there has been with adult stem cells has been largely attributable to a 20-year head start in Federal funding of this research. I plan to work with Senators Specter and Harkin as they develop legislation to expand the number of stem cell lines derived from embryos no longer needed in the in vitro fertilization process beyond those lines deemed eligible by the administration for Federal funding.

The issues we face today are difficult, but not totally unprecedented. For example, our society successfully addressed the issues attendant to recombinant DNA research and in vitro fertilization.

Our bill, along with criminalizing reproductive cloning, contains a number of strict ethical protections. These include making this

private sector research comply with the Federal Protection of Human Subjects regulations; separating the egg collection site from the nuclear transplantation research laboratory; a prohibition on exporting cloned embryos to any foreign country that does not ban human reproductive cloning; a prohibition on conducting nuclear transplantation research on fertilized eggs for a requirement that each egg donation be made voluntarily and that there be no profiteering on donated eggs; and a prohibition similar to the English rule on research conducted more than 14 days after the nuclear transplantation has occurred.

These are sound rules. If we adopt these ethical requirements, it is likely that other countries will follow our lead. Unless we act to build an environment that encourages the United States to remain the leader in stem cell research, we will have lost much.

Failure to enact legislation patterned after S. 303 can only undermine our Nation's leadership in biomedical research. Investors and firms will be reluctant to commit the necessary resources to succeed in this costly, new arena if there is not a measure of certainty in the legal environment for this activity.

Andy Grove, CEO of Intel, recently sent me an article that details how China is attempting to take the lead in this field of research. If this research is stifled, some of our best young scientists may feel compelled to move offshore and away from American patients. Such an outcome will not be good for the citizens of Utah and our neighbors across the country.

Let me close by sharing with you a letter I recently received from Nancy Reagan that I think frames the issue in a helpful way. That letters says, "Dear Orrin, as you may know, Ronnie will observe his ninety-second birthday soon. In earlier times, we would have been able to celebrate that day with great joy and wonderful memories of our life together. Now, while I can draw strength from these memories, I do it alone, as Ronnie struggles in a world unknown to me or the scientists who devote their lives to Alzheimer's research. Because of this, I am determined to do what I can to save other families from this pain. I'm writing, therefore, to offer my support to offer my support for stem cell research and to tell you I am in favor of new legislation to allow the ethical use of therapeutic cloning. Like you, I support a complete ban on reproductive cloning. However, I believe that embryonic stem cell research, under appropriate guidelines, may provide our scientists with many answers that are now beyond our grasp. Orrin, there are so many diseases that can be cured, or at least helped, that we can't turn our back on this. We've lost so much time already. I can't bear to lose anymore. Sincerely, Nancy."

Well, she is very dear to me, as is her husband. We have always been very good friends. Nancy Reagan is just one of thousands and thousands, and millions of people who are hoping that we might be able to find some breakthroughs that would help the living to be able to have lives that are more worthwhile, more healthy, and more resolving of the problems that they face everyday.

With that, I am going to turn to Senator Feinstein for her remarks, and then if anybody on our side would care to remark, we will be glad to have that.

Senator Feinstein?

STATEMENT OF HON. DIANNE FEINSTEIN, A U.S. SENATOR FROM THE STATE OF CALIFORNIA

Senator FEINSTEIN. Thank you very much, Mr. Chairman, and I am very proud of your leadership on this issue. I know how hard you have worked. I know the prayer and soul-searching that you have gone through to come to the position which you hold today, and that is a position which I share. I am very proud to cosponsor with you certain legislation which I will discuss in a moment. Also, we are joined by Senators Specter, Kennedy, Harkin, Corzine, Boxer, Lautenberg, and Durbin.

If I may, Mr. Chairman, I would like to introduce a statement for the record from the ranking member, Senator Leahy.

Chairman HATCH. Without objection.

Senator FEINSTEIN. Thank you very much.

Mr. Chairman, I hope that this hearing will help convince people that it is possible to draw a line between human cloning and valuable nuclear transplantation; that is, so-called stem cell research or therapeutic cloning.

Many of us were disappointed with the House vote on this issue last month, and we know that a majority of Senators appear to disagree with the House's position. I am hopeful that the Senate will pass our legislation that we introduced to ban human reproductive cloning, while ensuring that important medical research can go forward under strict oversight from the Federal Government.

Simply put, this research offers hope to millions of Americans suffering from paralysis and debilitating diseases, including juvenile diabetes, Parkinson's and Alzheimer's. But let's be very clear: human reproductive cloning is immoral and unethical. It must not be allowed under any circumstances. But at the same time, we must not, and we should not, I believe, prohibit nuclear transplantation research. It holds too much promise for millions of Americans.

Just this past December, we were told that the Raelians had cloned a human being. This is almost certainly a hoax. However, it underscores the point: we must ban human reproductive cloning now before some unethical scientist is successful in creating a human clone.

I believe this is a point on which we all agree. Human reproductive cloning is wrong. It should be banned forever, and our legislation which we have introduced does just that. But our legislation also allows medical researchers to continue to use what appears to be the most promising technique to cure debilitative diseases—somatic cell nuclear transplantation, a process used to produce embryonic stem cells. Under our legislation, though, these researchers will not have a free hand. They must conduct this research ethically, under strict guidelines, and with close oversight by the Federal Government.

Now, I also believe that our bill is in the mainstream of American thinking on this subject. Just this morning, at nine o'clock, a poll was released that was done by Opinion Research for the Coalition for the Advancement of Medical Research. It was conducted on March 6 of this year, and what it shows is that 67 percent of those surveyed said they favored Congress allowing therapeutic cloning

research to continue, while 30 percent polled wanted to outlaw the research. This was a poll of 1,012 adult Americans.

So if I may, Mr. Chairman, I would like to place that in the record, as well.

Chairman HATCH. Without objection.

Senator FEINSTEIN. Mr. Chairman, our legislation will place tough regulations on scientists conducting nuclear transplantation research. It would impose a sentence of up to 10 years in Federal prison for anyone attempting to clone a human being, and establish a minimum civil penalty of $1 million, or three times the gross profits resulting from the violation, whichever is greater.

It would mandate that eggs used in this research be unfertilized. We do so so there is no question that it is not a fertilized egg. We would prohibit the purchase or sale of unfertilized eggs, including eggs that have undergone nuclear transplantation. This would prevent so-called embryo farms or the possible exploitation of women.

We would impose strong ethics rules on scientists, mandating informed consent by egg donors. We would have any nuclear transplantation research reviewed by an ethics board, and we would provide safety and privacy protections. We would also prohibit any research on an egg cell after 14 days, when that cell begins to divide and when cell differentiation takes place. So that egg would have to be disposed of before any of those things take place. These provisions establish a clear divide between nuclear transplantation research used only to produce embryonic stem cells and human reproductive cloning.

I deeply believe that embryonic stem cell research has the potential to save literally millions of lives and to improve the quality of life for millions more. The promise of embryonic stem cells is that they are easily replicated, undifferentiated cells that can be induced into changing into any cell in the body—a heart cell, a liver cell, a spinal cord cell, or a kidney cell.

Talented scientists across the country, and indeed the world, are conducting research using embryonic stem cells in the search for new cures and treatments. My point here is that this research is going to go on and it is going to go in other countries, and certain countries are establishing headquarters for this kind of research. So if we don't move, we also risk the likelihood that we will lose some of our best scientists to other countries where they can conduct this somatic cell nuclear transfer research.

In a preliminary study at Washington University, embryonic cells inserted into rats have led to regeneration of a rat's spinal cord. The once crippled animals have been able to walk and bear their own weight. Imagine what this could mean for the 250,000 Americans paralyzed by spinal cord injuries.

Similarly, preliminary findings at the University of Wisconsin have shown that human embryonic stem cells can differentiate and actually express the insulin gene. Imagine what this could mean to 17 million Americans suffering from diabetes. Much more research and testing needs to be done, but clearly these findings offer hope to those Americans who suffer from chronic, debilitating disease.

Now, some have suggested that this research can be done without nuclear transplantation. They point to research being done, for example, with adult stem cells. I strongly support adult stem cell

research and other research not involving stem cells, but I agree with leading scientists who argue that embryonic stem cell research offers much more promise than adult stem cell research.

Why? Because the fact remains that adult stem cells are less versatile than embryonic stem cells. They don't have the ability to be potentially grown into any organ or any tissue. They can be grown into certain organs or certain tissues, but not any.

In addition, I support using nuclear transplantation to generate embryonic stem cells. Embryonic stem cells generated through means other than nuclear transplantation are much less useful. Any new organs or tissues created would not have the same DNA as the patient, and this is critical, forcing him or her to take dangerous immunosuppressant drugs and increasing the chances of rejection.

In America today, there are more than 128 million Americans who could benefit from embryonic stem cell research. One of these is Emma Arvedon. Only a few years old, she suffers from juvenile diabetes. Her father wrote to us and this is what he said: "Our family is enormously hopeful that nuclear transplantation research may play a vital role in finding a cure for juvenile diabetes. There already exists empirical evidence that quite possibly this research could yield the insulin-producing pancreatic cells that my daughter's body lacks. If research into this process were to be criminalized, how would I explain to Emma that our Government cares more about a cloned cell, smaller than a grain of sand, than they do about her?"

So we today are introducing this legislation for Emma and the millions like her with the resounding support of the medical and scientific community. To deprive Emma and her family of a possible cure, to close the door on nuclear transplantation research, would be nothing short of tragic.

We can, and should, ban human reproductive cloning, without hurting Emma and her family and the 127 million families like her. That is why we are here today, to offer hope to millions of Americans, and to help turn that hope into reality.

So I am very proud, Mr. Chairman, to join you and to join Senators Specter, Kennedy, Harkin, Corzine, Boxer and Lautenberg, and as of yesterday, I believe, Senator Durbin, in sponsoring this legislation.

Chairman HATCH. Thank you, Senator. We are happy to have Senator Durbin as a cosponsor.

Senator Craig would like to make a short statement.

STATEMENT OF HON. LARRY E. CRAIG, A U.S. SENATOR FROM THE STATE OF IDAHO

Senator CRAIG. Well, thank you very much, Mr. Chairman. I am anxious to hear the testimony, and I will read most of it because I am going to have to leave. I will be brief.

Let me ask unanimous consent that my full statement be a part of the record.

Chairman HATCH. Without objection.

Senator CRAIG. Let me say that I, like I think most who have spoken already, you and Senator Feinstein, am opposed to human

cloning. I think morally and ethically I feel that the use of experimental science in the creation of human life is unacceptable.

However, I understand that biological research could provide assistance to burn victims, heart attacks, diabetes, Parkinson's, leukemia, and the list could go on and on, the crippling and fatal diseases that many of our citizens face and experience.

But we must also accept that there is a need for limits when research goes beyond the boundaries of what is considered to be ethical, and that is the responsibility of this Committee and that is the responsibility of this Congress to draw that line and that is what we are attempting to do here.

I am a cosponsor of S. 245. I am glad to see Senator Brownback here this morning. He has been an outspoken leader in this area. I also appreciate the work you are doing, Mr. Chairman and Senator Feinstein, and others, as we sort this out. And it really is that business that we are into at this moment because this is an issue that will be addressed legally and within the law, I do believe, in a reasonably short period of time, and it should be.

Again, I do want to stress the importance of advancing medical research. There are countless people living with devastating diseases who live with the hope that medical research will help save their lives. I look forward to learning more about how we can make those advances in the area without treading on the sanctity of human life. We have that responsibility.

Thank you.

[The prepared statement of Senator Craig appears as a submission for the record.]

Chairman HATCH. Thank you, Senator.

We will begin with two distinguished Members of Congress. We are honored to have both of you here. Both hold the right-to-life philosophy. While they agree on the need to ban reproductive cloning, they have reached opposite conclusions on the matter of nuclear transplantation for research purposes. At least that is my understanding.

Senator Brownback is no stranger to this Committee. We miss you. We wish you were still on the Committee, and on this issue I am sure you wish you still were on the Committee.

Senator BROWNBACK. Yes, I do.

Chairman HATCH. We welcome you back, Sam. We are grateful to have you here.

Senator Brownback is the lead sponsor of legislation that would ban somatic cell nuclear transfer for both reproduction and research purposes.

We also want to welcome to the Committee Representative Jim Langevin. Congressman Langevin is from Rhode Island and is in his second term in the House. We want to thank you for appearing with us today. It means a lot to us. I know that you have a commitment on the House side that will require you to leave as soon as you testify, and we will understand that.

Before we start with Senator Brownback, I want to mention that due to scheduling conflicts with some of our members, the Committee will recess this hearing at about 11:30 and then reconvene at 1:30. We may only be able to get through this first panel this morning. Maybe if we have enough time, I will call the fourth

panel so that we can do that. We will see how it goes and maybe we can reach that fourth panel, and then we will do the others as soon as we get back at 1:30.

So let's start with my friend, Sam Brownback.

Senator BROWNBACK. Mr. Chairman, thank you very for allowing me to be here. I would be happy to let Congressman Langevin go first if he has a scheduling conflict.

Chairman HATCH. That is very gracious of you.

Congressman would that help you if you go first?

Representative LANGEVIN. I am fine with waiting for the Senator. I don't mind waiting. It is up to you, Senator.

Chairman HATCH. Senator Brownback?

STATEMENT OF HON. SAM BROWNBACK, A U.S. SENATOR FROM THE STATE OF KANSAS

Senator BROWNBACK. Thank you very much. Thank you, Mr. Chairman, and I would like to be back on the Committee to do a great deal of very important work. I hope you can clear some judges on through. I think the Federal bench could sure use it, and the appellate court bench in particular.

Chairman HATCH. We are doing our best.

Senator BROWNBACK. I know it is a difficult task. I also have appreciated my association with the Chairman over many years on many different topics. We have worked closely and carefully together, and I have always appreciated his great leadership, his thoughtfulness and his legislative ability. He is an excellent legislator.

Chairman HATCH. Thank you. We are dear friends, there is no question about it. We do have our differences on this, but we can still be dear friends.

Senator BROWNBACK. I hope to persuade you of the reasonableness of my position.

Chairman HATCH. The error of ways?

Senator BROWNBACK. Yes.

Let me start with the good news, if I could. Senator Feinstein was talking about the hope and the promise of cloning and embryonic stem cell research. Let me produce for you a newspaper articles on cures from adult stem cells. This was in the Wall Street Journal March 6 of this year. Some of you may recall this story.

This was about the 16-year-old boy who was shot through the heart with a nail gun, the other gentleman being charged with the crime. About a third of his heart was destroyed in this. The next day after the nail gun was shot through his heart, he had a heart attack, destroying further areas around it.

They took stem cells from his bone marrow, so these are not heart stem cells; these are bone marrow stem cells. The first time in this country—this has been done overseas, but the first time in this country. They collected them, concentrated them and injected them back into his heart. He is now walking, talking, getting bored having to lie around. This has been an amazing repair procedure that has taken place with adult stem cells in humans. This isn't about a promise that is taking place that we might have this taking place with cloning. This is in humans and it is occurring today, and I would ask that this full article be submitted into the record.

Chairman HATCH. Without objection, we will put that in the record.

Senator BROWNBACK. It also shows the malleability, the pliability of adult stem cells, that were thought previously, as we haven't really understood these for very long, to be not particularly pliable, they weren't malleable. But it turns out that particularly bone marrow stem cells are.

We also learning from the scientific community that we have these stem cells throughout our bodies, adult stem cells. They are kind of like repairmen. They go around the building; they go around the Dirksen Office Building repairing different things. But if there is a massive attack somewhere, there are not enough of them to be able to fix the problem that might blow up, if we have a furnace that blows up, if we have some other problem. So they have to bring in more, and that is the idea of concentrating, sending them into a particular spot, and it is working.

Now, some in the scientific community when adult stem cells first came out said this is not an answer, this doesn't work; junk science, some referred to. I would say that this young man in Ohio would not refer to this as junk science at all. This is something that is saving his life.

We are seeing this taking place in a broad cross-section of areas in adult stem cells. I remember when we started this debate on cloning a couple of years ago, people were saying adult stem cells really don't work; well, sure, I support it, but it doesn't really work; they don't have the plasticity to be able to do it.

Here is a book of the research articles now in adult stem cells. These are human trials and animal trials that are taking place in a variety of different areas—brain damage, cancer, cerebral palsy, diabetes, heart damage, eye diseases, multiple sclerosis, muscular dystrophy, Parkinson's, spinal cord injuries, sickle cell anemia, transplants, overall versatility—and then sources at the end of it.

Chairman HATCH. Senator, would you submit that for the record?

Senator BROWNBACK. I would be happy to submit these to the record. We try to get these updated every 2 weeks. There is so much coming out in the area.

Chairman HATCH. Well, let's keep the record open so that you can submit whatever comes in, and then we will certainly look at every bit of that. We are all for what you are talking about.

Senator BROWNBACK. My point in saying this is as I have started this debate several years ago, the research and how you treat the young human and the need to clone is immoral, illegal and unnecessary, were the three points that we started this debate with about 3 years ago, maybe a few more.

I wanted to point to the last point on this about the unnecessary side of this. We have huge findings that are taking place in humans and in animal trials that these are occurring. We don't need to go the cloning route because you have to cross the fundamental issue which we are all struggling with, which is when does human life begin, and is that youngest of human life something that is owned by somebody or is its own life? Is it a person or is it property, which is a point I have posed to the Chairman numerous times? How are we going to treat this youngest of human life? Are

we going to treat it as a person or are we going to treat it as a piece of property?

This is a philosophical issue, an issue perfectly suited for the Judiciary Committee to discuss, but one which we as a society have been, to date, unwilling to decide. We have been unwilling to say it is property and therefore it can be disposed of as its owner chooses, or it is a person and therefore it has legal rights. We have been unwilling to decide.

Here, I would quote Ronald Reagan, when he said—and I am paraphrasing here—if you didn't know if a person was dead yet, you wouldn't bury him. I would put it in reverse, saying if you are not sure if it is a life or not, you wouldn't kill it. We are at one of those similar sorts of questions.

Are we sure or convinced that this is life, or isn't it human life? Some would say it is clearly human life, it is genetically defined as human life, it has a full set of chromosomes, it is human life; all it needs is care and nurturing and it can become a full human life under anybody's definition.

There are others who will say, well, without care and nurturing, without it being in the womb, it cannot be human life, it cannot grow to a full life expectancy, and therefore it must be property. We could treat it as such. We could patent it. We will need to patent these young embryos, we will need to patent these clones.

We haven't been willing to deal with that, and that is why I submit to you that we have a procedure and it is working and it is working brilliantly. It is working wonderfully and it is producing results today. Why would we kill it if we are not sure it is alive?

I also want to go into the issue about definition because this is a debate that is replete with questions about definition. First, I would submit, and I think this is very clear from the scientific evidence, that there is only one type of human cloning and it always results in the creation of a new human being.

Many of the proponents of human cloning would have society believe there are two different types, the so-called reproductive and the so-called therapeutic. Well, these are not two types of cloning. There is only one and it always results in the creation of a new human embryo.

There are others who would say we want to do nuclear somatic cell transfer. That is fine, but that is the name of a procedure that produces a clone. That is the name of a procedure and that procedure results in a human clone. Attempts to put a different label on it or change the intentions of the researcher by suggesting that are, I think, unhelpful to the debate.

At the end of the process of somatic cell nuclear transfer, you end up with a clone, and that is the question about how are we going to treat clones. Are we going to treat them as a person or are we going to threat them as property? I would submit that we should not create this human life just to destroy it for the research on it.

Recently, in what appears to be attempts to avoid negative opinion, a new term has been used to describe human cloning, the term of "unfertilized egg." It is a euphemism that is being used by people who are proponents of therapeutic cloning. This term, which is as confusing as can be, I think, needs closer examination.

Any biology textbook will define a human ovum or egg as a single cell. Moreover, it is a very unusual cell, a gamete cell, which means it has only 23 active chromosomes, half the number. Gender has not yet been determined. An ovum cannot grow stem cells or otherwise develop because it is just an egg.

However, once an egg contains a complete nucleus, the full set of chromosomes from any species that is activated and developing, whether that has occurred by sexual fertilization or by asexual somatic cell nuclear transfer, then one has a developing embryo of that species, whether it is a sheep in the case of Dolly, which was asexual reproduction, or whether it is a cow or whether it is a homo sapiens.

There is no such thing in biology or in any dictionary as a human egg or egg cell that has 46 chromosomes, has been determined to be either male or female and is 5 days old, consisting of several hundred cells, or 14 days old consisting of several thousand cells. Calling a 5-day-old or a 2-week-old human embryo an egg is an attempt really to hide the fact that this is an embryo and it is the true nature of a human clone, just as Dolly was at that stage a clone of a sheep.

The phrase "unfertilized blastocyst" is likewise being used in this debate. Now, the term "blastocyst," of course, refers to a stage of embryonic development, and an egg would never be a blastocyst. You are at an embryo stage. Human cloning is human cloning. All human cloning, I would submit to you, is wrong, no matter what one wants to call it or by what procedure you get to that clone.

I think these definitions are important because what we need to deal with is the issue of human clones and what we intend to do with them as a society. The House has passed a bill by a large margin saying we should not be researching on humans and we should not create human clones.

The cloning field is a very less-developed field to date. We saw Dolly was just put down, put to death, because of premature problems that she had. I think it is a very dangerous thing to submit human beings to. I think it is immoral to research on young humans. I don't think it is right for us to create life to research on it, and we don't need to; we have other routes to go. For all those reasons, I am here in opposition to human cloning either for therapeutic research purposes or for full reproductive purposes.

I would be happy to take your questions.

Chairman HATCH. Thank you, Senator Brownback.

Congressman Langevin?

STATEMENT OF HON. JIM R. LANGEVIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF RHODE ISLAND

Representative LANGEVIN. Thank you, Senator Hatch. I am honored to be here today and to be seated with Senator Brownback. I appreciated listening to his thought-provoking views, and I know they are well-thought-out, though we disagree on the issue. I enjoyed hearing his perspective.

Senator Hatch, I would like to thank you and Senator Brownback, Senator Kennedy, Senator Feinstein, and the entire Judiciary Committee for convening today's hearing on the topic of cloning.

I feel strongly that it is time to pass a law that will put this matter to rest. Patient advocacy groups, leading scientists, lawmakers, and a majority of the American people agree that human reproductive cloning should not be allowed. It is clearly the obligation of Congress to pass a law prohibiting and criminalizing this practice, and to encourage other nations to follow suit.

In the course of the debate on cloning, we have heard much discussion about somatic cell nuclear transfer, the procedure commonly referred to as therapeutic cloning. In the year-and-a-half since Congress first addressed this matter, I have studied the principles of nuclear transfer and analyzed the issue from the perspective of a policymaker, a pro-life Democrat and Member of Congress, and a devoted advocate of improving the lives of those with disabilities and diseases.

I particularly want to thank you, Senator Hatch, and Christopher Reeve and many others on both sides of this issue for your advice and counsel in helping to arrive at my position.

After a great deal of thought and discussion and personal struggle, it is my carefully considered position that we can and should ban the cloning of human beings without impeding ground-breaking and promising biomedical research in the area of somatic cell nuclear transfer. Like Senator Hatch, my pro-life beliefs include a commitment to defend, extend and improve the lives of those who are living among us.

As many of you know, in the 107th Congress I became the first quadriplegic ever elected to the United States House of Representatives. While my physical condition does not define me, it does affect me on a daily basis, providing me with a unique perspective, shaping my pro-life position and my understanding of the value of the type of research that we are here to discuss.

At the age of 16, I was in my fourth year of participating in the Warwick Police Cadet Explorer Scout program. I thought I was well on my way to realizing my dream of being a police officer or an FBI agent. But on August 22, 1980, my dream was shattered and my life was changed forever.

I stood in a locker room with a fellow cadet watching two members of the SWAT team examining a new handgun. It accidentally discharged, launching a bullet that ricocheted off a metal locker and through my neck, severing my spinal cord and leaving me paralyzed for life.

But perhaps now there is new hope for me and millions of others. Having come so close to losing my own life, I am reminded everyday of how precious a gift life truly is, and that is what has led me to be pro-life. I see my position in supporting therapeutic cloning as consistent with my pro-life views.

In somatic cell nuclear transfer, the nucleus of a donor's unfertilized egg cell is removed and replaced with the nucleus of a patient's own cell; for example, a skin cell. Doctors are then able to develop stem cells that will not be rejected by the patient's own immune system. The cells are never transplanted into a womb, and to me that is the difference between ethical regenerative medicine and immoral human cloning.

Nuclear transfer is the cloning of one's own cells, not the cloning of any viable form of life. A legal prohibition against implantation,

as provided by the bill offered by Senator Hatch, provides sufficient assurances that nuclear transfer is ethical and should be allowed to proceed.

Scientists believe that the knowledge they can gain from somatic cell nuclear transfer can lead to cures and treatments for conditions including Alzheimer's, Parkinson's, cystic fibrosis, diabetes, and even spinal cord injuries. The research done with cloned cells produces stem cells which have the potential to yield life-saving and life-enhancing treatments for millions of people living with diseases and disabilities. With appropriate safeguards, we can remove the risk of misuse of this technology and encourage scientific research that is likely to yield undeniably life-affirming results.

Please understand that I am here to speak today not just for myself as a lawmaker and as someone living with a disability, but on behalf of the millions of people who struggle daily with the pain, suffering and debilitating effects of disease and disability.

Many lives could be saved, lengthened and dramatically improved by this research. Large numbers of Americans could benefit from therapeutic cloning, including 1 million children with juvenile diabetes, 4 million Alzheimer's sufferers, 230,000 people living with spinal cord injuries, 30,000 children and adults affected by cystic fibrosis, and 30,000 Lou Gehrig's Disease patients.

Every family in America has been touched by these diseases and conditions, and through the medical advances such as those being explored in somatic cell nuclear transfer and stem cell research, we have the opportunity to offer them real hope.

I must also acknowledge the progress being made on these issues through other aspects of stem cell research. We do not yet know which research project might yield the treatment for Alzheimer's or a cure for diabetes or the many other conditions and diseases that I have mentioned. We must explore all avenues of treatment for people living with disease and disability.

In my research that led me to support embryonic stem cell research, I spoke with one of the foremost experts in adult stem cell research, Dr. Peter Quisenberry, from my home State of Rhode Island. He has devoted his career to adult stem cell research and he believes so strongly in the hope that that particular research offers. Yet, he acknowledges to me that we don't yet know where the greatest potential for treatment of individuals with disabilities and diseases truly lies, whether it is adult stem cell research or embryonic stem cell research.

Therefore, he believes that we should proceed on both tracks. In the quest to find new treatments and cures, we must leave no stone unturned, and it is essential that we continue to explore both adult and embryonic stem cell research, as well as somatic cell nuclear transfer.

As legislators, we have a responsibility to protect society against abuses of technology. We also have an obligation to maximize its benefits in a responsible and ethical way. Clearly, human cloning is such an abuse and Congress must take the necessary measures to protect society from this exploitation.

The bill offered by Senator Hatch provides these measures to offer the opportunity to ban human cloning without concurrently halting critical research in the area of area somatic cell nuclear

transfer which promises a significant increase in quality of life, and in many cases the promise of extending and improving life itself for millions of Americans, and indeed for millions of people around the world.

When we addressed this issue last month in the House of Representatives, an amendment was offered by Representative Greenwood containing the provisions protecting somatic cell nuclear transfer that you see in the Hatch bill. It generated 174 votes, indicating a significant amount of support for therapeutic cloning. However, it failed to pass the House.

Subsequently, it may now be up to the Senate to make sure that the door is not closed on promising medical research. It is my hope that the Senate will pass a bill banning reproductive cloning, yet encouraging somatic cell nuclear transfer research, and setting the criteria for it to move forward in a responsible fashion under the direction and oversight of credible, trusted entities like the NIH.

To that end, I urge my colleagues in the Senate to support S. 303, in recognition that it provides appropriate safeguards against the ethically questionable practice of reproductive cloning, while maintaining the promise of the best in medical technology for all Americans.

Mr. Chairman, I thank you for your time here today.

Chairman HATCH. Well, thank you. I want to thank both of you for your testimonies. They are divergent in some ways, but both very sincere and dedicated testimonies. So I commend both of you.

Congressman we will let you go. We know you have got to get back over to the other side of the Hill, but we are honored to have you here and we are very appreciative of your testimony.

Representative LANGEVIN. Thank you, Senator.

Chairman HATCH. Thank you so much.

Sam, only one question from me, and that is it may be that neither bill will pass. But if that is not the case, we ought to join hands and at least pass a ban on reproductive cloning. I hope that is the minimum that we do this year. Hopefully, we can do that. That is all I wanted to say.

Does anybody else have any questions?

[No response.]

Chairman HATCH. We are grateful to have you here.

Senator BROWNBACK. Thank you very much. We will be having a hearing on the impact of therapeutic cloning on women next week because, as noted, if we move forward with this, there would be millions of eggs needed. We are going to look at that procedure in the Commerce Committee next week because there will be markets being created.

Chairman HATCH. We will look forward to seeing what your panels say at that time.

Senator BROWNBACK. Thank you.

Chairman HATCH. We are very close to where we have to get over to that top-secret meeting.

Senator FEINSTEIN. I beg your pardon?

Chairman HATCH. We are very close to where we need to get over to that top-secret meeting. Should we try and do the fourth panel?

Senator FEINSTEIN. If they are here. My understanding was—I know the signals have changed about this meeting—that there were going to be these opening comments and then we were going to recess until 1:30 today. Perhaps that has changed.

Chairman HATCH. Well, I wonder if Jim Kelly and Greg Wasson are here.

You are Mr. Wasson. Is Jim Kelly here?

Mr. KELLY. Yes.

Chairman HATCH. Well, I wonder if we could take both of your testimonies at this time. We will try and do it. If you can limit your testimony to 5 minutes, we can still make our appointment over in the Capitol. We will start with you so that you don't have to stick around all day if you don't want to.

This next panel consists of two patient advocates. We want to thank Jim Kelly and Greg Wasson for traveling here today. While you both have reached different conclusions with respect to the best course for public policy with respect to stem cell research, no one can doubt that you share the ability to passionately convey your views. So we are pleased to have both of you before the Committee today. If you can summarize your remarks within 5 minutes, we will put your full statements in the record as thought fully delivered.

Mr. Kelly, we will start with you first.

STATEMENT OF JAMES KELLY, GRANBURY, TEXAS

Mr. KELLY. Thank you, Mr. Chairman.

Two years ago while closely researching my own condition, I blindly accepted media reports claiming embryonic stem cells were our best hope to cure other conditions. When I realized the push for cloning was supported by companies that claimed they had no interest in pursuing the field, I wondered why.

When I read media reports that sharply contrasted with information I had gathered from medical journals, I became concerned. When I read of my own condition being used to justify cloning, I began studying the issue in earnest. This is what I found.

In embryonic stem cells derived from cloning, chromosomes transferred in the cloning process retain physical changes that accrue with age. These age-related changes are known to contribute to age-related disease. Investors are unwilling to invest in cloning, since its potential for leading to clinical treatments, if any, is considered decades away, or as a recent New York Times articled concluded, "in the distant future." Biotechnology corporate leaders believe its chances of success are "vanishingly small."

The public is being told that therapeutic cloning does not require the creation and killing of human embryos, when, in fact, that is exactly what it does. We have been led to believe that cloning's widespread and variable genetic defects pose no therapeutic risk. The truth is that researchers don't know how many genes are affected by cloning, or cloning's potential for mutation or aberrant imprinting during adult cell mitotic division, or the long-term consequences of introducing such cells into adult organs.

Dr. Robert Marcus, Director of the East Anglia Bone Marrow Transplant Unit, explains the risks: "Any time you transfer genes within the cloning process, or change the genetic material within

a cell, there may be defects introduced into a natural organ or species development. I think I would be quite cautious there."

Embryonic stem cells derived from cloning are not expected to perfectly match the donor. They may face rejection and require immune suppression. Dr. John Gearhart told the President's Council on Bioethics there is "no question" in his mind that embryonic stem cells derived from cloning "could be rejected." "Absolutely," Dr. Gearhart says.

Dr. Irving Weissman explains: "I should say when you put the nucleus in from a somatic cell, the mitochondria still come from the host"—that would be the egg—"and in mouse studies it is clear that those genetic differences can lead to a mild but certainly effective transplant rejection and so immune suppression, mild though it is, will be required for that."

If custom treatments from cloning could someday exist, they are expected by leading scientists to be astronomically expensive. Australia's leading embryonic stem cell expert, Professor Alan Trounsen, says the pace of stem cell technology has been so rapid that therapeutic cloning is now unnecessary. "My view," he said, "is there are at least three or four other alternatives that are more attractive already."

In citing the clinical results using adult stem cells to repair human hearts, the director of a prestigious German medical journal presents a truth that Americans are not being told: "The promises of unscrupulous embryo researchers that clone without clear clinical goals and experiments are unsupportable. This remarkable proof has now given us a clear sign that the Americans with their prohibitions are exactly right. The biotechnological revolution can take place without embryonic stem cells if the alternatives are developed."

Embryonic stem cells from any source are not considered by most scientists to be the optimal transplantation cell of choice. This is another truth America is not being told which further explains why, in New Jersey, science and biotech are pushing for access to cloned late-term fetuses and newborn babies.

To summarize, embryonic stem cells derived from cloning do not perfectly match the patient; contain known and unknown genetic defects, as well as defective imprinting; are expected to require immune suppression for immune-sensitive conditions; retain the genetic age of the donor; are not considered desirable for transplantation; and may be too expensive for patients to afford.

Regarding the likelihood that science will overcome just one of these defects, Dolly's creator predicted in Nature: "It should keep a lot of us in business for a long time."

Moreover, these flaws are in addition to critical defects already inherent in embryonic stem cells from any source. Regarding this point, the Institute of Science in Society, an international organization of 462 scientists from 57 countries, issued a statement: "The risks of cancer, uncontrollable growth, genome instability and other hurdles make ES cells a bad investment in terms of finance as well as public health benefits." The Institute adds that adult stem cells "are more likely to generate affordable therapies that can benefit everyone."

In other words, even if cloning's very real practical concerns could be overcome, including its need for female eggs and its expected exorbitant costs, and even if rejection issues and genetic flaws could be addressed, it would still do nothing more than provide cells known to be genetically unstable, grow uncontrollably, and cause cancer.

Why then are millions of dollars which could have been used to develop cures instead being spent on a national campaign to convince Americans that therapeutic cloning offers the brightest hope for cures?

The ISIS offers an explanation: "Commercial imperatives are the major impetus for ES cell research, much more so than for adult stem cells. There are more opportunities for patenting cells and cell lines as well as isolation procedures."

The Institute concludes: "Scientists should stop manipulating public opinion to promote research that is both morally and scientifically indefensible. At the same time, governments need to invest our tax money in scientific research that can genuinely benefit the health of the nation, and not be misled by false promises of the next economic boom."

The exaggerated promise of therapeutic cloning is not a path to cures in our lifetime, but a dangerous diversion away from cures. It is in the interest of cures that I urge you to support S. 245, the Brownback-Landrieu ban on all human cloning.

Thank you.

[The prepared statement of Mr. Kelly appears as a submission for the record.]

Chairman HATCH. Thank you, Mr. Kelly.

We will turn to you, Mr. Wasson.

STATEMENT OF GREG WASSON, COTATI, CALIFORNIA

Mr. WASSON. Chairman Hatch, Senator Feinstein, and members of the Committee, thank you for giving me the opportunity to testify before you today.

The potential of regenerative medicine is of great importance to my life. My name is Greg Wasson and I am here on behalf of the Coalition for the Advancement of Medical Research, CAMR. CAMR is comprised of universities, scientific and academic societies, patients' organizations, and other entities that are devoted to supporting stem cell research.

I, along with CAMR, support every effort to criminalize and ban human reproductive cloning. It is unsafe and it is unethical. However, it is imperative that we protect stem cell research using therapeutic cloning to provide better treatments and hopefully cures for a number of debilitating and presently incurable conditions.

Eight years ago, I was diagnosed with Parkinson's disease. My fiancee, Ann Campbell, who is here with me today, was given the same diagnosis that year. I was a lawyer. Ann was an editor and a children's book author. Within 5 years of our diagnosis, we were both forced to retire on disability. I was later diagnosed with diabetes, a problem which runs in my family.

An estimated 1 million Americans have Parkinson's, a progressive, degenerative brain disorder that is presently incurable, whose

cause is unknown, and which slowly robs its victims of the ability to move properly and eventually to move at all.

We live with the knowledge that 30 percent of all Parkinson's patients develop dementia and that we are three times as likely as the general population to develop Alzheimer's. We have lesser cognitive problems which plague us as well.

Eight years after my diagnosis, I take 25 pills per day. Yet, I have increasing difficulty controlling my symptoms. These medications do nothing to slow the progress of my disease. For both Ann and myself, the time will come when our medications will fail us permanently and we will be totally functionally disabled. We will leave this world and enter a twilight world of immobility, encased in our bodies as if entombed, able to think but not speak, understand but not communicate. Death will inevitably follow, and by then it may be welcome.

Parkinson's is just one of the many chronic diseases and conditions that are fatal, at worst, and leave their victims permanently disabled at best. These diseases and conditions affect more than 100 million Americans. Each of us here today has a loved one or a friend who has a disease such as Alzheimer's, ALS, diabetes, or Parkinson's.

Time is of the essence in pursuing promising research. Two years ago, I worked with a number of persons suffering from ALS. They became my friends. Now, 2 years later, most of them are dead. John Davis, an Alabama ALS victim and fellow advocate, fortunately still living, once said of embryonic stem cell using SCNT, "this dog will hunt." He meant that such research had the potential for saving countless lives, and he was right. But this research will hunt only if it is not leashed and muzzled.

We are not without hope. Regenerative medicine, including responsibly regulated therapeutic cloning, may lead to a cure or treatment for Parkinson's disease, ALS, and a host of other diseases and conditions. As you will hear today from the scientific panel, human reproductive cloning and cloning for therapeutic medical purposes are not the same. An unfertilized ball of perhaps 100 cells the size of a pinhead is not a human being or anything near to one. The use of SCNT does not destroy human life; it is an attempt to restore human life.

Ann Campbell and I, along with millions of other Americans, are human beings, human beings living with terrible diseases that will kill us unless cures are found. The willingness of some people to sacrifice our lives, to place less value on our lives than on a chemically-produced unfertilized mass of cells, perhaps grown from one of our own hair follicles, is to me the real shame and the real crime.

Compassion and common sense must prevail. Ignoring the potential of therapeutic cloning would be a national tragedy and a huge mistake. But as with other scientific advances, a vocal and well-organized minority is trying to stop this research. Galileo, Columbus, and a South African physician named Christian Barnard all held scientific beliefs that frightened their contemporaries. But the earth does revolve around the sun, the earth is not flat, and today heart transplants are commonplace.

Today, the target of scientific fear is therapeutic cloning. Opponents argue that legalizing therapeutic cloning will open the flood gates to a black market industry in reproductive cloning. But similar claims were once made that organ transplantations would lead to a huge black market in harvested organs. This fear was unfounded, and today donation and transplantation of organs is strictly and effectively regulated.

Senators we believe that you understand and appreciate the enormity of the potential for saving human beings from fates such as Parkinson's, ALS, diabetes and spinal cord injuries. We believe that, individually and collectively, you will make the choice to protect and to restore life. What greater legacy could any government leave its citizens?

So because we have hope and faith that this country will recognize the value of research into regenerative medicine, Ann and I will be married this fall. On our wedding day, we will raise a glass to the promise of a new day when diseases like Parkinson's are simply a terrible memory. In this Committee, in the Senate and in Congress, we place our highest hopes and most sacred trust.

Thank you very much.

[The prepared statement of Mr. Wasson appears as a submission for the record.]

Chairman HATCH. Well, thank you. We thank both of you for being here.

Questions, Senator Feinstein?

Senator FEINSTEIN. No, Mr. Chairman, but I did want to read into the record—I should have done this when Senator Brownback was here—I would like to read something from Dr. Berg's statement. For those who don't know, Dr. Berg is the Chair of the Public Policy Committee of the American Society for Cell Biology. He is also a Nobel laureate in chemistry and he is known as, I think, a world expert on this subject.

On page 5 of the testimony he is going to give—and I want to draw everybody's attention to it—he says, "Both Congressman Weldon and Senator Brownback have accepted the assurances of their advisors that adult-derived tissue-specific stem cells, that is specialized stem cells that already exist in many of our tissues, are sufficient for meeting the clinical needs of repairing damaged or diseased tissue."

He goes on to say, "Those assurances contradict the evidence. The claims on which those assurances rest are largely anecdotal"—for example, the heart incident that Senator Brownback mentioned—"relying on experiments that most often have not been replicated by others and, in some cases, are now known to be flawed." For example, this heart incident had no science behind it. It was something that was tried, and so far it has worked and that is just great.

"Indeed, recent experiments have documented that claims that bone marrow can reconstitute tissues of other organs have been shown to be artifacts. Moreover, multipotent adult-derived stem cells have, with few exceptions, not been maintained in culture for any significant period."

"It is certainly true that bone marrow harbors rare stem cells, the so-called hematopoietic stem cells that can reconstitute the en-

tire blood-forming system. Similar evidence exists that neural stem cells obtained from embryos can give rise to different neural cell types. But neural cells obtained by differentiation of cultured embryonic stem cells"—and this is the key—"can populate the brain and deliver sufficient dopamine to alleviate the symptoms of Parkinson's disease in the mouse."

So the point I wanted to establish is this is what our legislation is really going to help develop, this new line of embryonic stem cells, where these cells can replicate themselves to be used with minimal rejection in virtually any part of the body. So I think that that point has to be made and we have to keep making it.

For somebody like Mr. Wasson who has a problem and needs help, this is really the one area where he can get that help, and that is why it is so important. I just want to thank you for being here today. We are very grateful.

Chairman HATCH. Yes?

Mr. KELLY. Mr. Chairman, I would like to make a request of you, sir.

Chairman HATCH. Yes, sir.

Mr. KELLY. I would like to address you and Senator Feinstein on a couple of things.

Senator Feinstein, you made some comments about spinal cord injury. Before I left last night from Dallas-Forth Worth, I downloaded the Rutgers University—Dr. Wise Young keeps a website where he keeps the spinal cord community up to date on the most promising developments in spinal cord research.

He has a very comprehensive list here of the seven different areas of spinal cord research, and then he breaks each area down into whether it is neuro-protective, regenerative or reparative. It is very comprehensive and it is very clear and distinct. I would appreciate, sir, if you would accept this for the Senate record.

Chairman HATCH. We will make that part of the record.

Mr. KELLY. I am sorry. Senator Feinstein, I have to tell you that what you were told by Dr. Berg is not correct. The truth of the matter is the heart studies that you were saying have not been duplicated have been duplicated, Senator. They were duplicated in Australia, in Germany, in France, and now this is the first time it has been used in the United States, and they have been duplicated in humans in all those countries.

The truth of the matter, Senator, is that adult stem cells are definitely the most promising area of research we have. As a matter of fact, Senator, I personally am not going to stay in the United States and wait for biotech to decide that they are going to try to bring treatments to the American people. This summer, I am going to Portugal and be treated with olfactory mucosa from my own nose that has adult neural stem cells that are already getting people on their feet who have been chronically paralyzed with spinal cord injury.

I sincerely suggest, Senator Feinstein, that you question what you are being told because you are not being told the truth.

Chairman HATCH. Well, I hope you have success in what you are doing.

Mr. KELLY. Thank you, sir.

Chairman HATCH. Let me just ask one question to both of you, though. Let's assume that the Brownback bill passes. I don't think that is going to be the case, but let's assume that it does. If a therapy that could help you with your respective difficulties and disabilities were invented overseas with stem cells derived from a cloned embryo—if that therapy could actually be developed, would you avail yourselves of your treatment?

Mr. WASSON. Answering personally, if the Brownback bill were passed, it is my understanding that I would, upon entry into this country, be imprisoned for using that therapy.

Chairman HATCH. Well, let's assume that they changed part of the original bill, which I think they are doing, that would not make that a crime for you to come back into this country with a cure or treatment that occurred from embryonic stem cell research overseas. Would you avail yourself of that treatment?

Mr. WASSON. Certainly.

Chairman HATCH. How about you, Mr. Kelly?

Mr. KELLY. If I understand correctly, you are asking me would I avail myself of an embryonic stem cell cure using cloning, if it was possible?

Chairman HATCH. That literally was developed overseas, if it worked.

Mr. KELLY. If it was possible?

Chairman HATCH. Yes.

Mr. KELLY. I will tell you the truth, sir. A year ago, I told a Congressman when he asked me the same question that, yes, I would, because my No. 1 reason for taking the view that I am taking is I am trying to promote research that can genuinely lead to cures.

But now, sir, I have to tell you that in the last year I have come to change my mind on that. The reason why I have changed my mind is my background is in blue-collar heavy industry, railroading, and I see things in very clear, black-and-white simplicity. And when I went to New Jersey to present what I believe is the pro-cures perspective on this issue and I saw that in New Jersey they are trying to promote cloning of not only fetuses for therapeutic cloning, but also newborn babies, I realized that I myself will not allow a baby to be killed to get out of this wheelchair. And I swear to you, sir, nobody wants to be cured more than me, but I draw the line at killing babies.

Chairman HATCH. Well, that is a principled position. I don't agree with you, but it is a principled position. I agree with Mr. Wasson.

You are both excellent people. We appreciate having you here. We appreciate the testimonies that you have given. We will let Dr. Berg speak for himself on this issue, because he will be one of the panelists as we resume this afternoon at 1:30. So we are going to recess until 1:30 because we both——

Senator FEINSTEIN. Mr. Chairman, may I put a number of letters in the record?

Chairman HATCH. We will, of course, do that, without objection, and keep the record open.

We just want to thank all the witnesses so far. I am sorry we have to recess, but this is a very important meeting both of us have to go to.

Mr. WASSON. Thank you.

Chairman HATCH. Thank you. We will recess until 1:30.

[Whereupon, at 11:44 a.m. the Committee was adjourned, to reconvene at 1:36 p.m. this same day.]

Chairman HATCH. I am going to ask the two panels to come together all at once. We were going to have four panels, but we will put panels two and three together now. I think we had a good session this morning, and I understand that both Dr. Kass and Dr. Varmus have travel plans for later this afternoon, so I think it is best that we consolidate the two panels.

We have two distinguished ethicists with us. Dr. Leon Kass is on leave from the University of Chicago, where he serves as Addie Clark Harding Professor in The College and the Committee on Social Thought. He is also a Fellow of the American Enterprise Institute. In his spare time, Dr. Kass chairs the President's Council on Bioethics. I understand that he appears before us today in his individual capacity and not on behalf of the Council or the administration. So we welcome you, Dr. Kass. We are honored to have you here.

We are also fortunate to have with us today Dr. Tom Murray, who serves as President of the Hastings Center, a non-profit, nonpartisan institution that focuses on ethical issues raised by health and the environment. Among Dr. Murray's many accomplishments was his service on the National Bioethics Advisory Committee that studied the ethical issues attendant to stem cell research during the previous administration.

We also have with us some respected scientists. Dr. Harold Varmus is President and CEO of the Memorial Sloan-Kettering Cancer Center, in New York. He also chairs the Joint Steering Committee for Public Policy, a coalition that represents 50,000 biomedical research scientists.

Previously, Dr. Varmus served as the Director of the National Institutes of Health, one of the most important and prestigious positions in the world. Prior to his 6 years leading the NIH, he was on the faculty of the University of California in San Francisco. He was awarded the Nobel Prize in Medicine in 1989 for his groundbreaking work in discovering cancer genes called oncogenes.

Next, we will hear from Dr. Anton-Lewis Usala. Dr. Usala wears two hats. He is Clinical Professor and Medical Director at the Office of Clinical Trials at East Carolina University. Dr. Usala is also CEO of Ectocelle, a start-up biotechnology company that is attempting to develop mechanisms whereby a body can regenerate its own cells.

Next, we will hear from Dr. Micheline Mathews-Roth. She is an Associate Professor of Medicine at Harvard Medical School and a physician at the Brigham and Women's Hospital in Boston. Much of Dr. Mathews-Roth research has centered on a rare genetic disease known as EPP. I will let Dr. Mathews-Roth explain what this acronym means and how she developed an approved treatment for this disease.

Finally, we will receive the testimony of Dr. Paul Berg, who won a Nobel Prize in Chemistry for his ground-breaking work in developing recombinant DNA technology. Dr. Berg is Cahill Professor of Cancer Research and Biochemistry, and Director Emeritus of the

Beckman Center for Molecular and Genetic Medicine at Stanford University. In addition, Dr. Berg serves as the Chairman of the Public Policy Committee of the American Society for Cell Biology.

Before we begin this panel, I want to urge all of you to confine your oral presentation to 5 minutes, if you can, so that we will have time for questions. Of course, we will put your full, extended comments into the record so that we can have them.

So we will proceed in the following order: Dr. Kass, Dr. Murray, Dr. Varmus, Dr. Usala, Dr. Mathews-Roth, and we will wind up with you, Dr. Berg, in the end.

Dr. Kass, we turn the time over to you, and thank you so much for giving me your book this afternoon. I really appreciate it.

STATEMENT OF LEON KASS, M.D., HERTOG FELLOW IN SOCIAL THOUGHT, AMERICAN ENTERPRISE INSTITUTE, WASHINGTON, D.C.

Dr. KASS. Thank you very much, Mr. Chairman and Senator Feinstein. I am very grateful to you for this invitation to present some of my thoughts on human cloning, a topic about which I have been thinking and writing for 35 years.

Mr. Chairman, I share your views that human cloning is immoral, as I also share your wish to advance ethical approaches to regenerative medicine. Human cloning constitutes unethical experimentation on the cloned child-to-be, confounds his genetic and social identity, represents a giant step toward turning procreation into manufacture, and would be a despotic attempt of parents to select and control the genetic makeup of their children.

I conclude that human cloning threatens the dignity of human procreation and that it should be banned. The question is how best to do it effectively and ethically, with as little interference as possible to potentially beneficial biomedical research.

With all due respect, I regret to say that the approach proposed in Senate bill 303 will not, in my opinion, do the job that we want to have done. It offers an ineffective and even counterproductive means of preventing the cloning of children. It is ethically problematic. It offers inadequate regulatory safeguards. And, in truth, I think it is unnecessary for advancing the mainstream of stem cell research, both embryonic and adult, about which the bill is, in fact, largely silent.

Before trying to back up some of these claims, I want to speak first about the matter of terminology because the ethical discussion we need to have is obscured by some confusing language in the bill.

Whether undertaken for the ultimate purpose of producing children or for the purpose of extracting stem cells for research, the deed of nuclear transplantation itself is an act of cloning. This is the deed that produces the genetic replica and its product is in both cases identical. The product is a cloned human embryo. This is the view of the earlier NBAC, and also of the current President's Council on Bioethics, including all of the members who actually support the kind of cloning for research that this bill would endorse.

When identical cloned embryos are grown to the blastocyst stage, their different fates depend solely on the purposes of the human users—baby-making or research. The language of the bill

"unfertilized blastocyst" is confusing and has no scientific currency or basis. And its definition as, quote, "intact cellular structure" hides the fact that this structure is a self-developing embryonic human organism.

We should, of course, then have arguments, scientific and ethical, about why it would be important or permissible to create such cloned human blastocysts solely for research. But if we are to have that argument forthrightly, we should not hide from ourselves or others what we are doing and we should not try to win this moral argument by definitional sleight of hand.

Here, then, would be a summary of my reasons for believing that a ban that tried to block cloning to produce children, while permitting cloning for biomedical research, is a bad idea and why I support a comprehensive ban on all human cloning. I have four arguments. I will summarize the large points. The details are in the written testimony.

First, I regard this approach as ineffective and counterproductive. If wants to prevent the development of anthrax bombs, we do best to block the production of anthrax spores, not just their transfers to a weapon delivery system.

Similarly, if we mean to be fully serious about stopping the cloning of human children, we should try to stop the process before it starts, at the creation of the embryonic human clones, not merely rely on efforts to prevent their transfer to women for delivery.

A law such as S. 303 that tried to prevent cloning babies by banning only implantation of cloned embryos would be ineffective and unenforceable. It would be difficult to know when the law had been broken; it would be impossible to enforce it once it had. Further, by endorsing cloning for research, such a law would, in fact, increase the likelihood of cloning to produce children because it would allow the technique that was required to be perfected in the process.

Second, I regard this approach to be ethically problematic. Allowing cloned embryos to be produced for biomedical research and stem cell extraction is highly problematic. It crosses several important moral boundaries, accelerating our slide down a slippery slope into a dehumanizing world of genetic control of offspring and the routine use of nascent human life as a mere natural resource.

I would single out only one of the subordinate points for your attention. The use of cloned embryos in research, once allowed, will be impossible to limit. The arguments that are now used to justify creating cloned embryos to produce stem cells will also justify growing these embryos beyond the blastocyst stage. Experiments already done with cloned cow embryos have shown the possibly greater therapeutic value of fetal tissue derived from later stages. Any boundary you now try to set up here will be overridden by scientific events.

Third, I believe that the regulation that is proposed in this bill is inadequate, given the unique status and dangers related to the creation of cloned embryos. They fall far short of the regulatory recommendations even of those members of the President's Council on Bioethics who are in favor of doing cloning for research.

Last, and this would be a long discussion, I think that cloning for biomedical research is unnecessary for promoting the main-

stream of regenerative medical research. The benefits of embryonic stem cell research in both knowledge and potential therapy do not require the creation of cloned embryos or stem cells from cloned embryos.

The putative benefits of cloning research are at best speculative at present and it is unlikely to be the solution for the immune rejection problem. In contrast, a narrowly constructed yet complete ban on all human cloning would not interfere with stem cell research, adult or embryonic, using the cells derived from non-cloned embryos.

In sum, even if no single argument above is by itself decisive, their cumulative weight leads me to support a comprehensive an on all human cloning, including the cloning of embryos for research. Such a ban would be prudent, moral and virtually cost-free, and it is the only real ban on human cloning.

In contrast, a ban only on implanting cloned embryos would be imprudent and morally dubious and would likely yield little benefit that cannot be obtained by other morally unproblematic means. Purporting to be a ban on reproductive cloning, it would, in fact, increase the chances that cloned human beings would be born, and sooner rather than later.

If I might take 30 seconds to conclude, Mr. Chairman, a more general point on the current deliberations.

Chairman HATCH. Go ahead.

Dr. KASS. Opposition to human cloning to produce children in America is overwhelming. The vast majority of our fellow citizens, including most scientists, would like to see it banned. Nearly every Member of Congress has condemned it.

Yet, despite this near unanimity and despite the fact that bans on all human cloning are being enacted in many nations around the world, we have so far failed to give national public force to the people's strong ethical verdict. The failure of the last Congress to enact a ban on human cloning casts grave doubt on our ability to govern the unethical uses of biotechnology, even when it threatens things we hold dear.

If Congress fails again to act this time around, human cloning will happen here and we will have acquiesced in its arrival. It is my profound hope, Mr. Chairman and Senator Feinstein, that Congress will rise to the occasion and strike a blow in defense of human dignity.

Thank you for your attention.

[The prepared statement of Dr. Kass appears as a submission for the record.]

Chairman HATCH. Thank you, Dr. Kass. We appreciate your testimony.

Dr. Murray, we will turn to you.

STATEMENT OF THOMAS MURRAY, PRESIDENT, THE HASTINGS CENTER, GARRISON, NEW YORK

Mr. MURRAY. Senators Hatch and Feinstein, it is a great honor to be asked to speak before you today. What I say I will say with gratitude and respect.

First, briefly, I will address reproductive cloning. In the 6-years since the birth of Dolly the cloned sheep was announced, the eth-

ical case against reproductive cloning has grown ever stronger. For one thing, the scientific evidence on the dangers of reproductive cloning has progressed from informed speculation to hard evidence.

Scientists are beginning to understand the specific and powerful obstacles against reproductive cloning in primates. Indeed, one soon to be published study will indicate that using all the most advanced techniques in more than twice as many attempts as were used to make Dolly, there has been no success in cloning in monkeys. Trying to create a human child by cloning would be grossly unethical human experimentation. I think no one on the panel will disagree with that.

Furthermore, the reasons why anyone would want to try to do reproductive cloning are themselves dubious. The most sympathetic case for cloning to make a child is to try to bring back someone, perhaps a child who died. The sad truth is that this is an illusion. For one thing, reproductive cloning works poorly when it works at all. Most cloned mammals die before or shortly after birth. Those that survive are almost certainly abnormal because of failures to reverse and redo epigenetic programming or other problems.

If, despite the odds, a healthy child were born, it would be the same child only genetically. There is little reason to believe that this child would have the same personality, temperament, enthusiasms or interests as its progenitor. That child would live under a suffocating shroud of expectations that it would be just like the fantasy, really, of the child who was lost. And the parents would learn that there are no technical fixes for grief. Grief is a lifelong affliction that lies beyond the reach of science.

A law to ban human reproductive cloning, such as bill 303, would be useful not to deal with the plague of human clones. There is no such plague, and despite the claims of would-be cloners, we can be virtually certain that there are no human clones alive or likely soon to be born, no healthy ones at least.

We need the law to deny all legitimacy to that handful of entrepreneurs who are growing famous and wealthy with their ludicrous boasts to protect gullible, desperate, or hopelessly narcissistic people from exploitation, and most of all to prevent the almost certain harm befalling any child born through cloning. Such a law, I think, would be welcome by almost all Americans.

The ethics of nuclear transplantation in research with human stem cells presents a very different picture. The commission of which I was a member, which has now sunsetted, did a report that was issued in September 1999 on "Ethical Issues in Human Stem Cell Research." That report recommended funding for research on human embryonic stem cells derived from embryos left over after IVF, those embryos destined to be discarded and explicitly donated for research by the couple. That commission also proposed very stringent safeguards against commercialization and coercion largely consistent with, I believe, the language of 303.

An important point: The National Bioethics Advisory Commission in its deliberations consulted not merely philosophers, lawyers, doctors and scientists, but quite a number of theologians, including from four great religious traditions—Roman Catholicism, Protestantism, Judaism and Islam. We found a great range of moral views within some of those traditions and across them all. So to

equate having a religious view with a particular stance on human cloning or embryonic stem cell cloning is, I think, a mistake.

The ethical arguments in favor of not criminalizing nuclear transfer in human stem cells is straightforward. The most compelling reason is that this research may contribute, in time, to the relief of suffering and the postponement of untimely death.

Success is, of course, not certain. It is also possible that the greatest contributions to human health from research cloning will come from the basic research it makes possible as scientists create stem cell lines for an enormous variety of diseases, cell lines that may allow us to understand and ultimately treat or prevent those diseases. So nuclear transfer in human embryonic stem cells is not merely about transplantation, but a potentially incredibly powerful basic science model for the study of an enormous range of diseases.

What is sometimes overlooked is the deep human truth that suffering and death afflicts families, not merely individuals. Our lives are entwined with the lives of others whom we love. Their suffering and their death profoundly affects our own lives. When we minister to suffering, we minister not only to the individual, but also to all of those who love and care for her or him. Any one of us who has loved someone who has suffered or died knows the truth of this.

A second argument in favor of not criminalizing nuclear transfer in human stem cells appeals to our moral, legal and political traditions of freedom of speech and freedom of inquiry. Americans value the quest for new frontiers. Today's explorers are more likely to wear white coats and inhabit laboratories than to paddle canoes.

But scientific inquiry is also obliged to respect moral limits. That principle was resoundingly affirmed in the trials of Nuremburg and in our own Nation's apology to the subjects of the Tuskegee syphilis study. But when we have no consensus that a particular form of research is ethically improper, the wiser course is to allow people to follow their individual consciences. This respects the value of freedom of inquiry without forcing people to violate their own beliefs.

What reasons do people give for criminalizing nuclear transfer to create stem cells? Well, it is one thing to decide not to fund an activity because some Americans have moral objections to it. If we applied that principle broadly, there would be no funding of research on blood transfusion, or for that matter on transfusions themselves on the grounds that Jehovah's Witnesses object to transfusions, which they do. The same would be true of all research using animals because many Americans object to any scientific use of animals.

So it is one thing to object to funding and it is quite another to create a new Federal crime for doing what the majority of Americans do not find inherently wrong. We must acknowledge that morally thoughtful Americans are not of one mind on the moral status of 4- or 6-day-old blastocysts.

In my book, The Worth of a Child, I posed a challenge. Imagine some entirely new ethical argument or scientific fact that was introduced into the debate over the moral status of the embryo that persuaded almost everyone on the other side that they were wrong; they dropped their objection and they agreed with you.

Now, notice I didn't say which side of the argument this came down on because I cannot imagine such a new argument or new fact. This is, I believe, not because people are impervious to logic, but because our beliefs about embryos are woven into a complex tapestry of other beliefs, about what it means to be a woman, a man, a child, about the value of families, about the importance of being a nurturing parent. This tapestry of beliefs and commitments affects everything, from our attitudes toward sex discrimination in employment, to the importance of family leave, to education opportunities for women, and to the moral status of embryos.

Respecting the diversity of sincere and thoughtful beliefs about families, about women, men, children and embryos honors our most noble traditions. Where there is a clear and ringing consensus, as there is against cloning to create a child, let us act on it. Where there is a profound and principled disagreement, let our laws respect that.

Declining to fund research can be an honorable choice and a wise public policy, depending on the circumstances. But sending scientists to prison for 10 years and subjecting them to fines of $1 million or more devalues and dismisses the ethical views of the very many Americans for whom the possibility of alleviating suffering justifies research cloning.

Just yesterday, I was with Rabbi Elliot Dorff, who is the chief rabbi at the University of Judaism in Los Angeles. Rabbi Dorff informed me that the three major strands of American Judaism—the Reform, Conservative and Orthodox traditions—have jointly issued a teaching that research on human stem cells is not merely permitted, but obligatory, if it has any hope of dealing with human suffering, disease and death. We would be in a very curious position indeed if we passed a law that sent someone who was following what they believe their religious tradition requires them to do to prison for 10 years for doing so.

Thank you very much.

[The prepared statement of Mr. Murray appears as a submission for the record.]

Chairman HATCH. Thank you, Dr. Murray.

We will turn to Dr. Varmus now. We welcome you back to the Committee and look forward very much to hearing your testimony.

STATEMENT OF HAROLD VARMUS, M.D., PRESIDENT, MEMORIAL SLOAN-KETTERING CANCER CENTER, NEW YORK, NEW YORK

Dr. VARMUS. Thank you very much, Mr. Chairman and Mrs. Feinstein. Thank you for a chance to discuss the contentious issues that have been raised by the possibilities of human cloning.

Two bills are now before the Senate which seek to ensure ethical behavior in this new research arena. Both bills would ban efforts to create cloned human beings, an appropriate prohibition given the unsafe nature of the procedure you have heard detailed by Dr. Murray.

However, the bill by Senator Brownback and his colleagues would set an unfortunate precedent. It would criminalized scientists, doctors and patients who pursue the benefits of some parts of cloning technology, even if those steps were taken without any

intention of making a cloned human being. Your bill, Mr. Chairman, would allow those benefits to be pursued under the kinds of regulatory guidelines that have worked well for medical science in the past.

Now, before returning to the legislation, let me briefly outline, at your staff's request—I hope this will allow me to have an extra minute or two—the science involved, beginning usefully with the widely practiced procedure of in vitro fertilization, shown on the first chart.

In IVF, as in normal human reproduction, a single sperm fuses with or fertilizes an egg in a dish, forming a cell that divides several times to produce an early embryo called a blastocyst. At this point, the cells are disordered; they lack any characteristics of specific organs or tissues.

Now, if the blastocyst is transferred into the uterus, a pregnancy may result, and after a complex process of development a child might ultimately be born. If, instead of implanting the blastocyst, its immature cells are grown in a culture dish, as shown on the far right, they can divide and under appropriate circumstances can develop into various kinds of cells and tissues.

Now, these so-called embryonic stem cells are a valuable by-product of IVF and have enormous potential, as you have heard, for discovery and therapy. Fortunately, for the hundreds of thousands of families with children born as a result of IVF, this procedure was not banned and it was not criminalized when introduced in the 1970's, even though it was obvious even then and known in practice now that many blastocysts would remain unused and might eventually be discarded, as indeed they are today.

Likewise, it is permissible to derive embryonic stem cells from blastocysts without imposition of criminal penalties as long as Federal funds are not used. In fact, some existing stem cell lines can even be studied with Federal funds, with regulatory oversight.

Now, unlike IVF which begins with the union of sperm and egg, cloning begins with the transfer of an intact nucleus from a mature cell to an egg from which the nucleus has been removed. That is shown on your left.

As experiments with animals have shown, this procedure can, surprisingly to all, generate a blastocyst that is similar or identical to the one produced by fertilization. And if this unfertilized blastocyst were transferred to a uterus, development into an infant could conceivably occur, although judging from animal experiments, as you have heard, inefficiently and imperfectly.

Embryonic stem cells can also be generated from these blastocysts for study and therapeutic use, as they would be after IVF, but with the important advantage that they could usually be transplanted without rejection to the individual who donated the nucleus.

So, Mr. Chairman, let me return to the question of why I am unhappy with the bill proposed by Senator Brownback and happy with yours. Most importantly, his bill would ban all of the steps shown in that second chart. Your bill would selectively and judiciously ban only the transfer of an unfertilized blastocyst into the uterus, preserving the benefits and forbidding the abuses of these methods.

But there are also four other issues I would like to mention briefly. First, I am troubled by the precedent of imposing criminal penalties on scientists, doctors and patients, even on patients who might return after treatment abroad.

In the past, we have had ethically-sensitive science regulated in a variety of means, by Federal guidelines, for example, for work on recombinant DNA where Dr. Berg had a major role, and on gene therapy; regulated by prohibitions on the use of Federal funds, for example, as we have today with embryo research; or by classification, as for military research.

Criminalizing the science I have described is unnecessary, unjustified and unprecedented. Further, by threatening to impose fines and imprisonment on well-meaning scientists, it sends a signal that could undermine the confidence of our remarkable research enterprise in this country.

Second, legislative solutions tend to be inflexible, so rapidly changing science is a poor target for legislative remedy or control. The NIH and other Government agencies have shown repeatedly that they are well-equipped to oversee ethical conduct in research.

Third, advocates for the Brownback bill, for the complete ban on all steps in nuclear transfer, have obscured the profound differences between studying immature human cells in a culture dish and making a cloned human being. Unlike the allegations made by Dr. Kass, there is no slippery slope here. The boundary between the two activities is broad and unambiguous. Federal rules and medical guidelines can easily delineate them.

Under your bill, Mr. Chairman, crossing that clear boundary by trying to introduce cells into a uterus could lead to prosecution. The regulatory guidelines under your bill would require responsible Government oversight by the NIH or others, informed consent by cell donors, a 14-day limit on the growth of early embryos, physical separation of this activity from IVF clinics, and other things.

Finally, the draconian legislation proposed by Senator Brownback and others shows inadequate appreciation for the pace and difficulty and for the long-range promise of science. Let's face it, we are just beginning to understand how a fertilized egg develops into a mature organism. Embryonic stem cells derived from fertilized and unfertilized blastocysts have incredible potential to tell us how the instructions for making an organism are laid down, how they can be reversed, how they might be reconstituted, for example, to convert liver cells to nerve cells.

Now, if we pursue such studies, we will discover great truths, and later use those truths in ways that are now difficult to predict to benefit patients who suffer from disease and disability. But if we don't, somebody else somewhere else surely will.

This year's 50th anniversary of the discovery of the DNA double helix provides a vantage point for thinking about these problems. In 1953, it was evident that DNA embodied genes and that its structure was profoundly significant, but it was very difficult to know what we would learn by studying it.

Fortunately, no one proposed that studies of human DNA ought to be banned. But if there had been prohibitions on the study of DNA, we might not now, 50 years later, have, for example, a vaccine for hepatitis B virus, drugs to protect the bone marrow of pa-

tients undergoing cancer therapies, tests to alert people to their risks of certain diseases, or a powerful new way, Mr. Chairman of the Judiciary Committee, to exonerate people who have been falsely imprisoned.

With recent advances in the study of cells and the human genome, we have now, in fact, arrived at the starting line in a race to understand biology and to help the disabled with that knowledge. It is too early to know how to get to the finishing line, whether it is through embryonic stem cells derived from fertilized or unfertilized blastocysts or from adult stem cells.

So I must finally ask why should any Member of Congress wish to punish those who wish to learn and to treat when we have so much more to learn, and who has such moral authority that they would impose on our pluralistic society an ethical standard that only a portion would endorse?

Thank you, Mr. Chairman, for my chance to express these views and I will be pleased to answer any questions you might have.

[The prepared statement of Dr. Varmus appears as a submission for the record.]

Chairman HATCH. Thank you so much, Dr. Varmus. We appreciate having you here.

Dr. Usala, we will turn to you.

STATEMENT OF ANTON-LEWIS USALA, M.D., CLINICAL PROFESSOR AND MEDICAL/ADMINISTRATIVE DIRECTOR, OFFICE FOR REGULATORY REVIEW OF CLINICAL TRIALS, EAST CAROLINA UNIVERSITY, GREENVILLE, NORTH CAROLINA

Dr. USALA. Thank you, Senator.

In order to replace the function of destroyed patient tissues in human disease, cellular transplant material obtained from developing cloned embryos must first overcome the problem of appropriate integration into the transplant site. Without such integration, recovery of clinical function is not possible.

Scientifically, it may make more sense to induce the patient's own tissues to replicate at the injury site. If the patient's own tissue could be induced to regenerate the site of injury, the communication and integration networks are already in place.

I would like to share with the Committee the preliminary results of a product I developed while with my first biotech company which I left 18 months ago and currently have less than a 1-percent equity interest in.

My hypothesis was that exposing cells to an environmental structure similar to that present during natural embryogenesis would induce the same explosive generation in tissue even in already mature cells, as the DNA template remains the same from the point of conception until death.

This injectable material was made from modified naturally-occurring cow pounds synthetically polymerized to give the desired structure. The product contained no cells, only structures that patient cells would bind to upon injection at the damaged tissue site. The results I am about to show have been presented at several scientific meetings and have been recently submitted by the principal investigator from the University of North Carolina at Chapel Hill to a peer-reviewed journal.

Shown is an example of the rapid wound healing induced in a dog that had naturally-occurring diabetes and had developed multiple full-thickness skin ulcers, similar to foot ulcers seen in diabetic human patients. The ulcers would not heal because of the chronic destruction of blood vessels commonly seen with long-standing diabetes.

After a one-time injection of the artificial embryonic scaffolding, the wounds healed with regenerated tissue. And as you can see on the left side of the screen, we injected around the periphery of the lesion on that particular ulcer which was full thickness down to the bone. Within 6 days, it had generated skin and hair follicles. I was excited about the hair follicles. The new tissue resulting from exposure to the embryonic-like matrix was determined to be structurally identical to non-wounded areas.

This photo micro graph shows the result of injecting this synthetic biopolymer into an adult dog's liver. After 3 weeks, the section of liver was removed and brought to Dr. Ron Dudek, a medical embryologist, for interpretation. Shown are cells that have the appearance of undifferentiated mesenchymal cells morphologically similar in appearance to stem cells apparently associated with differentiating fibroblasts and more mature endothelial cells. Endothelial cells are the cells that make up blood vessel walls.

Nucleated red blood cells found in large quantities only during fetogenesis are found in the newly formed blood vessels, apparently differentiating from the lining of the endothelial vessel wall. This process occurs only during fetogenesis as red blood cells, without nuclei, are made in the bone marrow later in development which does not exist early in fetal development.

Further large and small animal studies confirmed our finding, and a six-page feasibility study was reviewed by the Food and Drug Administration to examine the effect of a one-time injection in patients with chronic diabetes foot ulcers refractory to conventional therapy.

What we are looking here is the foot ulcer from our first patient who had diabetes for 20 years, and this ulcer was present for 4 years. The ulcer is down to the lining of the bone in the heal. Just to orient the audience, what we are looking at is the heal down to the middle of the slide and the toes would be off to the north side of the slide.

This is the appearance of the ulcer 15 minutes after the one-time injection. And, again, we injected the embryonic-like scaffolding around the perimeter and then through the center to try to get the damaged cells exposure to the embryonic matrix. Within 7 days, we had what we termed explosive generation of tissue. This has the morphology of fetal-type tissue, with the soft, glassy appearance.

Over the course of two or 3 months, the tissue continued to mature. This is at 2 weeks, 4 weeks, 2 months, and 3 months. Again, this was a man who couldn't really walk for 4 years because of the ulcer and he had gone every other week for that time to the University of North Carolina wound treatment center. Two months after this photo was taken, he was able to dance at his daughter's wedding.

Within days of a one-time injection, all the patients experienced rapid diminution of ulcer size, with apparent regeneration of skin,

blood vessels and surrounding structures. Because these are human patients, it was unethical for us to take biopsies, as these ulcers were unhealing before we injected our matrix. However, in large-animal studies we did confirm that we had new tissue that was morphologically correct for that area.

Since the new tissue derived from the patient's own tissue, there was seamless integration with no evidence of rejection. It is important to remember, however, that further study is required to determine if this particular product is safe and effective, but clearly the large-animal and human patient studies suggest cellular transplantation is not necessarily required to replace damaged tissue.

Shortly after conception, an individual is created with a new DNA template that begins the process of differentiation that continues until death. Transplantation strategies, whether derived from foreign donors or cloned cells from the patients themselves, are clearly not the only approach to replace damaged tissues. Such transplantation strategies require destruction of the newly formed individual DNA template.

Other avenues are further along in clinical trials in human beings and should be considered as a first approach for study that do not require destruction of a new human embryo. Indeed, the patient's existing cells provide the most rational source for fully integrating replacement tissues, as occurred during natural embryogenesis.

Thank you, Senators.

[The prepared statement of Dr. Usala appears as a submission for the record.]

Chairman HATCH. Thank you, Doctor. We appreciate it.

We will now turn to Dr. Mathews-Roth.

STATEMENT OF MICHELINE M. MATHEWS-ROTH, M.D., ASSOCIATE PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL, BOSTON, MASSACHUSETTS

Dr. MATHEWS-ROTH. As you were saying, I do work on a genetic disease called erythropoietic protoporphyria, but since nobody wants to say erythropoietic protoporphyria, that is why we call it EPP. I did develop what is the FDA-approved treatment for EPP, and my collaborators and I have cured the mouse model of EEP with gene therapy aimed at the bone marrow stem cells.

I also want to say that I want to make it clear that I am not speaking as a representative of either Harvard Medical School or the Brigham, but as an individual physician and medical researcher. My testimony wants to give you some scientific facts you should know about therapeutic cloning.

The science of embryology tells us that all human beings start their lives as one cell which we call the zygote, and I am sure the gentlemen here know that because they took embryology. The zygote of a cloned embryo, whether it is made for reproductive cloning or for therapeutic cloning, is the egg donor's oocyte whose nucleus was removed and to which the nucleus of the person to be cloned was added.

So it is scientifically incorrect to say that a human life begins in the mother's womb. By the time the growing embryo, cloned or oth-

erwise, implants in its mother's womb, it is already about 5 days old and at the blastocyst stage of development.

Embryos growing in a mother or made by IVF or made by reproductive or therapeutic cloning go through the identical stages of development. In fact, the publication called "Scientific and Medical Aspects of Human Reproductive Cloning," put out by the National Academy of Sciences, shows in a diagram—and I have that as part of the hand-out that I gave you, and it shows that the development up to the blastocyst stage of an embryo which is made for reproductive cloning and an embryo made for therapeutic cloning is exactly the same. This is science, not philosophy.

At the blastocyst stage, all contain the inner cell mass which is the group of embryonic stem cells. There is some differentiation between the inner cell mass and the layer around the inner cell mass, in that there are some antigens that are present in the outer layer that are not present in the inner cell mass. The outer layer of the blastocyst which is broken open is what is going to become the placenta. So there is a difference. There is already differentiation between the inner cell mass cells and the cells around the outside of it.

Now, the important thing for everybody to realize is that presently the only way that embryonic stem cells can be obtained from any embryo is to break open the embryo of usually 5 to 7 days of life and remove them. This obviously kills what we know from science is a growing human being, a very young human, but nevertheless an individual member of our species.

I want to point out an error in the S. 303 bill which I think was alluded to by Dr. Kass. There is no such thing as an unfertilized blastocyst. The somatic cell nucleus of the person to be cloned which was put into the oocyte was formed by fertilization. That nucleus has its full component of 46 chromosomes, as does the nucleus of every cell which will form when the cloned zygote starts to divide.

So a cloned baby or cloned cells for therapeutic cloning has two genetic parents, the mother and the father of the nucleus donor. The clone is essentially an identical twin of the nucleus donor. There is no such thing, as I say, as an unfertilized blastocyst or an unfertilized egg. If there is an unfertilized egg, it is got half the number of chromosomes that you and I have.

Cells and tissues derived from cloned embryonic stem cells can still cause problems in the recipient of the cloned material, and this again was pointed out in the National Academy of Sciences' report. They can cause immunologic rejection problems, and this is caused by the mitochondria in the cloned tissue which comes from the egg donor's cell. So they are foreign to the recipient.

Mutations and imprinting and programming errors occurring in the early cloned embryo—and they will occur in any early embryo and these would be transmitted to the cloned cells and the cloned tissues.

In addition, everybody knows that teratoma formation, these odd tumors, are very common to embryonic stem cells when you transplant them into animals, and these still exist with cloned embryonic stem cells. In fact, there is a recent paper—I think it is just with embryonic stem cells, though—that they transplanted some

embryonic stem cells into knee joints of a rat, I believe, and ended up getting whopping teratomas which made the poor little rat lose its legs.

Physicians are obliged to give complete and accurate information about treatment options to their patients. So patients receiving IVF embryo-derived or therapeutic cloning-derived stem cells will need to be clearly informed that a very young human, and in the case of therapeutic cloning their very young identical twin, will need to be killed to obtain the stem cells needed for this treatment.

I notice that this was not mentioned—informed consent to the recipients was not mentioned in this bill. Now, interestingly enough, the society that is concerned with IVF, the American Society for Reproductive Medicine, has a statement that says, "Couples should also know that ES cells research typically involves deriving cells from the inner cell mass of an embryo at the blastocyst stage which leads to the embryo's destruction."

I will repeat that: "that ES cells research typically involves deriving cells from the inner cell mass of an embryo at the blastocyst stage which leads to the embryo's destruction." So they are saying parents who donate their embryos should be informed that embryo research kills what we all know from embryology is a little growing human.

The people who receive cloned tissues should also be informed of this. If these facts are withheld from the patients, then the physicians are being intellectually dishonest and the scientists are being intellectually dishonest if they don't inform people about the fact that they are getting products that are being made unfortunately by the killing of a member of our species. They will have failed in their obligation to the patients to provide enough information so that patients can give truly informed consent to their treatment.

As a physician doing research and dealing with patients like this, I know, and I am sure Dr. Varmus knows because he is—you are practicing, aren't you?

Dr. VARMUS. No.

Dr. MATHEWS-ROTH. You are not, okay; you are in research.

But those of us who deal with patients know how important it is to give our patients all the information they need to make truly informed consent. We can get into trouble if we don't. In fact, some patients may choose not to undergo stem cell treatment if they learn that killing a young human is involved. And if they find out after the fact, if the scientists weren't honest enough to tell them that, they may be angry enough to sue their doctors. And if you think we have got problems with malpractice now, this is going to add to it. So I think this is a very serious thing.

It is to everyone's advantage that potential patients be informed that to obtain stem cells, a young growing human being has to be killed. So are we denying treatment to our patients if we deny them the use of embryonic stem cells? I don't think so.

Certain kinds of adult stem cells can be transformed into many kinds of cells needed to treat serious diseases, not just stem cells that are characteristically found in one organ. There are some bone marrow-based stem cells that have indeed been shown to be able to be transformed into many different kinds of organs, and this is not fusion and it is not some little laboratory's strange finding.

For example, Dr. Catherine Verfaillie has discovered what she calls multipotent adult progenitor cells in human and mouse bone marrow which can be made to differentiate into cells from all three embryonic layers. I heard her not too long ago at Harvard and she really thinks that these have great possibilities to make a lot of different organs. They don't form teratomas. They can multiply extensively.

In fact, this was one of her points that they can multiply, and she showed a comparison slide between them and embryonic stem cells and they can do, as far as expansion and things are concerned, just about what embryonic stem cells can do. So they have this great potential and they multiply a lot, and they do this without losing their potential to differentiate into different tissues.

This is one of the problems I have with hematopoietic stem cells right now, that if I try to expand them, they end up differentiating to red cells or white cells and I really don't have enough time to put my gene therapy stuff in. I have a small window and I can only just transform so many. But with her MAPCs, you can grow them and make lots and lots of the undifferentiated cells. So you would have a greater opportunity to transform them with the gene therapy that you want to do, with the genes that you want to add. So these are cells that have a lot of promise to them.

Dr. Eliezer Huberman, for another example, has found a cell from peripheral blood which can also multiply easily and can be differentiated into endothelial cells, nerve cells and liver cells. So here is another example of another kind, and there are many in the literature. Papers come out everyday. I mean, it is hard to keep up with the literature. Reviews are being written, new papers are coming up. It is hard to make definite statements, oh, embryological stem cells are better than adult stem cells. Time will tell. But the unbending embryological fact is if you take an early embryo, you are destroying a human life. And this is not going to change; this is not philosophy, it is embryology.

To summarize, do we as a country, and especially people with diseases who might be helped by stem cell therapy, really want to sanction the practice of deliberately starting the lives of members of our own human species for the sole purpose of killing them to harvest their useful parts, especially when there exists the alternative of using adult stem cells?

If you check the literature on adult stem cells, you will find that, at least in animals and starting in humans, one can make with them the different kinds of cells that people really want to use in therapy, like heart cells. There are some examples of pancreas being made; also, blood cells and different kinds of cells. There are other examples of other kinds of adult stem cells that you could harvest that will differentiate. So, again, this is a tough ethical question. Do we want to justify this?

So I will close with say you, our legislative leaders, had better think long and hard about this because if you allow, by law, the production of embryonic stem cells from either extra IVF embryos or from embryos made by therapeutic cloning, you are going to be sanctioning this killing of early humans.

Now, it is hard to say at this point whether embryonic stem cells or adult stem cells are going to be better, but I would say work

with animals, work with primates, see what you can do in primates, see what you can do in mice, and work like heck with adult stem cells. But remember that if you do this in humans, you are killing members of our species.

I know a lot of the scientists who are working with adult stem cells will just say, oh, but I still think we ought to keep on working with embryonic stem cells. It is still killing humans. Do we really want to get into that?

Thank you.

[The prepared statement of Dr. Mathews-Roth appears as a submission for the record.]

Chairman HATCH. Thank you, Doctor.

Dr. Berg, you have your work cut out for you here, and I want to know if you differ with Dr. Mathews-Roth.

STATEMENT OF PAUL BERG, CAHILL PROFESSOR EMERITUS OF CANCER RESEARCH AND BIOCHEMISTRY, STANFORD UNIVERSITY MEDICAL CENTER, PALO ALTO, CALIFORNIA, AND CHAIR, PUBLIC POLICY COMMITTEE, AMERICAN SOCIETY FOR CELL BIOLOGY

Mr. BERG. Well, one of the disadvantages of being last on a panel of six is that everybody has said some of the things that I wanted to say. I will be brief, but I do want to specifically address Dr. Mathews-Roth's comments.

First of all, let me just say that the congressional and public debate about cloning people is, I believe, a non-issue. Very few, if any, reputable biomedical scientists condone attempts to produce a cloned human being. A distinguished National Academy of Sciences panel that considered this issue concluded that it is dangerous and likely to fail, as we heard from Dr. Murray.

In short, the risks to the mother and any fetus that would result from the procedure are unacceptable. If for no other reason than this, your bill, S. 303, and Senator Brownback's bill, S. 245, are in agreement in mandating a legally enforceable ban on reproductive cloning.

Dr. Kass raised the issue of this impasse and allowing us to continue in a situation where there is no prohibition on that, and his concern, which is many people's concern, that this will move ahead if there is no such prohibition. So in one sense, we have the opportunity to agree on this one issue: We are all opposed to the cloning of human people and we ought to then produce legislation that will enforce that claim.

But in contrast to Senator Brownback's proposed legislation, your bill takes, I believe, a more enlightened position in permitting the somatic cell nuclear transplant procedure for research and therapeutic purposes. This research is supported by overwhelming scientific opinion because the technology may enable us to develop new forms of therapies for some of the most debilitating diseases and crippling disabilities.

Presently, there are only proofs of principle behind this optimism, but these strongly suggest that if scientists are permitted to explore these opportunities, their benefits can be achieved. I believe we are ethically and morally obligated to pursue them for the benefit of those who suffer.

Now, a particularly promising opportunity that is also foreclosed by the Brownback bill is the preparation of stem cells using cell nuclei from individuals with inherited mutations, particularly ones that pre-dispose them to an increased probability for developing a variety of life-threatening and debilitating illnesses in late life.

Examples include breast, colon, prostate and other cancers, as well as heart, neurological and autoimmune diseases. Such currently unavailable stem cell lines would provide a new way to explore how these life-threatening, late-onset diseases develop, and they could possibly generate clues to their prevention or cure. Such studies might help reveal the interrelations between inherited and environmental contributions that govern much of the balance between health and disease.

So in the end, I think, as was said earlier, we need safeguards, not a ban, and I think your bill includes safeguards as the predominate way to regulate this type of scientific research.

Both Congressman Weldon and Senator Brownback, and we have just heard Dr. Mathews-Roth, have accepted the assurances of their advisers that adult-derived tissue-specific stem cells—that is, specialized stem cells that already exist in many of our tissues—are sufficient for meeting the needs for therapeutic repair of damaged or diseased tissue. Many of these claims are contentious, for they rely on experiments that often have not been replicated and in some cases are known to result from artifacts.

But I believe here is not the place nor the time to debate the relative therapeutic prospects of adult-derived versus embryonic stem cells. There are scientific issues, there are deep issues, there are huge disagreements. Just as in the law profession, conjecture and hearsay are not considered evidence. Much of what we have learned and heard about adult-derived stem cells doing the magic wonders of curing everything are, in my view, still hearsay and conjecture. And unless they are replicated on multiple occasions and verified, I would not accept that adult stem cells can do the entire job.

Having said that, it is quite clear that the people who support—and I consider myself one of them—going ahead with embryonic stem cells are not opposed to work on human adult stem cells. The President, in his address on August 9, 2001, encouraged research along both lines. It is the people who are working with adult stem cells who want to prohibit work with embryonic stem cells.

I believe that most scientists working in this field recommend strongly, as do I, that research with both adult and embryonic stem cells should proceed vigorously, so as not to delay or forgo the benefits for patients. Just such a recommendation was actually made in a letter to Senator Specter last year by Dr. Catherine Verfaillie, whom Dr. Mathews-Roth cited as providing us with cells that are going to obviate the need for embryonic stem cells.

She writes, "It is far too early to say whether the adult stem cells will stack up when compared to embryonic stem cells in longevity and function. There are still too many unknowns for researchers or policymakers to begin closing doors to opportunities of learning."

Given the present state of our knowledge, I believe it is premature to choose one line of investigation over the other. Doing so could prove to be as great a historical embarrassment as when the

Soviets bet on Lysenko's prejudices against genetics and lost out on improving their own agricultural productivity and on an entire generation of genetic science and geneticists and scientists.

One justification for the criminalization of the nuclear transplant procedure is to guard against rogue attempts, or the slippery slope argument, to implant the product into a woman's uterus for the purposes of creating a cloned child.

But like any socially deviant behavior, we can discourage this with appropriate punishment. We punish murder under criminal statutes, but we fail to criminalized possession of the weapons used for the crimes. Prohibit what we all agree is presently an objectionable practice, but protect the means for producing life-saving therapies. And we should not be threatening to put people in prison for seeking cures for themselves or their children, even if those therapies were developed elsewhere.

Now, we take considerable pride in being a pluralistic society, so there must be ample room for differences concerning the moral and ethical interpretations of early and intermediate stages of human development. We have heard some of that debate from Dr. Murray and from Dr. Kass. I think we have to be very careful in not foreclosing or acknowledging these alternative and legitimate views because they can mean the difference between life and death for many of our citizens.

I want to point out that even on the President's Bioethics Commission which studied this issue for at least half a year, they still were split in their decision or conclusions. Forty percent of the members of that commission came down in support of somatic cell nuclear transplantation being permissible. That reflects in large part, I think, the kind of diverse views that exist in society.

I think Harold made an important point that, given that kind of split, dare we then foreclose for those people who are in dire need the opportunity to develop the cures? And I hold out that adult stem cells and embryonic stem cells don't at the present time tell us which is the better, but we should certainly not ignore or make a premature bet today on choosing one and then allowing 5 years to pass before we decide we have made the wrong bet.

Thank you.

[The prepared statement of Mr. Berg appears as a submission for the record.]

Chairman HATCH. Well, thank you so much.

Let me ask a question of the two Nobel laureates, Dr. Varmus and Dr. Berg. Some, including Senator Brownback and Representative Weldon and Mr. Jim Kelly this morning, suggest and sometimes assert, as you have said, that the scientific evidence to date suggests that adult stem cell research is sufficient or even appears to hold more promise than embryonic stem cell research.

I would like to know what the prevailing view is among scientists today—and both of you have as good a handle on that as anybody—and what, if any, are the unique advantages of embryonic stem cells, including stem cells that might 1 day be derived from nuclear transplantation research.

Can we go to you first, Dr. Varmus?

Dr. VARMUS. Thank you, Senator. Let me make a few points about this debate. Fundamentally, I think you have heard from a

few of us already that it is very difficult to say in this very short time that we have had to work on embryonic stem cells what will prove to be the most effective as a source of therapy in the long run. But let me just reflect on a couple of things.

First, it is important to point out that we, as physicians, have been using adult stem cells in therapy for some time for treatment, for example, of loss of bone marrow capacity. So we have known that you can take a cell that has the capacity to regenerate itself and to make a multiplicity of cell types—for example, different blood cell types—and use that in therapy.

We know that the adult has cells that regenerate and can make different kinds of cells, not all kinds of cells and not appropriate for treating most kinds of diseases, but for some. So there is a long head start here. There is no doubt that the study of adult stem cells ought to continue, and in a very vigorous way.

But let me make the more important point, which is that in my estimation one of the most remarkable things that has happened in modern science is the discovery that you can take a nucleus from an adult cell, put it into the environment of an egg and basically reprogram it so that it losses its ability to regulate expression of its genes in a way that was appropriate for the cell from which it came, wipes the slate clean and has the capacity to make cells of virtually any type. That is a fundamentally thrilling point of view that should inspire us to think about how it happens.

The reason I tried to emphasize the long view here, the fact that it has taken us 50 years to go from an understanding of the double-helical nature of DNA to have all these remarkable accomplishments that followed the study of DNA, is to point out that we have a long road ahead of us.

My dream is that we learn over the course of the next decade or two the way in which a cell nucleus can become reprogrammed, and that we develop very simply tools so that ultimately we can take a cell from an adult with a disease and reprogram that cell appropriately. We are not going to learn how best to do that if we follow only limited leads, restrict ourselves in our approach to the science and don't give ourselves adequate time to understand what it takes to make the kinds of contributions to science and to medicine that are never accomplished in less than decades.

Chairman HATCH. Thank you.

Dr. Berg?

Mr. BERG. Yes. I would like to just reiterate what Dr. Varmus just said particularly about the use of the hematopoietic stem cell. What has been shown is that you can isolate from bone marrow a specific type of cell which by itself, injected into animal whose bone marrow has been destroyed, repopulate the bone marrow and produce all of the blood cells. So we know the hematopoietic stem cell, which is an adult-derived stem cell, does, in fact, have the property of being able to differentiate into all of the blood cells.

But in experiments that have been done now several times, that cell is incapable of populating any other tissue in the body. The experiments have been done by introducing just a single cell into an irradiated animal, repopulating or reconstituting the bone marrow, and then searching every tissue in the body for any trace of derivatives of that cell. And the answer is none have been found.

What has been found is that there are artifacts which can explain a lot of the data that is out there because sometimes these derivative cells confuse with existing cells in the tissue. So when you looked at the fused cell, the occasional one that occurs, you think it is derived from the original input cell. But it is, in fact, not derived; it is a product of fusion. This has now been documented in a number of laboratories.

So many of the people who work in this field are now concerned that many of the claims that are out there are, in fact, artifactual. I think that has to be sorted out just like any other scientific issue on which there are opposing views or appears to be opposing evidence. But in the end, the way science proceeds is verification by duplication and continued repetition to establish that as a scientific fact.

We can't live with just conjecture and people giving lectures and claiming this or not, saying there is a paper in press, or it appears in a newspaper, or my uncle called me and told me that this is a possible cure. That is not science, and if we are going to make law on that kind of conjecture, then I think we would be making a terrible mistake.

Dr. MATHEWS-ROTH. Can I just add to that? I agree that there have been some papers that have shown cell fusion, but there have also been recent papers to show that there hasn't been cell fusion. And you can take indeed one—and it is not a hematopoietic stem cell; I think it is further back in the stem cell's evolution, more primitive—that can indeed not only form hematopoietic tissues, but have been found in other tissues in the body.

And again going back to our mutual friend, Catherine Verfaillie, she has shown that her MAPCs, without fusion, can form cells that are characteristic of tissues of all of three embryonic layers, what they call endoderm, ectoderm and mesoderm. And these studies—some of them have been confirmed, some of them have not. This is true.

Dr. Berg is right. There are some specialized stem cells in almost each tissue that will only make that tissue, but we have as adults also non-specialized stem cells which have a repertoire of being able to make a couple of different tissues. And it is not fusion; it is just a characteristic of these a little bit more primitive cells.

And I want to assure Dr. Berg that people who are interested in stem cells aren't afraid of competition from embryonic stem cells. I think what should happen is the ideal situation would be at this time ban embryonic stem cell work on people; work with the lines that are already available, don't make new ones. Don't make embryos to kill them, but work with animals, do the same experiments that you would want to do in primates, especially primates, because we are primates. Let's face it, monkeys are our closest relatives. If it is going to work in a monkey, it will probably work in man.

With all due respect to the animal rights people, I think it would be better to sacrifice animals than growing little humans. No matter what you want to do, you have to remember the basic principle of embryology: you are still killing a growing human if you are going to work with a blastocysts, with these early cells.

Chairman HATCH. Dr. Berg, you seem to indicate that you disagree with some of——

Mr. BERG. I am sorry. I didn't hear that.

Chairman HATCH. Were you in agreement with what Dr. Mathews-Roth said?

Mr. BERG. She said a lot of things that I am not in agreement with, but are you saying——

Chairman HATCH. I saw you shaking your head and I thought you were in disagreement.

Mr. BERG. One of the things which I neglected to mention, unfortunately, is hematopoietic stem cells which can do this wondrous thing of repopulating bone marrow cannot be grown at the present time.

Dr. MATHEWS-ROTH. That is right, they can't.

Mr. BERG. There is no way to propagate them.

Dr. MATHEWS-ROTH. Yes.

Mr. BERG. Most of the so-called adult-derived stem cells have not been grown. There is no way to amplify them to be able to even use them for therapeutic purposes. There is good evidence that some of the cells which reside in the various tissues are circulating most of the time. So when people take bone marrow and then use the words "stem cells," they are using the words to describe a complex mixture which we really don't have well characterized. I almost likened it one time to studying sewage and calling it E. coli.

But, in fact, the bone marrow probably contains a variety of cells that are there transiently. And these may be the ones that give these very low repopulation results that have been found, but they can't be propagated. So as a therapy, one would have to solve the problem of how could you propagate these adult stem cells so that they could, in fact, be used therapeutically.

Dr. MATHEWS-ROTH. Well, Catherine Verfaillie has solved that.

Mr. BERG. Hold on for a moment, please.

Dr. MATHEWS-ROTH. Yes.

Mr. BERG. The virtue of the embryonic stem cells is you can propagate them virtually indefinitely. You can freeze them away, you can recover them, and you can invariably differentiate them, providing the appropriate cues, so they differentiate into different kinds of tissues.

There are a number of papers that are clearly published which show that one can, in fact, generate beta islet cells which can, in fact, treat animals that are diabetic. You can regenerate a severed spinal cord with embryonic stem cell-derived neural cells, and you can do the same thing with curing Parkinson's disease by appropriate neural cells derived from stem cells. So you can grow stem cells and learn how to differentiate them into different populations.

Chairman HATCH. Let me interrupt for a minute. I can't imagine anybody not being willing to go ahead and proceed with adult stem cell research. Naturally, we all want to do that. I mean, that is a given.

I asked Senator Brownback to submit for the record his whole notebook of studies which he relies upon in concluding that adult stem cell research is the only way to go. I wonder if all of you would work on helping to coordinate an analysis of these particular

studies by recognized and fair experts, and compare them to the opportunities for embryonic stem cell research.

I understand that NIH and NAS have issued similar assessments in the last few years, but could you help us to be more certain that we are up to date by looking at and evaluating the particular information that Dr. Weldon and Senator Brownback rely upon so that we can be certain that we have the best knowledge we possibly can?

Mr. BERG. We are in science, Senator. We are not in certainty.

Chairman HATCH. But to the extent that you can help us——

Mr. BERG. I mean, to ask for certainty today is asking for something that is not available. They are both promising and we should be pursuing both. We needn't make a bet today.

Dr. VARMUS. Senator, I think it would be appropriate for people to make an evaluation of that kind, and if we were given the notebook I am sure we would be able to put together——

Chairman HATCH. We will get that to you.

Dr. VARMUS. But I would point out to you that we are not going to give you an answer that will be ironclad, and that is the case because these problems are incredibly difficult. The idea of trying to make a hematopoietic stem cell that can grow is a big problem. The difficulty of learning how to differentiate an embryonic stem cell so it becomes all the tissues we would like it to become has been plaguing science for the last several years, and indeed being pursued not just with human stem cells, but also with animal stem cells.

So I think the plea that you are hearing from the scientific community is we don't know where the best answers are going to reside and we would encourage you to keep as many doors open as possible.

Dr. MATHEWS-ROTH. But then again we still have the issue with the killing and, as I say, do the animal work.

Chairman HATCH. I have that point.

Dr. Kass?

Dr. KASS. Senator, if I might, a lot of this discussion over the last 10, 15 minutes has been about stem cells, embryonic versus adult. I wouldn't want you to understand anything that I said to be taken——

Chairman HATCH. Let me interrupt you just for 1 second.

Dr. KASS. Please.

Chairman HATCH. Where I have always had some problem here is, first of all, although I agree that the blastocyst is a living cell, a human cell, I have a real difficult time believing that it is a human being until it is implanted in the mother's womb. Now, it has the potential of becoming one. We all know that, but it doesn't have a chance of becoming a human being without being implanted in a womb.

I accept that, and I accept Dr. Mathews-Roth's feeling that she is right on this and you are wrong. I agree with you, however. I just don't think that we should foreclose what scientists have told me is the most promising avenue of research in their lifetimes that might help hundreds of millions of people in our country, or over 100 million people in our country, and perhaps billions around the

world to alleviate pain, suffering and difficulties. That is also pro-life, in my view.

I thought, Dr. Kass, you made some very interesting ethical remarks in your discussion here today. We have discussed ways to find common ground on this issue. You and I spoke in my office about a hypothetical development that, as I recall, you did find at first blush at least morally troublesome.

One way to maybe test the hypothesis is to just ask you this question. Of course, you say whatever you were going to say. I just had to interrupt for this reason and the question would be this: If an egg could be rendered incapable of implantation or of implanting in a mother's womb by a chemical or genetic manipulation of a haploid egg cell, could you personally view the process of somatic cell nuclear transfer in another light?

In short, if the cell produced for nuclear transplantation could not implant due to manipulations made before the somatic cell nucleus was introduced into the non-implantable egg, are the ethical concerns bridged under those circumstances?

Dr. KASS. I missed the verb. Are the ethical concerns——

Chairman HATCH. Are the ethical concerns bridged in that regard? Given the recent reports in the scientific literature about new insights into how blastocysts affix to the uterine wall, I think one could imagine the day when scientists would reverse-engineer—am I on the right track here—and render an egg incapable of implanting? Now, if that were so, would that be as ethically troublesome to you, or would that be as ethically concerning to you?

Dr. KASS. Certainly, some of my concerns having to do with this matter would be alleviated. I mean, after all——

Chairman HATCH. That is my understanding.

Dr. KASS. Some. Others, I think, might——

Chairman HATCH. But you are still worried about renegades doing full cloning?

Dr. KASS. Well, what I want to say is that we seem in the discussion to have gotten the cloning question mixed up with the stem cell question. The bill, as I see it, is primarily about cloning for reproduction and what I would prefer to call cloning for biomedical research. Nothing that I——

Chairman HATCH. One of the problems I have—I keep interrupting you and I apologize, but this is a matter of great concern to me. One of the problems I have is if we don't have NIH involved and we don't set the moral and ethical standards for this research, then others are going to do it all over the world. This is going on now, and I would rather have our country lead the way and set the standards and the parameters pursuant to which this kind of research can be done. If we don't do that, then I guarantee you you are going to have the results that you are talking about that we all would deplore.

Dr. KASS. Senator, we agree on the principle that the United States has to be not only the leader in biotechnology, but the leader in the ethical uses of biotechnology. This has been a big division. Many nations around the world are, in fact, passing a ban on all cloning even in those countries where they are encouraging and permitting and funding embryonic stem cell research. I think it is

a mistake to get the embryonic stem cell research mixed up with cloning.

Chairman HATCH. But how do we get all these other countries to conform to our point of view without setting the moral and ethical standards ourselves through the most recognized and most important research agency in the world, the National Institutes of Health? The very thing that you are concerned about ethically is going to happen if we don't do the basic, necessary things that should be done here.

Dr. KASS. We are in agreement. I am not one of these people who thinks you have to choose between adult and embryonic stem cell research. I am in favor of allowing both of these things to go forward. It is too early to tell which of these lines will prove most promising.

Chairman HATCH. But, again, on these lines—well, I am sorry. Go ahead.

Dr. KASS. But I want to distinguish between embryonic stem cell research from in vitro fertilized embryos and the creation of cloned embryos for research. They are different.

Chairman HATCH. Okay, they are different and let me tell you why I find that. It is true that when I got into this, my major argument was that since these fertilized eggs are going to be discarded anyway, why wouldn't we utilize them for the benefit of mankind?

Dr. KASS. Right.

Chairman HATCH. And I think we would have gone a long way had the President allowed that type of research to go forward with fertilized eggs that were going to be discarded anyway. But as I understand it, he limited it to 70 stem cell lines worldwide, or at least in this country. In practicality, those are basically Caucasian stem cell lines. They are not diverse stem cell lines.

I have been led to believe that there may be as few as nine that are functional because of intellectual property concerns, patent concerns, and a whole variety of other high-technology and informational technology concerns. I have also been led to believe that if we take—and I would like you all to help me understand this better, but if we take even the somatic cell nuclear transfer-changed eggs, we actually could reach a point where you would never have to use a mother's egg again. But that would take 3, 4 or 5 years of very intensive work to be able to reach that point.

Dr. KASS. That could be done first in animals, Senators.

Chairman HATCH. What?

Dr. KASS. Proof of that should be done in animals. It hasn't been shown.

Chairman HATCH. That may be, except for one thing, that the rest of the world is going ahead with this research and we could be left behind, with our greatest scientists in this area leaving this country to go where the research can be done. I am concerned about that.

Dr. KASS. That is technically not so. I mean, there are a few countries—Britain, China, Singapore, Sweden, Israel, I think, are——

Dr. VARMUS. Australia.

Dr. KASS. I am sorry?

Dr. VARMUS. Australia.

Dr. KASS. Not on cloning. Sorry. The Australians have imposed a ban, I think, on all cloning, including cloning for research, so has Norway, so has South Korea, so has France, so has Germany, so has Spain, so has Italy. The French and the Germans will probably come back to the UN to try to promote an international convention trying to stop all cloning, whether for research or for reproduction. It is true that the world is not of one opinion here.

See, if you start where I start that we should do whatever we can to prevent cloning for baby-making, the most secure way would be to stop that process before it starts. This is not just creating an embryo; this is creating a genetically-engineered embryo, the first one. And until somebody does the research which shows me that it is not just a promise of something but that there is a real likelihood, either in animal studies—that there is something for which this is absolutely necessary, because the matter is so grave I don't want to open Pandora's box, especially when the technique to practice cloning for research is going to make cloning for baby-making much more likely. They are going to perfect this.

Chairman HATCH. Doctor, I have tremendous respect for you. You know that. It is already opened. I mean, I read an article called "The First Cloning Superpower: Inside China's Race to Become the Clone Capital of the World." The Chinese pay an awful lot of attention to what we do, and so does everybody else in the world.

There are those, as you have mentioned—France, Germany—I would have preferred maybe a couple of other countries besides them.

Dr. KASS. I did.

Chairman HATCH. I know. I am just kidding.

Dr. KASS. South Korea, Australia, Canada.

Chairman HATCH. I would prefer not to use France and Germany at this time. I am only trying to be humorous.

The fact is that I am concerned that there are countries that are going ahead with all forms of cloning. And I agree with you and I agree with everybody on this panel that there should be no human cloning. That is the least we should do this year, but because we are involved in a fist-fight here over this, we may not even get that done.

Go ahead. I have interrupted you so much and I apologize.

Dr. KASS. No. I am enjoying this, Senator, if you don't mind. I mean, this is dear to me.

Chairman HATCH. You are saying you are enjoying it or you are——

Dr. KASS. I am enjoying the exchange and I am grateful for your generosity.

Chairman HATCH. Well, I am, too. I am just sorry I am interrupting you so much, but I want to go to Dr. Murray.

Dr. KASS. This is a momentous time in lots of ways, but it is a real question, Senator, whether we have the will and the capacity to give some direction to where biotechnology is taking us.

I have the greatest regard for our research. My reputation isn't that, but that is a mistake. I esteem biomedical research both in terms of its discoveries and its cures. I think it is a very bad thing

for the most part to have legislative interference with scientific research, a very bad thing.

Chairman HATCH. I agree with you, but we are pushed into doing this.

Dr. KASS. But there come occasions where the things which are at issue and which are being threatened suggest that if we leave it to business as usual, we might regret it. I would submit this is one of those cases where we shouldn't simply hope that if you let this genie out of the bottle, you are going to be able to control it.

Sure, rogues in China might do this, but they also buy and sell organs in other parts of the world and we don't follow suit even though it would save lives. We have the capacity to set an ethical standard without restricting very much of the research and allowing the embryonic stem cell research to go forward.

Chairman HATCH. But how do you do that, Doctor? First of all, the Brownback bill won't pass the Senate. There is no way that it has enough votes to pass the Senate. We have close to the 60 votes to pass this bill which would do away with reproductive cloning, but would permit the scientific research to go forward and would set moral and ethical standards for the NIH. And you would have the Federal Government involved.

Dr. KASS. It doesn't govern the private sector, Senator.

Chairman HATCH. It would have us involved all over the world, in the World Health Organization and everywhere else, to make sure that your fears would at least have a chance of being alleviated.

What we are going to wind up doing here probably is nothing, which means that the rogue countries where they are going to do this will be able to get away with it.

Mr. BERG. England is not a rogue country and they have opted for a regulatory process that oversees the legitimacy of the work——

Chairman HATCH. Well, I agree with that.

Mr. BERG [continuing]. Which is exactly what I think you are saying.

Chairman HATCH. Yes.

Mr. BERG. So it is being done and it can be done, and it can be done ethically and legitimately.

Chairman HATCH. Well, let me go to Dr. Varmus, and then I have got to get to Dr. Murray. I have been trying to get to him. He had his hand up here a while ago.

Go ahead, Doctor.

Dr. VARMUS. I think that one misconception that Dr. Kass is portraying here is the idea that if there were no legislation banning cloning, suddenly there would be a tremendous waterfall of human reproductive cloning. That is not going to happen. Even without legislation, it is not going to happen.

We all endorse the idea of having legislation, but the fact is it would be malpractice. You would have your pants sued off if you tried to do this because the great likelihood is it would be almost impossible to do it and if you succeeded, you would have a child deformed and you would be subject to tort law.

So the idea that there is going to be a dramatic increase in human reproductive cloning without a law is frankly in my mind

silly. If there are renegades who want to try this for publicity sake or something else, they will always be able to find a place to do this. What worries me about the argument is it is driving into an illegal state research that could lead to very important benefits.

I am trying to make the reverse argument, Dr. Kass, that you are setting up a straw man here that we are going to be inundated with human cloning exercises, and that that is the motivation behind a bill such as the Brownback bill that would cut off important avenues for productive research to help human beings.

Chairman HATCH. If the bill that we are talking about, the Hatch-Feinstein-Specter, et al, bill, passes, that bill would set criminal penalties for reproductive cloning.

Dr. VARMUS. Absolutely.

Chairman HATCH. It would set the rule in our country, at least. It would then designate NIH to set the standards that are moral and ethically proper in this.

Dr. KASS. It doesn't touch the private sector, Senator.

Chairman HATCH. What?

Dr. KASS. It does not touch the private sector.

Chairman HATCH. No, but nothing touches them now. It does apply the common rule to the private sector, sure, and we also touch it from a criminal law standpoint.

Dr. KASS. On the implantation, yes.

Chairman HATCH. Well, yes.

Dr. KASS. But on the research——

Chairman HATCH. We also apply the common rule. Frankly, if NIH is involved, the private sector can't afford to not work with NIH. I think your very moral arguments really can be fulfilled by having a bill that sets parameters, which is what we have tried to do with this bill and I think we have accomplished that.

I would like you to read it carefully. I know that you have studied this as much as anybody.

Dr. KASS. I will do so.

Chairman HATCH. And you have every right to your opinion, and I happen to respect you so much that the fact that we differ on this affects our relationship not in the least. But I can't imagine going another year without having some way of setting the standards that have to be set here. I can't imagine the right-to-life community not wanting that done. I can't imagine anybody who believes that human suffering ought to be alleviated not wanting to do something here that would benefit the living.

Dr. Murray, I said I would come to you next. I don't mean to be preaching to you, but I am just saying it is flabbergasting to me that this is—go ahead.

Mr. MURRAY. It is flabbergasting to others as well, Senator, myself included. It is always dangerous to do philosophy after 3 p.m. because people fall asleep. I will try to do it very quickly.

There are really two kinds of arguments being put here against nuclear transfer and embryonic stem cells. The first is the argument that Dr. Mathews-Roth has repeated several times in her testimony, namely that the creation of stem cells—and this is about all stem cells—is killing them to harvest their useful parts. That is against all forms of human stem cell research.

I think I need to grant Dr. Mathews-Roth the sincerity——

Dr. MATHEWS-ROTH. Not adult stem cells.

Mr. MURRAY. Please don't interrupt me.

I think we need to grant the sincerity of her belief. On the other hand, you, Senator Hatch, and many others, equally morally thoughtful people, think that an in vitro blastocyst at the 4- to 6-day stage is not the same thing, and that the creation of stem cells from that is not the same thing. So let's put that argument aside. We have addressed that. I think criminalizing those who would feel as you do or others would be disrespectful of the diversity of moral beliefs in the United States. That is what I tried to say in my testimony.

The other set of arguments were really the ones that Dr. Kass offered, and he offered four arguments. The fourth one has really been dealt with, and that was the claim that the claims that nuclear transfer in embryonic cells that they would be useful therapeutically or scientifically are putative and speculative. Well, that is true of all scientific research.

Until we actually do the research and find out whether it can deliver, all claims of usefulness are putative and speculative. Scientists make judgments all the time about what lines of research are more likely to be fruitful than others, and most knowledgeable scientists about this are very excited about the possibilities here.

His third argument—I am going to go backwards quickly—was really about complaints that your current bill may not adequately regulate all aspects of it. And since that is in details, I won't go into that one.

Chairman HATCH. We, by reference, pull into the legislation all of the NIH moral and ethical standards. So I think it is adequate, as I read it.

Mr. MURRAY. Yes.

Chairman HATCH. Now, if anybody has suggestions on how we might make it better, that is one reason we are holding this hearing. We would be very happy to see what we could do.

Mr. MURRAY. Yes, and I think clarifying things such as whether, as Dr. Kass has asked, private research is covered, which I believe it is, or whether patenting is permitted, and permitted on the stem cell lines, say, rather than the actual cloned entity itself—those would be helpful clarifications, but I don't think they go to the heart of the bill.

The second complaint is that we will be on a slippery slope if we permit nuclear transfer in human embryonic stem cells, and that we will end up down at the bottom of a very nasty hill. Nearly 25 years of working in bioethics has convinced me that all of life is lived on slippery slopes and the point is to try to carve out good, firm footing. I believe your bill is exactly an effort to carve out good, firm footing so that we can establish ourselves and live a morally decent life at that point on the hill.

His first argument was that conditions for culturing blastocysts for stem cells—well, the first argument was that what we learn from doing nuclear transfer in embryonic stem cells for research will be immediately and perfectly transferable to trying to make a human baby by cloning. That is an empirical claim.

The scientists I speak to who work with human embryonic stem cells indicate that what they are finding actually is if you want to

develop stem cells of a certain type, say neural stem cells, it pays from the very beginning to use a culture medium and a culture procedure that drives them toward becoming such stem cells.

So, actually, there may be a real divergence between efforts to create a human baby by cloning, the conditions you would have to try to do that, versus the conditions you would have to try to create stem cell populations. So that is an empirical claim, and the scientists here are better qualified than I am to say whether it is correct or not. But it may, in fact, be incorrect, and if the empirical premise is incorrect, then the conclusion is incorrect.

Chairman HATCH. Well, Dr. Murray, your written testimony states that you would be pleased to comment on President Bush's Commission on Bioethics' call for a moratorium on the so-called cloning for biomedical research. I will bite. Why don't you make a comment on that?

Mr. MURRAY. Well, it was a close vote, but a majority did vote in favor of a moratorium. I disagree. It would be less interesting to hear that I disagree than it is to hear the details of the arguments. In fact, what I just did was basically respond to some of the principal arguments in the report, but thank you for asking, Senator.

Mr. BERG. Senator Hatch, may I just make a comment?

Chairman HATCH. Yes, Dr. Berg.

Mr. BERG. My one experience with Government regulation of research goes back 25 years on recombinant DNA.

Chairman HATCH. Right.

Mr. BERG. At that time, one of the interesting arguments was raised that the best we could was to have the NIH supervise this regulatory process and it would not apply to the private sector. As it turned out, the private sector was delighted to follow the same guidelines that were elicited for the rest of the scientific community because, in fact, they needed that guidance themselves.

Rather than go off and do their own thing and go against what was generally conceded to be a sensible way to approach this problem of the potential risks of the research, they all followed it.

Chairman HATCH. And had 4 or 5,000 different directions and they actually followed what the NIH came up with.

Mr. BERG. Absolutely. I mean, that was an interesting and unexpected outcome. We were worried about what private industry would do, but it turned out that they were, as Harold pointed out, much more concerned about the threats to their integrity, being picketed outside their research establishment because they were violating or found to be violating reasonable regulations. So they all adopted them. They set up internal review panels and followed exactly the same procedures that were mandated for the universities or for federally-funded scientists.

So again, although I think the legislation, as I understand it, is, in fact, intended to cover all research in this country, I would not be so fearful whether the private sector is out looking for some way to get out of it.

Chairman HATCH. Well, let me ask this last question because we have a vote. I know that a couple of you really have to go, too, but I am really enjoying this discussion. To have this quality of science discussion is really uplifting to me. Even though you disagree, you

are all excellent people and I don't think we could have had a better panel.

Let me just ask the panel this question, and we will start with you, Dr. Kass. It is a question that Dr. Berg asked Senator Frist last year at a Health, Education, Labor and Pensions Committee hearing. Suppose that the United States bans both reproductive and therapeutic cloning, as has been suggested by those in opposition to this bill, and a therapy was developed overseas in a nation that allows such research that would be very beneficial to a great number of our folks here in this country.

Now, if you were a treating physician—and I would like each of you to think this through—if you were a treating physician, would you have a moral obligation to prescribe such treatment to your patient, even though such treatment could not be directly developed or originated in the United States?

If you gave the same answer that Dr. Frist gave, I will be interested if you would, but wouldn't you be morally obligated if they came up with a cure or came up with a treatment that was beneficial to your patients to use that treatment, even though it was developed through a regenerative medicine approach?

Dr. Kass?

Dr. KASS. Yes, I would, Senator, and I find the part of the House-passed bill, if I may say so publicly, that bans the importation of products regrettable.

Chairman HATCH. I do, too.

Dr. Murray, what would you do?

Mr. MURRAY. I agree with Dr. Kass.

Chairman HATCH. You would use that therapy?

Mr. MURRAY. I would recommend it. I would inform my patient that this was a therapy that was proving itself to be safe and effective, if that was the evidence. If I felt there was any chance that my patient might have a moral objection to receiving embryonic stem cells, I would tell them that is what it came from. And it would be up to them whether they would overcome their personal moral qualms about it, but I would do as Dr. Kass did and tell them.

Chairman HATCH. Dr. Varmus?

Dr. VARMUS. Of course, I would do that, but it would be heartbreaking to have to say that when you return to this country, you might be subject to possible imprisonment or fines.

Chairman HATCH. Which is what the Brownback-Weldon bill calls for.

Dr. Mathews-Roth?

Dr. MATHEWS-ROTH. Well, I would explain the therapy to them. I would tell them that this does involve killing a very young human being, if we are using cloned material. I would tell them that I am personally objecting to it; that I, because of my personal objection to killing and the Hippocratic Oath I took when I became a doctor, would not be involved with the implementation of this therapy; that it is up to them to choose to do it if they want to and they should go to someone else to do it.

Chairman HATCH. Thank you.

Dr. Berg?

Mr. BERG. I asked that question of Dr. Frist because he was a physician.

Chairman HATCH. That is right.

Mr. BERG. And I wanted to see how he would respond to the issue of having to inform a patient that he had voted against the implementation of that kind of therapy.

Chairman HATCH. He said basically that he would have to give his patient the best available treatment.

Mr. BERG. He did say that, and yet at the same time subsequently he backed the Brownback bill fully even though it still contained that particular provision.

Chairman HATCH. I was hopeful they would take that provision out, but even if they took that provision out, there would still be the feelings of Dr. Mathews-Roth.

Mr. BERG. I think Dr. Mathews-Roth has suggested that the therapy would be available. It would just be the doctor's choice. But, in fact, if the bill passes, that therapy is not available in this country. So the issue comes, as I think was implied by Dr. Varmus, somebody going to England to have the therapy having implanted in them cells derived from nuclear transfer-derived stem cells and coming back.

The question was, in the interpretation of the bill, whether that person is liable to criminal penalties for bringing back derivatives of somatic cell nuclear transfer material. That is probably an arguable question, but the point was it is saying that we are prepared to prohibit 280 million from access to therapies that might save their lives because somebody is offended by the technology that was used to develop that therapy.

Chairman HATCH. I have to say that Senator Brownback, I think, did modify his bill to alleviate that provision, in his defense, but I think the House bill has it in there.

Dr. Usala, I am sorry I have been ignoring you here today, and yet I found your testimony very interesting.

Dr. USALA. Senator, you are probably the most patient man I have ever had the pleasure of sitting with for listening to all of us. Actually, if I could just make a comment——

Chairman HATCH. I am starting to like you a lot.

[Laughter.]

Dr. USALA. I actually think that scientifically most of us agree with things, and I will answer your question directly in a second. Dr. Varmus is excited about the possibility of taking a DNA template, putting it in another environment and having it reproduce. It is horribly exciting and I agree with it, and I think that as physician-scientists or scientists, we do see the potential for making a DNA template replicate and to use it in therapeutic ways.

But we can't minimize, as has been done, I believe, the concept that the human being does start shortly after conception, scientifically speaking, because that is when that differentiation process—the DNA joins, the template is formed with all the machinery of the chaperon proteins.

You can't arbitrarily say, well, at this point of differentiation it is human, and at this point it isn't. It can't be done.

Chairman HATCH. I acknowledge it is a human cell. The egg is a living human cell, no question about it. The question is whether

we will utilize that to help the living or we won't. It is just that simple.

Dr. USALA. And that is where, as a physician, a pediatrician, I would have to agree with Dr. Mathews-Roth. I took the Hippocratic Oath. Now, you know, if somebody goes to China and they execute a prisoner and they get his heart and transplant it, do we prosecute them here in the United States? I don't believe so. So that is what it comes down to.

As a physician, I took one of those old Hippocratic oaths. You know, we don't believe in killing, and there are physicians in States where assisted suicide is legal in some circumstances that they do it. In their view, they are doing the best for their patients. I could not do that because of the oath I took and because of my understanding as a scientist.

Chairman HATCH. Well, I think this has been one of the most interesting panels I have ever listened to, and I certainly want to compliment each of you. I respect each of you very much, in spite of the fact that I may differ on some matters.

All I can say is that my goal here is to do the very best I can for mankind, and I think we should help the living as much as we help anybody. I have to say that I have learned so much here today and I don't know when we have had a better panel on any subject. Even though you differ with each other, it has meant a lot to me that you would take the time to come and try and enlighten us.

Hopefully, we can resolve this problem in a way that will bring most of us together. If not, we should resolve it in a true scientific way, it seems to me. You noticed I used the word "true." I think that is a very important word in what we are trying to do with this bill.

So I just want to thank each of you for being here. I have got to go and vote, and rather than have you wait for me to come back, I think we have had a good discussion and I will keep the record open so that if you care to offer any further written comments about these issues that might help us, I would be very grateful. That goes for each and every one of you. I want to thank each of you for being here today.

With that, we will recess until further notice.

[Whereupon, at 3:22 p.m., the Committee was adjourned.]

[Submissions for the record follow.]

[Additional material is being retained in the Committee files.]

SUBMISSIONS FOR THE RECORD

www.agingresearch.org

2021 K Street, NW | Suite 305 | Washington, DC 20006
T 202.293.2856 | F 202.785.8574

National Chairman
John L. Steffens

National Vice Chairman
Robert N. Butler, MD

Executive Director
Daniel Perry

Board of Directors
Mark H. Beers, MD
Merck & Co. Inc
Robert N. Butler, MD
International Longevity Center
W. Daniel Bowman, Ph.D.
Procter & Gamble
David L. Brown
Sabrient Systems, LLC
Mary Ellen Courtright
Archstone Foundation
Ronald W. Dollens
Guidant Corporation
James S. Eden, EP.D.
The Eden Group, LLC
Allen M. Fox, J.D.
Foxhaver
Nick Franklin
PacifiCare Health Systems, Inc.
The Honorable Jack D. Gordon
Hospice Foundation of America
Raymond L. Handlan
Atlantic Philanthropies, Inc.
William A. Haseltine, Ph.D.
Human Genome Sciences, Inc.
Denis M. Lennon, MD, JD
GlaxoSmithKline
David V. Morton
Johnson & Johnson
John F. Santos, Ph.D.
Retinitis Research Foundation
Matt Simon
Robertson Stephens
John L. Steffens
Spring Mountain Capital, LLC
Frederick W. Telling, Ph.D.
Pfizer Inc

Science Advisory Board
(Partial Listing)
*Julius Axelrod, Ph.D.
National Institutes of Health
Richard W. Bagshaw, MD
Brown University
James E. Birren, Ph.D.
University of California, Los Angeles
Robert N. Butler, MD
Mt. Sinai Medical Center
Judith Campisi, Ph.D.
Lawrence Berkeley Laboratories
Carroll L. Estes, Ph.D.
University of California, San Francisco
Maria Fiatarone Singh, MD
University of Sydney
Caleb E. Finch, Ph.D.
University of Southern California
Allan Goldstein, Ph.D.
The George Washington University
William Hazzard, MD
University of Washington
*Joshua Lederberg, Ph.D.
The Rockefeller University
Lewis Lipsitz, MD
Harvard Medical School
George M. Martin, MD
University of Washington
Edward L. Schneider, MD
Andrus Gerontology Center

*Nobel Laureate

January 13, 2003

The Honorable Orrin G. Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch,

The Alliance for Aging Research, an independent, not-for-profit organization, dedicated to improving the lives of older Americans through medical research, strongly supports the Human Cloning Ban and Stem Cell Research Protection Act of 2003, sponsored by you, Senator Tom Harkin, Senator Edward Kennedy, Senator Dianne Feinstein, and Senator Arlen Specter.

The 108th Congress is in a position to affect the future of American biomedical research and our nation's efforts to combat such age-related scourges as Alzheimer's, Parkinson's, diabetes and stroke. The Alliance stands in strong opposition to cloning for human reproduction, but we support the promise of therapeutic cloning which can produce stem cells leading to life-saving treatments and cures. The legislation you and your colleagues will introduce would ban the cloning of a human baby; however the bill does not interfere with valuable stem cell research which has the potential to develop promising treatments and cures for many age-related diseases and disabilities. Given the scientific potential of therapeutic cloning and regenerative medicine, the Alliance for Aging Research strongly supports your efforts to allow for responsible research using the laboratory tools of somatic cell nuclear transfer, also known as therapeutic cloning. Stringent provisions in the bill require comprehensive oversight of the research conducted, with review by an ethics board and protections for research participants, and the enforcement of substantial financial penalties for infringements.

It is a growing possibility that physicians one day, perhaps soon, will be able to replace damaged tissues using a person's own cells to treat blindness, coronary artery damage, spinal cord injuries and other serious disabilities that result from injured, malfunctioning or aged cells. Our aging population may have the opportunity to benefit from this research and recent biomedical progress toward permanent cures against conditions that otherwise will compromise quality of life. On behalf of the millions of older Americans who are suffering from dementia, arthritis, heart disease, cancer and other chronic health problems of aging, as well as younger people facing devastating health problems, the Alliance for Aging Research salutes and thanks you for your strong and dedicated leadership in the fight to preserve the promise of medical research for all Americans.

We look forward to working with you to enact the Human Cloning Ban and Stem Cell Protection Act of 2003.

Sincerely,

Daniel Perry
Executive Director

Advancing Science. Enhancing Lives.

January 17, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

On behalf of the Alpha-1 Foundation, the Alpha-1 Association and the individuals we represent, thank you for your sponsorship of the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*. We commend your colleagues Senators Dianne Feinstein, Arlen Specter, Ted Kennedy, and Tom Harkin for joining you in this commitment to important and necessary medical research.

We strongly support the provisions of the *Human Cloning Ban and Stem Cell Research Protection Act of 2003* and agree that reproductive cloning is unsafe and unethical. More importantly we commend the bill's effort to allow for therapeutic cloning, which has the potential to treat life-threatening diseases, including the degenerative lung and liver disease Alpha-1 Antitrypsin Deficiency (Alpha-1). Alpha-1 strikes individuals in the prime of life with debilitating genetic emphysema and is a leading cause of pediatric liver transplantation. **To date there is nothing that repairs the lung or liver destruction caused by this condition.** Current therapy consists of augmentation via weekly infusions of the Alpha-1 protein derived from pooled plasma for the lung disease associated with Alpha-1. At end stage, the only treatment is lung or liver transplantation.

Therapeutic cloning may hold tremendous hope for individuals with Alpha-1 and others suffering from chronic disease. The Alpha-1 Foundation Medical and Scientific Advisory Committee passed a resolution stating that given the scientific and medical potential of this area of research, it strongly opposes any legislative or regulatory action that would ban therapeutic cloning and further strongly opposes criminalizing this research or the researchers, and prohibiting the importation of therapies derived from this technology in other countries. Thus the medical and research community and the patient population are aligned in our support for this bill.

The Alpha-1 Foundation and Alpha-1 Association applaud your leadership in sponsoring legislation that provides hope for better therapies and potential cures for the millions of Americans living with life-threatening diseases.

We look forward to working with you.

Sincerely,

John W. Walsh
President and CEO, Alpha-1 Foundation

John P. Morton
Chair, Board of Directors, Alpha-1 Association

Alpha-1 Foundation
2937 SW 27th Avenue
Suite 302
Miami, FL 33133

Alpha-1 Association
815 Connecticut Avenue
Suite 1200
Washington, DC 20006

CC: Senator Ted Kennedy
Senator Arlen Specter
Senator Dianne Feinstein
Senator Tom Harkin

Alpha-1 Foundation
2937 SW 27th Avenue
Suite 302
Miami, FL 33133

Alpha-1 Association
815 Connecticut Avenue
Suite 1200
Washington, DC 20006

Statement of the
Alpha-1 Foundation and Alpha-1 Association
Supporting the Introduction of the Human Cloning Ban and Stem Cell Research Protection Act of 2003

The Alpha-1 Foundation and Alpha-1 Association commend Senators Orin Hatch, Dianne Feinstein, Arlen Specter, Ted Kennedy, and Tom Harkin for introducing legislation that makes a commitment to important and necessary medical research, while ensuring that this research will proceed with appropriate ethical oversight.

The Foundation and Association strongly support the provisions of the Human Cloning Ban and Stem Cell Research Protection Act of 2003 and agree that reproductive cloning is unsafe and unethical. More importantly we commend the bill's effort to allow for therapeutic cloning, which has the potential to treat life-threatening diseases, including the degenerative lung and liver disease Alpha-1 Antitrypsin Deficiency (Alpha-1). Alpha-1 strikes individuals in the prime of life with debilitating genetic emphysema and is a leading cause of pediatric liver transplantation. **To date there is nothing that repairs the lung or liver destruction caused by this condition.** Current therapy consists of augmentation via weekly infusions of the Alpha-1 protein derived from pooled plasma for the lung disease associated with Alpha-1. At end stage, the only treatment is lung or liver transplantation.

Therapeutic cloning may hold tremendous hope for individuals with Alpha-1 and others suffering from chronic disease. The Alpha-1 Foundation Medical and Scientific Advisory Committee passed a resolution stating that given the scientific and medical potential of this area of research, it strongly opposes any legislative or regulatory action that would ban therapeutic cloning and further strongly opposes criminalizing this research or the researchers, and prohibiting the importation of therapies derived from this technology in other countries. Thus the medical and research community and the patient population are aligned in our support for this bill.

This legislation provides hope for better therapies and potential cures for the millions of Americans living with life-threatening diseases.

About Alpha-1
More common than Cystic Fibrosis, Alpha-1 is under diagnosed and often misdiagnosed as asthma or smoking-related Chronic Obstructive Pulmonary Disease (COPD). COPD is the fourth leading cause of death in the U.S. and the only major cause on the increase. An estimated 100,000 Americans and a similar number in Europe have the deficiency. An estimated 21 million people in the U.S. are undetected carriers of an abnormal gene that causes Alpha-1 and may pass the gene on to their children.

About the Alpha-1 Foundation
The Alpha-1 Foundation supports research and information exchange to find a cure for Alpha-1. The Foundation is the major funding organization within the scientific community studying Alpha-1, and has funded more than $10.4 million in Alpha-1 research and programs including grants and awards at more than 31 institutions in North America and Europe. The Foundation's support of annual International Scientific Conferences and a series of Critical Issues Workshops, and a growing number of working groups and advisory committees has made possible the exchange of ideas and concepts that have advanced the understanding of a variety of genetic conditions. For more information call toll free, (877) 2-CURE-A1 (228-7321) or visit the Foundation web site, at www.alphaone.org

About the Alpha-1 Association
The Alpha-1 Association is a member-based nonprofit organization founded to identify those affected by Alpha-1 Antitrypsin Deficiency (Alpha-1) and to improve the quality of their lives through support, education, advocacy, and research. For more information call 1-800-521-3025, email info@alpha1.org, or visit www.alpha1.org.

MARGARET FOTI, Ph.D.
Chief Executive Officer

January 17, 2003

The Honorable Orrin G. Hatch
The United States Senate
104 Hart Senate Office Building
Washington, DC 20510

By Fax, 1 page/by US mail

Dear Senator Hatch:

The American Association for Cancer Research strongly supports the *Human Cloning Ban and Stem Cell Research Protection Act of 2003* that you are sponsoring. We urge your colleagues to join with you in this landmark biomedical research legislation.

We concur that human reproductive cloning is unsafe and unethical and should be prohibited, as provided by this bill. However, a growing body of scientific evidence supports the potential of therapeutic cloning for finding cures for diseases and disabilities that affect millions of Americans.

This bill preserves critical biomedical research and therapeutic cloning that may be used to treat life-threatening diseases such as cancer, spinal cord injury, Parkinson's disease, Alzheimer's disease, ALS, heart disease, and diabetes. The bill also imposes rigorous oversight of such research, including review by an ethics board and protections for research participants. It assesses serious penalties for violations.

The American Association for Cancer Research agrees with leaders in the scientific community, and with a majority of the American public, that therapeutic cloning research is in the best interest of the nation's health and should be encouraged to continue.

We applaud you for your leadership in sponsoring legislation that provides hope for better treatments and cures for the millions of Americans living with life-threatening diseases. We appreciate your support to maintain America's scientific primacy and we look forward to working with you.

Yours truly,

Margaret Foti, Ph.D.
Chief Executive Officer

615 Chestnut Street • 17th Floor • Philadelphia, PA 19106-4404
Telephone: (215) 440-9300 • Fax: (215) 440-9313
www.aacr.org

THE AMERICAN SOCIETY OF HEMATOLOGY
1900 M Street, NW, Suite 200, Washington, DC 20036 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

2003

President
Ronald Hoffman, M.D.
University of Illinois - Chicago
College of Medicine
900 S. Ashland Ave., M/C 734
Chicago, IL 60607-4004
ph 312.413.8306
fax 312.413.7969
rhoff@uic.edu

President-Elect
Stanley L. Schrier, M.D.
Stanford University School of Medicine
CCSR, Room 1155
Stanford, CA 94305-5156
ph 650.723.5958
fax 650.730.0974
schrier@leland.stanford.edu

Vice President
James N. George, M.D.
University of Oklahoma Health Sciences Ctr.
1200 N. Everett Drive, Room EB271
Oklahoma City, OK 73104
ph 405.271.4922
fax 405.271.3444
jamesgeorge@ouhsc.edu

Secretary
Nancy Berliner, M.D.
Yale University School of Medicine
Section of Hematology, WWW428
333 Cedar Street
New Haven, CT 06510
203.785.4144
203.785.7232
nancy.berliner@yale.edu

Treasurer
J. Evan Sadler, M.D., Ph.D
Washington University School of Medicine
660 South Euclid Avenue, Box 8022
St. Louis, MO 63110-1093
ph 314.362.9026
fax 314.454.3012
esadler@im.wustl.edu

Councillors
Charles L. Abkowitz, M.D.
Karl G. Blumer, M.D.
Hal E. Broxmeyer, Ph.D.
George R. Buchanan, M.D.
Janice L. Gabrilove, M.D.
Armand Keating, M.D.
Sharon Murphy, M.D.
Kenneth R. Ray, M.D.

Editor-in-Chief
Sanford J. Shattil, M.D.
The Scripps Research Institute
10550 N. Torrey Pines Road, VB-5
La Jolla, CA 92037
ph 858.784.7148
fax 858.784.7422
email@scripps.edu

Executive Director
Martha L. Liggett, Esq.
The American Society of Hematology
1900 M Street, NW, Suite 200
Washington, DC 20036
ph 202.776.0544
fax 202.776.0545
mliggett@hematology.org

January 14, 2003

The Honorable Orrin Hatch
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

On behalf of the American Society of Hematology (ASH), thank you for your sustained leadership on Capitol Hill for stem cell and somatic cell nuclear transfer (SCNT) research issues. ASH strongly supports the *Human Cloning Ban and Stem Cell Research Protection Act of 2003,* which you are co-sponsoring with Senators Dianne Feinstein, Arlen Specter, Ted Kennedy, and Tom Harkin.

As an organization of physicians who care for desperately ill patients and scientists devoted to understanding the basic mechanisms of disease and discovering new therapies, ASH is excited about the enormous potential of all avenues of stem cell research and related scientific mechanisms such as SCNT. Your legislation ensures rigorous oversight of the research conducted, including review by an ethics board and protections for research participants, and imposes large financial penalties for violations. With the long-term possibility to treat life-threatening diseases, including cancer, Alzheimer's disease, Parkinson's disease, diabetes, spinal cord injury, and heart disease, SCNT research must be allowed to move forward.

Moreover, ASH urges that important SCNT research avenues not be limited in the worthwhile effort to ban human reproductive cloning. The Society strongly endorses your legislation's provisions to criminalize human reproductive cloning.

ASH represents 11,500 clinicians and scientists committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant disorders such as leukemia, lymphoma, and myeloma; non-malignant conditions that include anemia and hemophilia; and congenital disorders such as sickle cell anemia and thalassemia. In addition, hematologists have been pioneers in the fields of bone marrow transplantation, gene therapy, and the development of numerous drugs for the prevention and treatment of heart attacks, strokes, and life-threatening blood clots.

If you have questions, or want more information about ASH, you can contact me directly or the Society's Government Affairs Manager, Jeff Coughlin, at (202) 776-0544 or jcoughlin@hematology.org.

Thank you for your support.

Sincerely,

Ronald Hoffman

Ronald Hoffman, MD
ASH President

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
2450 N STREET NW WASHINGTON, DC 20037-1127
PHONE 202-828-0460 FAX 202-828-1125
HTTP://WWW.AAMC.ORG

Jordan J. Cohen, M.D., President

January 15, 2003

The Honorable Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The Association of American Medical Colleges (AAMC) strongly endorses the Human Cloning Ban and Stem Cell Research Protection Act of 2003, sponsored by you and Senators Dianne Feinstein, Arlen Specter, Edward Kennedy, and Tom Harkin.

The AAMC joins with you in strongly opposing human reproductive cloning. To expose any person to the known risks and uncertainties involved in reproductive cloning would be unethical and unconscionable. However, it is important to recognize, as your bill does, the difference between reproductive cloning and the scientific potential of therapeutic cloning and regenerative medicine. Your bill will allow this potentially life-saving research to move forward.

We recognize the significant ethical issues that are raised about embryonic stem cell research and we respect the view of those who oppose such research, including some in our own medical school community. However, we are persuaded otherwise by what we believe is an equally compelling ethical consideration, namely, the unique potential afforded by embryonic stem cells, to alleviate human suffering and enhance the quality of human life.

The current opportunities in medical research are unparalleled in our nation's history. Among the brightest opportunities in medical research is the further study and application of both adult and embryonic stem cell technologies. The production of stem cells by nuclear transplantation may yet prove the most powerful and widely beneficial of all. However, we will never see the fulfillment of any of this promise if we choose to take the perilous and unprecedented path of banning through legislation research on nuclear transplantation to produce stem cells. We applaud your courageous leadership in support of medical research to improve the health of the American people.

We look forward to working with you.

Sincerely,

Jordan J. Cohen, M.D.

A • R • H • P

ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS

BOARD OF DIRECTORS

EXECUTIVE COMMITTEE
FELICIA H. STEWART, MD
CHAIR

TRENT MACKAY, MD, MPH
IMMEDIATE PAST CHAIR

GOODIE HILLE, NP
SECRETARY

IRIS KNUTSON, RNC, MSN, ARNP
TREASURER

LEE LEE DOYLE, PhD
CHAIR, EDUCATION COMMITTEE

WAYNE C. SHIELDS
PRESIDENT and CEO

DIRECTORS AT LARGE
BARBARA CLARK, PA-C

MITCHELL GRIMES, MD

CHARLOTTE ELLERTSON, PhD

HENRY M. FORTER, JR., MD

PABLO RODRIGUEZ, MD

LEE E. SCHULMAN, MD

JAMES TRUSSELL, DPhil, PhD

STANDING POSITIONS
ANESSA CULLINS, MD, MPH, MBA
PPFA VP for MEDICAL AFFAIRS

LESLIE WALTON, MD
PPFA NATIONAL MEDICAL COMMITTEE CHAIR

MEDICAL DIRECTOR
LOUISE B. TYRER, MD

January 10, 2003

Senator Orrin Hatch
United States Senate
SH-104 Hart Senate Office Building
Washington, DC 20510-4402

Dear Senator Hatch:

On behalf of the 2,500 clinicians, researchers, and educators who are members of the Association of Reproductive Health Professionals (ARHP), we would like to thank you for recognizing the importance of somatic cell nuclear transplantation (SCNT), also known as therapeutic cloning, to women and men in the United States.

By supporting the ***Human Cloning Ban and Stem Cell Research Protection Act of 2003***, you have taken a much-needed step toward ensuring future advances in medical research and development of effective treatments. As you know, SCNT research has the potential to help treat and cure individuals living with non-incurable diseases such as Parkinson's, Alzheimer's, diabetes, and spinal cord injuries.

Enclosed you will find some background information about ARHP. We encourage you to visit ARHP's special web site about the science of human cloning and genetic modification at www.arhp.org/cloning. Please contact us if we can ever serve as an expert resource for your staff. We support and praise your legislative action that will help raise the standards of health care for women and men in the United States.

Sincerely,

Felicia H. Stewart, MD
Chair, Board of Directors

Wayne C. Shields
President and CEO

2401 PENNSYLVANIA AVENUE, NW • SUITE 350 • WASHINGTON, DC 20037-1718
PHONE (202) 466-3825 • FAX (202) 466-3826 • WEB SITE www.arhp.org • E-MAIL arhp@arhp.org

Statement of Paul Berg

Robert and Vivian Cahill Professor, Emeritus of Cancer Research and Biochemistry
Director, Emeritus of the Beckman Center for Molecular and Genetic Medicine, Stanford University Medical Center
Chair, Public Policy Committee, The American Society for Cell Biology

Mr. Chairman, Members of the Committee, thank you for inviting me to testify on this most important issue. I have followed the debate on the cloning questions we will address today and I welcome the opportunity to submit my own views on the matter.

For the record, I am Paul Berg, Robert and Vivian Cahill Professor of Cancer Research and Biochemistry, Emeritus, and Director, Emeritus, of the Beckman Center for Molecular and Genetic Medicine at Stanford University. I am also Chairman of the American Society of Cell Biology Public Policy Committee. For my work in developing recombinant DNA technology, I received the Nobel Prize in Chemistry in 1980.

The term 'cloning', before it was tainted by attributing nefarious purposes to it, is a legitimate scientific term to describe the preparation of an 'infinite' number of copies of, for example, a

single molecule, a cell, a virus or a bacterium. Indeed, cloning is at the core of some of the most important recent advances in biomedical research. For example, cloning DNA molecules was essential for revealing the human genome sequence. Similarly, cloned DNA is critical to the fight against bioterrorism because it has already been used in the determination of the entire genome sequences of several organisms identified as bioweapons. Furthermore, cloning is integral to modern forensic procedures, medical diagnostics, vaccine development, and the discovery and production of many of the most promising drugs. In short, cloning is not a dirty word! We must not allow the term to be high jacked to frighten the public and to cloud the issues that confront us.

The congressional and public debate about cloning people is, I believe, a non-issue. Very few, if any, reputable biomedical scientists condone attempts to produce a cloned human being. The distinguished National Academy of Sciences panel that considered this issue concluded that it is dangerous and likely to fail; in short, the risks to the mother and any fetus that would result from the

procedure are unacceptable. If for no other reason than this, your bill (S.303) and Senator Brownback's bill (S.245) are in agreement in mandating a legally enforceable ban on reproductive cloning.

But in contrast to Senator Brownback's proposed legislation, your bill takes a more enlightened position in permitting the somatic cell nuclear transplant procedure for research and therapeutic purposes. This research is supported by overwhelming scientific opinion because the technology may enable us to develop new forms of therapies for some of the most debilitating diseases and crippling disabilities. Presently, there are only proofs of principle behind this optimism, but these strongly suggest that if scientists are permitted to explore these opportunities, their benefits can be achieved. Research and demonstrations of clinical efficacy are the only means for validating whether stem cell-mediated therapies will materialize. We are ethically and morally obliged to pursue them for the benefit of those who suffer.

What is it that is being so vehemently opposed? Transplanting a body's cells nucleus into an unfertilized egg

ultimately yields a hardly visible ball of cells from which embryonic stem cells can be recovered. These cells can be propagated in Petri dishes indefinitely, all the while retaining their capacity to be coaxed into forming all of the body's many cell types. The unique value of nuclear transplantation technology is that the embryonic stem cells and the differentiated cells and tissues they yield have the same genetic makeup as the individual that donated the nucleus. Consequently, they can be used to repair or replace damaged or diseased tissues without invoking the immune rejection that would occur with unmatched cells. Thus, a person's own DNA is used to create compatible cells for the treatment of, for example, that individual's cancer, diabetes, spinal cord injury or Parkinson's disease.

A particularly promising opportunity that is also foreclosed by the Brownback bill is the preparation of stem cells using cell nuclei from individuals with inherited mutations; particularly, ones that predispose them to an increased probability for developing a variety of life-threatening and debilitating illnesses late in life.

have been shown to be artifacts. Moreover, multi-potent adult-derived stem cells have with few exceptions not been maintained in culture for any significant period.

It is certainly true that bone marrow harbors rare stem cells, the so-called hematopoietic stem cells that can reconstitute the entire blood-forming system. Similar evidence exists that neural stem cells obtained from embryos can give rise to different neural cell types. But neural cells obtained by differentiation of cultured embryonic stem cells can populate the brain and deliver sufficient dopamine to alleviate the symptoms of Parkinson's Disease in the mouse.

Every scientific review of the therapeutic opportunities afforded by adult-derived and embryonic stem cells has concluded that embryonic stem cells are far more versatile for medical therapies.

In a letter to Senator Specter last year, Dr. Catherine Verfaillie, whose research on adult stem cells has been cited by opponents to nuclear transplantation as reason to limit human

embryonic stem cell research, said that, "It is far too early to say whether they [adult stem cells] will stack up when compared to embryonic stem cells in longevity and function… There are still too many unknowns for researchers or policymakers to begin closing doors to opportunities of learning."

Most scientists working in these fields recommend strongly, as do I, that research with both adult and embryonic cells should proceed vigorously so as not to delay or forgo the benefits for patients as soon as possible. Choosing a single option could prove to be a great historical embarrassment, like when the Soviets bet on Lysenko's prejudices against genetics, losing out on improving their agricultural productivity and forsaking an entire generation of genetic science and scientists.

One justification for the criminalization of the nuclear transplantation procedure is to guard against rogue attempts to implant the product into a woman's uterus for the purpose of creating a cloned child. But like any socially deviant behavior, we can discourage it with appropriate punishments. We punish

murder under criminal statutes but we fail to criminalize possession of the weapons used for the crime! We should prohibit what we all agree is presently an objectionable practice but should not preclude the means for producing life-saving therapies. Nor should we be threatening to put people in prison for seeking cures for themselves or their children even if those therapies were developed elsewhere.

We take considerable pride in being a pluralistic society. So, there must be ample room for differences concerning the moral and ethical interpretations of early and intermediate stages of human development, especially where acknowledging these alternative legitimate views can mean the difference between life and death for many of our citizens.

Thank you for the opportunity to express my views.

02/04/2003 17:10 BIO OUTBOUND → 2282258 NO.915 P06
FEB-04-2003 TUE 04:25 PM FAX NO. P. 09

STATEMENT ON THERAPEUTIC CLONING

Rev. Dr. Michael Bledsoe, Ph.D.
Pastor, Riverside Baptist Church
Washington, D. C.
Adjunct Professor, Philosophy of Religion
Howard University School of Divinity

I oppose human cloning but believe regenerative medicine might very well end the scourge of diseases like cancer, diabetes, Parkinson's and Alzheimer's.

My view of the nature of human life is developmental. I can, in other words, make a distinction between stem cells and whole, living human beings. By way of analogy, I can make a distinction between a chunk of stone and the National Cathedral. The stone is valuable and its value lies primarily in what it is not. In other words, its potential to be carved into a gargoyle, a pulpit, an altar or fitted as a column is what makes the stone valuable. It ought not, however, be equated in value to the cathedral as a whole. The stem cell is analogous to the blank stone. It is truly valuable and yes, even sacred inasmuch as life is sacred. And it is the potential of the stem cell for creating a variety of tissues that makes it so valuable. But to equate it to the Temple of Being, fully flowered, is a mistake both logically and theologically. For those who want to insist upon the equivalence of stone/cathedral, stem cell/human being are confronted with a monstrous notion of God: on any given day in this world, such cells are being spontaneously sloughed off from the body. Women spontaneously miscarry every day in the world and often are completely unaware that they have had a fertilized embryo within them. Is God then destroying human beings? God forbid we end up with this monstrous notion of the Creator. A developmental view of human nature makes more sense and is in keeping with a view of Intelligent Design in the universe.

I do not believe in giving science a blank check. This technology is rife with risk and my hope is that science, religion, intellectuals and ethicists can remain engaged with one another so that what is humane and moral is safeguarded. I oppose human cloning and fear that governments might use scientists to create Orwellian societies. Yet, I am a pastor and pastors have a window onto the entire journey of life. We bless infants in the hospital crib and we bless the departing elderly person at the hospice. I think regenerative medicine holds great promise for the whole spectrum of life. Its risks need to be checked, of course. To ban this research, however, is to give primacy to cells smaller than the punctuation marks of this text over human beings, fully flowered in the temple of being.

Don C. Reed
382 Riverside Ave.
Fremont, CA 94536

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

Nine years ago, my son Roman Reed was paralyzed in a college football game. In his honor, I sponsored California's Roman Reed Spinal Cord Injury Research Act, signed into law three years ago by Governor Gray Davis.

I strongly support the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*, sponsored by yourself, Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA), and Senator Tom Harkin (D-IA).

Your bill strikes a positive balance between science and simple morality. Like every parent, I am deeply concerned with the rights of unborn children, and appreciate very much your bill's strict ban on the reproductive cloning of humans. At the same time, millions of Americans and people all around the world with incurable diseases and disabilities must be allowed to benefit from modern science, particularly therapeutic cloning of stemcells.

Rival legislation which would ban all forms of cloning seems to me arbitrary and unfair. Should we ban electricity because it is possible to electrocute a person?

Please count on my support, and the backing of my friends at CALIFORNIANS FOR CURE, as you battle for the rights of all Americans to be healed.

Sincerely,

Don C. Reed
Chair, Californians for Cure

January 10, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The Children's Neurobiological Solutions Foundation (CNS) strongly supports the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*, sponsored by yourself, Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA), and Senator Tom Harkin (D-IA).

The bill would criminalize reproductive cloning; a technique we would all agree is unsafe and unethical. Given the scientific potential of therapeutic cloning and regenerative medicine, however, we strongly support the bill's effort to allow for therapeutic cloning, which has the potential to treat life-threatening diseases, including helping the 14 million children in this country with developmental disabilities, and patients with spinal cord injury, Parkinson's disease, Alzheimer's disease, ALS, heart disease, diabetes, and cancer. The bill ensures rigorous oversight of the research conducted, including review by an ethics board and protections for research participants, and imposes large financial penalties for violations.

CNS represents millions of children whose lives are only beginning, yet fraught with difficulties due to neurological damage and disease. Never in the history of medicine has there been such an opportunity to improve the lives of special needs children, giving them the quality of health that so many of us may take for granted. The Foundation agrees with the scientific community, and a majority of Americans, in believing that therapeutic cloning research should be allowed to continue.

On behalf of the millions of children with developmental disabilities and on behalf of their families and caregivers, CNS Foundation applauds your leadership in sponsoring legislation that provides hope for better treatments and cures for the millions of American children and adults living with life-threatening diseases.

We look forward to working with you.

Sincerely,

Fia Richmond

Fia Richmond
President

BOARD OF DIRECTORS

JEFFREY D. MACKLIS, M.D., D.HST
Associate Professor of
Neurology (Neuroscience)
Harvard Medical School

M. MORTON MITCHELL
Treasurer, CNS
President & CEO
Test Components International, Inc.

FIA A. CHVOJKA, M.A.
President & Treasurer, CNS

PHILLIP H. RICHMOND
Co-Founder, CNS
Director
The Richmond Organization, Inc.

EVAN Y. SNYDER, M.D., PH.D.
Assistant Professor of Neurology
Harvard Medical School

SUE ELLEN STRONG, B.S., M.B.A.
Vice President & Secretary, CNS

SCIENTIFIC
ADVISORY BOARD

STEVE GOLDMAN M.D., PH.D.
Professor of Neurology & Neuroscience
Cornell University Medical College

HARLEY KORNBLUM, M.D., PH.D.
Assistant Professor of Pediatrics
UCLA School of Medicine

JEFFREY D. MACKLIS, M.D., D.HST
Associate Professor of
Neurology (Neuroscience)
Harvard Medical School

RONALD McKAY, PH.D.
Senior Investigator
National Institute of Neurological
Disorders and Stroke

MARK DAVID NORIE, PH.D.
[illegible]
University of Rochester
School of Medicine

MAHENDRA S. RAO M.D., PH.D.
Section Chief, Stem Cell Program
National Institutes of Aging
Laboratory of Neuroscience

JEFFREY D. ROTHSTEIN M.D., PH.D.
Professor of Neurology & Neuroscience
Johns Hopkins University

EVAN Y. SNYDER, M.D., PH.D.
Assistant Professor of Neurology
Harvard Medical School

CLIVE SVENDSEN, PH.D.
Professor of Neurology & Anatomy
University of Wisconsin-Madison

JAMES THOMSON, V.M.D., PH.D
Associate Professor
University of Wisconsin-Madison

ANGELO L. VESCOVI, PH.D
Co-Director
Institute for Stem Cell Research
Milan, Italy

1726 FRANCESCHI RD SANTA BARBARA CA 93103 tel 805 965 8838 email info@cnsfoundation.org www.cnsfoundation.org

STATEMENT OF SENATOR LARRY E. CRAIG
"PROMOTING ETHICAL REGENERATIVE MEDICINE RESEARCH AND PROHIBITING IMMORAL HUMAN REPRODUCTIVE CLONING"

Senate Committee on Judiciary
Wednesday, March 19, 2003

I'd like to thank the Chairman and Ranking Member for holding this hearing today.

Let me start by saying I am opposed to human cloning. Morally and ethically, I feel that the use of this experimental science in the creation of human life is unacceptable. I understand that biomedical research could provide assistance to burn victims, heart attack victims, those with diabetes, Parkinson's, leukemia and a host of other crippling or fatal diseases. However, we must also accept there is a need for limits when research goes beyond the boundaries of what is considered to be ethical.

I think this is an important hearing because I feel its necessary that we closely examine all legislation that deals with cloning. We should have as much information as possible so we can craft effective legislation that will protect the valuable advances in medical research while banning the use of human cloning in the name of research.

Having said that, I would like to state for the record that I am an original cosponsor of S. 245, The Human Cloning Prohibition Act, introduced by Senator Brownback. As you will hear in Senator Brownback's testimony today, this bill explicitly bans the creation of embryos through cloning, and it imposes civil and criminal penalties on anyone who attempts to create a human clone through the process of human somatic cell nuclear transfer. S. 245 bans both reproductive, and destructive research cloning by banning the creation of cloned human embryos. At this time, this bill is the only effective ban of "reproductive cloning".

In addition, this bill does not ban the use of in vitro fertilization or other (non-cloning) medical procedures to assist a woman in becoming or remaining pregnant, which is an important distinction. This bill does not interfere with gene therapy, IVF practices, nor does it ban DNA, cell or tissue cloning, other than with cloned embryos.

Again, I do want to stress the importance of advancing medical research. There are countless people with devastating diseases who cling to the hope that medical research will help save their lives. I look forward to learning more about how we can make advances in these areas without treading on the sanctity of human life.

With that, I look forward to hearing from our witnesses today, and again thank Chairman Hatch for this opportunity.

CHRISTOPHER REEVE PARALYSIS FOUNDATION
a merger of the American Paralysis Association and the Christopher Reeve Foundation
500 Morris Avenue, Springfield, NJ 07081 • 800.225.0292 • 973.379.2690 • Fax: 973.912.9433 • www.paralysis.org

January 10, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The Christopher Reeve Paralysis Foundation strongly supports the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*, sponsored by you, Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA), and Senator Tom Harkin (D-IA).

The bill would criminalize reproductive cloning; a technique we would all agree is unsafe and unethical. Given the scientific potential of therapeutic cloning and regenerative medicine, however, we strongly support the bill's effort to allow for therapeutic cloning, which has the potential to treat life-threatening diseases, including spinal cord injury, Parkinson's disease, Alzheimer's disease, ALS, heart disease, diabetes, and cancer. The bill ensures rigorous oversight of the research conducted, including review by an ethics board and protections for research participants, and imposes large financial penalties for violations.

The Foundation agrees with the scientific community, and a majority of Americans, in believing that therapeutic cloning research should be allowed to continue.

The Christopher Reeve Paralysis Foundation applauds your leadership in sponsoring legislation that provides hope for better treatments and cures for the millions of Americans living with life-threatening diseases.

I look forward to working with you.

Sincerely,

Michael Manganiello
Senior Vice President

2120 L Street, NW, Suite 850
Washington, D.C. 20037
202-466-9888
www.camradvocacy.org

Coalition for the Advancement of Medical Research
supporting funding of stem cell research

January 10, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

On behalf of the Coalition for the Advancement of Medical Research (CAMR), I am writing to add our strong support for your sponsorship of the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*. Along with Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA), and Senator Tom Harkin (D-IA), your leadership in protecting research using therapeutic cloning and regenerative medicine is greatly appreciated.

This year Congress will address the future of biomedical research and the nation's efforts to prevent, treat, and cure such debilitating diseases as cancer, juvenile diabetes, ALS, Parkinson's disease, spinal cord injuries and many more. Let me be clear, CAMR supports a ban on reproductive cloning; it is unsafe and unethical. Given the scientific potential of therapeutic cloning and regenerative medicine, however, we strongly support the bill's effort to allow for this research, which may be essential tools allowing scientists to develop the promise of embryonic stem cell research. I am sure you will agree, therapeutic cloning is about saving and improving lives. It is fundamentally different from human reproductive cloning; it produces stem cells, not babies.

CAMR applauds your leadership in sponsoring legislation that ensures cures for devastating diseases continue to be developed. We look forward to working with you.

Thank you,

Michael Mangandello
President

CAMR is comprised of 75 nationally-recognized patient organizations, universities, scientific societies, foundations, and many individuals with life-threatening illnesses and disorders, advocating for the advancement of breakthrough research and technologies in regenerative medicine - including stem cell research and therapeutic cloning - in order to cure disease and alleviate suffering.

News from . . .

Senator Dianne Feinstein

of California

FOR IMMEDIATE RELEASE:
Wednesday, March 19, 2003

Contact: Howard Gantman
or Scott Gerber 202/224-9629
http://feinstein.senate.gov/

Statement of Senator Dianne Feinstein at a Hearing on Legislation to Ban Human Reproductive Cloning, but Allow Promising Medical Research to Continue Under Strict Oversight

***Washington, DC** – At a hearing of the Senate Judiciary Committee, Senator Dianne Feintein (D-Calif.) today urged her Senate colleagues to pass legislation to make the cloning of a human being a crime, while allowing other promising medical research – which may lead to cures of some of the most deadly and debilitating diseases – to proceed.*

The bill was introduced earlier this year by Senators Feinstein, Orrin Hatch (R-UT), Arlen Specter (R-PA), Edward M. Kennedy (D-MA), and Tom Harkin (D-IA). The following is the prepared text of Senator Feinstein's statement.

"Mr. Chairman, I hope that this hearing will help convince people that it is possible to draw a line between human reproductive cloning and the valuable technique of somatic cell nuclear transplantation. While many of us were disappointed with the House vote on this issue last month, we take comfort from the fact that a majority of senators appears to disagree with the House's position.

I am hopeful that the Senate will pass alternative legislation that we introduced to ban human reproductive cloning, while ensuring that important medical research can go forward – under strict oversight from the federal government.

Simply put, this research offers hope to millions of Americans suffering from paralysis and debilitating diseases including juvenile diabetes, Parkinson's and Alzheimer's. Let's be very clear: human reproductive cloning is immoral and unethical. It must not be allowed under any circumstances. But at the same time, we must not prohibit nuclear transplantation research – it holds too much promise for millions of Americans.

Just this past December, we were told that the Raelians had cloned a human being. This is very likely a hoax. However, it underscores the point: We must ban human reproductive cloning *now* – before some unethical scientist *is successful* in creating a human clone This is a point on which we all agree. Human reproductive cloning is wrong – and it must be banned forever. And our legislation does just that.

But our legislation allows researchers to continue to use what appears to be the most promising technique to cure debilitative diseases – somatic cell nuclear transplantation, a process used to produce embryonic stem cells.

- *more* -

Under our legislation, though, these researchers will not have a free hand. They must conduct this research ethically, under strict guidelines, and with close oversight by the federal government.

Our legislation will place tough regulations on scientists conducting nuclear transplantation research. It would:

- Impose a sentence of up 10 years in federal prison for anyone attempting to a clone a human being, and establish a minimum civil penalty of $1 million or three times the gross profits resulting from the violation, whichever is greater;
- Mandate that eggs used in this research be unfertilized;
- Prohibit the purchase or sale of unfertilized eggs, including eggs that have undergone nuclear transplantation – to prevent "embryo farms" or the possible exploitation of women;
- Impose strong ethics rules on scientists mandating informed consent by egg donors; review of any nuclear transplantation research by an ethics board; and safety and privacy protections;
- Prohibit any research on an egg cell after 14 days -- when that cell begins to divide and when cell differentiation begins.

These provisions establish a clear divide between nuclear transplantation research, used only to produce embryonic stem cells – and human reproductive cloning.

Embryonic stem cell research has the potential to save millions of lives -- and improve the quality of life for millions more.

The promise of embryonic stem cells is that they are easily replicated undifferentiated cells that can be induced into changing into any cell in the body – a heart cell, a liver cell, a spinal cord cell, or a kidney cell. And talented scientists across the country – and indeed the world -- are conducting research using embryonic stem cells in the search for new cures and treatments.

- In a preliminary study at Washington University, embryonic stem cells, inserted into rats, have led to regeneration of the rat's spinal cord. The once crippled animals have been able to walk and bear their own weight. Imagine what this could mean for the 250,000 Americans paralyzed by spinal cord injuries.
- Similarly, preliminary findings at the University of Wisconsin have shown that human embryonic stem cells can differentiate and express the insulin gene. Imagine what this could mean to the 17 million Americans suffering from diabetes.

Much more research and testing needs to be done. But clearly, these findings offer hope to those Americans who suffer from debilitative diseases. Some have suggested that this research can be done without nuclear transplantation. They point to research being done, for example, with adult stem cells.

I certainly support adult stem cell research and other research not involving stem cells. But I agree with leading scientists who argue that embryonic stem cell research offers much more promise than adult stem cell research. The fact remains that adult stem cells are less versatile than embryonic stem cells. They do not have the ability to be potentially grown into any organ or tissue.

- more -

In addition, I support using nuclear transplantation to generate embryonic stem cells. Embryonic stem cells generated through means other than nuclear transplantation are simply much less useful. Any new organs or tissues created would not have the same DNA as the patient, forcing him or her to take dangerous immuno-suppressant drugs and increasing the chances the changes of rejection.

In America today, there are more than 128 million Americans who could benefit from embryonic stem cell research. One of these is Emma Arvedon, only 5-years old, who suffers from juvenile diabetes. In a recent letter to me, her father wrote:

"Our family is enormously hopeful...that [nuclear transplantation] research may play a vital role in finding a cure for juvenile diabetes. There already exists empirical evidence that, quite possibly, [this research] could yield the insulin producing pancreatic cells that my daughter's body lacks. If research into this process were to be criminalized, how would I explain to Emma that our government cares more about a cloned cell, smaller than a grain of sand, than they do about her."

We are introducing this legislation for Emma -- and the millions like her -- with the resounding support of the medical and scientific community. To deprive Emma and her family of a possible cure – to close the door on nuclear transplantation research – would be nothing short of tragic. We can and should ban human reproductive cloning without hurting Emma and her family even further.

That is why we are here today – to offer hope to millions of Americans, and to help turn that hope into reality. I urge my Senate colleagues to approve this legislation."

###

HADASSAH
THE WOMEN'S
ZIONIST
ORGANIZATION
OF AMERICA, INC.

50 WEST 58 STREET
NEW YORK CITY
NEW YORK
10019-2300

TEL. 212.355.7900
FAX 212.303.8282
TTY 212.303.4549
HTTP://WWW.HADASSAH.ORG

FOUNDED BY
HENRIETTA SZOLD
IN 1912

January 14, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch

On behalf of the more than 300,000 members of Hadassah, the Women's Zionist Organization of America, I am writing to express my support for the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*, sponsored by yourself, Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA) and Senator Tom Harkin (D-IA).

Hadassah is the largest women's and the largest Jewish membership organization in the United States, with members in every congressional district. Our mission is to promote a prosperous and peaceful Israel, pursue social justice and advocate for the health, education and well being of American Jewish women and their families.

Hadassah believes that quality healthcare must include innovative medical and bio-technological research, including stem cell and Somatic Cell Nuclear Transfer (SCNT) research, commonly called therapeutic cloning. And, while Hadassah agrees that reproductive cloning must be banned, therapeutic cloning is a crucial medical research tool that has the potential to result in treatment for many life-threatening diseases. Thus, by criminalizing reproductive cloning but allowing for therapeutic cloning, the *Human Cloning Ban and Stem Cell Research Protection Act of 2003* balances the sanctity of human life with the importance of encouraging critical advanced scientific research.

Hadassah applauds your leadership in sponsoring this important legislation. If we can be of any assistance to you, please feel free to contact Shelley J. Klein, Esq., Director of American Affairs/Domestic Policy at (212) 303-8015 or Marla Gilson, Director of Hadassah's Washington Action Office at (202) 363-4600. We look forward to working with you.

Sincerely,

Bonnie Lipton
National President

NEWS RELEASE

ORRIN HATCH

United States Senator for Utah

FOR IMMEDIATE RELEASE
March 19, 2003

Contact: Adam Elggren (202) 224-3370

Statement of Sen. Orrin G. Hatch
before the
Committee on the Judiciary
United States Senate

Hearing on
"Promoting Ethical Regenerative Medicine Research
and Prohibiting Immoral Human Reproductive Cloning"

Good morning. Today the Judiciary Committee will explore whether and how it might be possible to draw a line between promoting ethical stem cell research and prohibiting immoral human reproductive cloning.

I am a co-sponsor – with Senators Feinstein, Specter, Kennedy, Harkin and others – of bi-partisan legislation, S. 303, "The Human cloning Ban and Stem Cell Research Protection Act of 2003."

Our bill has two goals:

First, to stop any attempts to facilitate the birth of a cloned baby. Virtually everyone in Congress and among the American public agrees that reproductive cloning should be criminalized so this practice can be stopped before it starts. At a minimum, the 108th Congress should pass legislation that bans reproductive cloning.

Second, our legislation allows a promising form of stem cell research to go forward under strict ethical guidelines. This research utilizes a cloning technique – and keep in mind that in biomedical science the term cloning merely means to make an exact copy of cells, proteins, molecules, viruses, DNA sequences or other such entities.

In the cloning technique of somatic cell nuclear transfer, also called nuclear transplantation, an egg's normal complement of 23 chromosomes is removed and replaced with a

full set of 46 chromosomes from a somatic, or body cell, such as the skin. This process does not involve a fertilized egg or any sperm cells.

There are two potential pathways for such engineered, non-fertilized embryonic cells. If introduced into a womb, it is possible that a cloned human being could be born. Let me repeat my opposition to reproductive cloning and stress that our bill would impose severe criminal penalties on that activity.

It is the other pathway – using nuclear transplantation as a source to derive stem cells – that has generated so much excitement in the scientific community and has spawned so much discussion of the ethical dimensions of this type of research.

I am proud to hold a Right to Life philosophy. I believe that human life begins in the womb, not in a petri dish. While I recognize that not everyone agrees with me, I am heartened that so many of people that I meet in Utah and throughout the country, including many fellow Right-to-Lifers, have supported me in my views. I believe that as the public studies and reflects upon these issues, support for the legislation we have drafted will grow.

Deciding where one stands on this matter is not easy. Among the difficult questions that must be carefully considered are:

What does it mean to be human?

When does life begin?

And, in our quest to improve the quality of human life, how can we best establish ethical safeguards to protect against doing harm to mankind?

These are not easy questions. Although some are calling for a moratorium on somatic cell nuclear transfer, I fail to see how a moratorium will help our society fully consider, debate, and attempt to resolve the ethical issues.

The cost of delay is real. Some 100 million Americans might one day benefit from embryonic stem cell research. We must not forget them. There is no way to impose a moratorium on their pain and suffering. We must also understand that this avenue of inquiry is still in the very early stages and we must conduct basic research before any new tests or treatments can be developed.

Some argue, including some of those you will hear today, that adult stem cell research is actually superior to embryonic stem cell research. I support a vigorous program of adult stem cell research.

I just hope that my colleagues will listen carefully to our scientific witnesses today

because it appears that the consensus among most scientists is that embryonic stem cell research, including stem cells derived through nuclear transplantation, offers unique, and perhaps revolutionary, opportunities. From my discussions with experts, including Dr. Irv Weissman of Stanford, and University of Utah faculty Dr. Mario Capecchi, a leading mouse stem cell researcher, and Dr. Stephen Prescott, the Director of the Huntsman Cancer Institute, I conclude that this line of research merits further investigation and our support.

At the least, we should all acknowledge that the progress that has been with adult stem cells has been largely attributable from the 20-year head start in federal funding of this research. I plan to work with Senators Specter and Harkin as they develop legislation to expand the number of cell lines derived from embryos no longer needed in the in vitro fertilization process beyond those lined deemed eligible by the Administration for federal funding.

The issues we face today are difficult but not totally unprecedented. For example, our society successfully addressed the issues attendant to recombinant DNA research and in vitro fertilization.

Our bill, along with criminalizing reproductive cloning, contains a number of strict ethical protections. These include:

- making this private sector research comply with the federal Protection of Human Subjects regulations;
- separating the egg collection site from the nuclear transplantation research laboratory;
- a prohibition on exporting cloned embryos to any foreign country that does not ban human reproductive cloning;
- a prohibition on conducting nuclear transplantation research on fertilized eggs for a requirement that each egg donation be made voluntarily and that there be no profiteering on donated eggs;
- and, a prohibition, similar to the English rule, on research conducted more than 14-days after the nuclear transplantation has occurred.

These are sound rules. If we adopt these ethical requirements, it is possible that other countries will follow our lead.

Unless we act to build an environment that encourages the United States to remain the leader in stem cell research, we will have lost much.

Failure to enact legislation patterned after S. 303 can only undermine our Nation's leadership in biomedical research. Investors and firms will be reluctant to commit the necessary

resources to succeed in this costly, new area if there is not a measure of certainty in the legal environment for this activity. Andy Grove, CEO of Intel recently sent me an article that details how China is attempting to take the lead in this field of research.

If this research is stifled, some of our best young scientists may feel compelled to move off shore – and away from American patients. Such an outcome will not be good for the citizens of Utah and our neighbors across the country. Let me close by sharing with you a letter I recently received from Nancy Reagan that I think frames this issue in a helpful way:

> Dear Orrin,
>
> As you may know, Ronnie will observe his ninety-second birthday soon. In earlier times, we would have been able to celebrate that day with great joy and wonderful memories of our life together. Now, while I can draw strength from these memories, I do it alone, as Ronnie struggles in a world unknown to me or the scientists who devote their lives to Alzheimer's research. Because of this, I am determined to do what I can to save other families from this pain.
>
> I'm writing, therefore, to offer my support for stem cell research and to tell you I'm in favor of new legislation to allow the ethical use of therapeutic cloning. Like you, I support a complete ban on reproductive cloning. However, I believe that embryonic stem cell research, under appropriate guidelines, may provide our scientists with many answers that are now beyond our grasp.
>
> Orrin, there are so many diseases that can be cured, or at least helped, that we can't turn our back on this. We've lost so much time already. I can't bear to lose any more.
>
> Sincerely,
>
> Nancy

Thank you.

###

INTERNATIONAL MYELOMA FOUNDATION
Serving the Myeloma Community Since 1990
12650 Riverside Drive, Suite 206
North Hollywood, CA 91607-1421
Tel 818.487.7455
Fax 818.487.7454
TheIMF@myeloma.org
www.myeloma.org

FOUNDER
Brian D. Novis

PRESIDENT
Susie Novis

BOARD OF DIRECTORS
CHAIRMAN Dr. Brian G.M. Durie
Michael B. Bell
Charles L. Briscoe
Mark DiCicilia
Michael S. Katz
Dr. Robert A. Kyle
Dr. Edith Mitchell
Dr. Gregory R. Mundy
Charles Newman
Susie Novis
Richard H. Salerno
John L. Seiler
E. Michael D. Scott
R. Michael Shaw
Donald B. Springer
Donald R. Woodward

SCIENTIFIC ADVISORY BOARD
CHAIRMAN Robert A. Kyle, USA
Raymond Alexanian, USA
Kenneth C. Anderson, USA
Giuseppe Avvisati, ITALY
Dan Barlogie, USA
Régis Bataille, FRANCE
Meral Beksac, TURKEY
William Bensinger, USA
James R. Berenson, USA
Daniel Bergsagel, CANADA
Ralf Bergsagel, USA
Juan Blade, SPAIN
Mario Boccadoro, ITALY
Y.C. Chen, R.O.C.
J. Anthony Child, ENGLAND
Raymond L. Comenzo, USA
Meletios A. Dimopoulos, GREECE
Brian G.M. Durie, USA
Dorotea Fenoi, ARGENTINA
Ian Franklin, SCOTLAND
Gösta Gahrton, SWEDEN
Jean-Luc Harousseau, FRANCE
Vanni Hungria, BRAZIL
Douglas Joshua, AUSTRALIA
Tadamitsu Kishimoto, JAPAN
Heinz Ludwig, AUSTRIA
Ian MacLennan, ENGLAND
James S. Malpas, ENGLAND
Jayesh Mehta, USA
Håkan Mellstedt, SWEDEN
Angelina Rodriguez Morales, VENEZUELA
Gareth Morgan, ENGLAND
Gregory R. Mundy, USA
Amaro Nassel, VENEZUELA
Martin M. Oken, USA
Linda Pilarski, CANADA
Raymond Powles, ENGLAND
David Rosenthal, USA
Jesús San Miguel, SPAIN
Seema Singhal, USA
Alan Solomon, USA
Pieter Sonneveld, THE NETHERLANDS
Benjamin Van Camp, BELGIUM
Brian Van Ness, USA

January 13, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The International Myeloma Foundation wishes to offer strong support of the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*, sponsored by you and your colleagues, Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA), and Senator Tom Harkin (D-IA).

We appreciate that this bill would criminalize reproductive cloning; a technique we agree is unsafe and unethical. However, because of the scientific potential of therapeutic cloning and regenerative medicine, we strongly support the bill's effort to allow for therapeutic cloning, which has the potential to treat life-threatening diseases, particularly including multiple myeloma, a life-threatening disease which is now diagnosed in 14,000 Americans every year, as well as several other forms of cancer. The bill ensures rigorous oversight of the research conducted, including review by an ethics board and protections for research participants, and imposes large financial penalties for violations.

The International Myeloma Foundation agrees with the scientific community, and a majority of Americans, in believing that therapeutic cloning research should be allowed to continue.

Furthermore, the Foundation applauds your leadership in sponsoring legislation that provides hope for better treatments and cures for the millions of Americans living with life-threatening diseases.

We look forward to working with you.

Sincerely,

Susie Novis

Susie Novis
President
IMF

Dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure.

Statement of Leon R. Kass, M.D., Ph.D.

Hertog Fellow in Social Thought, American Enterprise Institute;

Addie Clark Harding Professor (on leave), Committee on Social Thought and the College,

The University of Chicago

Testimony before the

Committee on the Judiciary

United States Senate

Hearing on

"Promoting Ethical Regenerative Medicine Research and Prohibiting Immoral Human Reproductive Cloning"

March 19, 2003

Mr. Chairman and Members of the Committee. My name is Leon R. Kass. I am the Hertog Fellow in Social Thought at the American Enterprise Institute and the Addie Clark Harding Professor (on leave) in the Committee on Social Thought and the College at the University of Chicago. I am grateful to you, Senator Hatch, for the invitation to present some of my thoughts on human cloning, a topic on which I have been thinking and writing for thirty-five years. I speak today in my own name, and not on behalf of, or as chairman of, the President's Council on Bioethics, though I shall have occasion to refer briefly to the Council's report, *Human Cloning and Human Dignity*.

Mr. Chairman, I share your view that human cloning is immoral, as I also share your wish to advance ethical approaches to regenerative medicine. Human cloning constitutes unethical experimentation on the cloned-child-to-be. It confounds his genetic and social identity; it would threaten his sense of individuality. It represents a giant step toward turning procreation into manufacture. And it is a despotic attempt of parents to select and control the genetic make-up of their children. For all these reasons, I conclude that human cloning threatens the dignity of human procreation, giving one generation unprecedented control over the next, and marking a major step toward a eugenic world in which children would become objects of manipulation and products of will. Human cloning should be banned.[1]

The question is how best to do it, effectively and ethically, with as little interference as possible to potentially beneficial biomedical research. With all due respect, I regret to say that the approach proposed in S. 303, "The Human Cloning Ban and Stem Cell Research Protection Act of 2003," will not, in my opinion, do the job we want done. It offers an ineffective, and even counterproductive, means of preventing the cloning of children. It is ethically problematic. It offers inadequate regulatory safeguards. And, in truth, it is unnecessary for advancing the mainstream of stem cell research, both embryonic and adult, about which the bill is, in fact, largely silent. Before

[1] I developed these arguments in my testimony before the Subcommittee on Science, Technology, and Space, of the Senate Committee on Commerce, Science, and Transportation, January 29, 2003. A fuller account is found in "Cloning and the Posthuman Future,"chapter five in my book, *Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics*, Encounter Books, 2002.

backing up these claims, I need to speak first about the matter of terminology. For the ethical discussion we need to have is obscured by the confusing and misleading language of bill S. 303.

Whether undertaken for the ultimate purpose of producing children or for the purpose of extracting stem cells for research, the deed of nuclear transplantation is itself an act of cloning (it is the deed that produces the genetic replica), and its product is in both cases identical: a cloned human embryo. This is the view of both the earlier National Bioethics Advisory Commission and the current President's Council on Bioethics—including those members who favor cloning-for-biomedical-research—which unanimously adopted this terminology as accurate and fair.[2] When identical cloned embryos are grown to the blastocyst stage, their different fates depend solely on the purposes of the human users: baby-making or research. The National Academy of Science report on *Scientific and Medical Aspects of Human Reproductive Cloning* (January 2002) also shares this opinion.[3] S. 303's term "unfertilized blastocyst" is confusing and has no scientific currency or basis; and its definition as "intact cellular structure" hides the fact that this "structure" is a self-developing, embryonic, human organism. We should, of course, listen to scientific or ethical arguments about why it would be important or permissible to create such cloned human blastocysts solely for research. But if we are to do so forthrightly, we should not hide from

---

[2] The PCBE report adopts the following definitions:
Human cloning (what it is): The asexual production of a new human organism that is, at all stages of development, genetically virtually identical to a currently existing or previously existing human being.
Human cloning (how it is done): It would be accomplished by . . . [a] procedure known as "somatic cell nuclear transfer" (SCNT).
Human cloning (why it is done): The same activity may be undertaken for the purposes of producing children or for purposes of scientific and medical investigation and use, a distinction represented in the popular discussion by the terms "reproductive cloning" and "therapeutic cloning." We have chosen instead to use the following designations: *Cloning-to-produce-children* . . . [and] *Cloning-for-biomedical-research*.
Cloned human embryo: (a) The immediate and developing product of the initial act of cloning, accomplished by SCNT. (b) A human embryo resulting from the somatic cell nuclear transfer process (as contrasted with a human embryo arising from the union of egg and sperm).
Human Cloning and Human Dignity: An Ethical Inquiry, The President's Council on Bioethics, July 2002, pp. 54-55. A copy of the entire chapter "On Terminology" is appended to this testimony. I would urge all members of the Committee to read it.

[3] "The experimental procedures required to produce stem cells through nuclear transplantation would consist of the transfer of a somatic cell nucleus from a patient into an enucleated egg, the in vitro culture of the *embryo* to the *blastocyst stage*, and the derivation of a pluripotent ES cell line from the inner cell mass of this *blastocyst*" (emphasis added). National Academy of Sciences, *Scientific and Medical Aspects of Human Reproductive Cloning* (January 2002), p. 2-6. The NAS report also makes perfectly clear that the blastocyst used for stem cell derivation is indistinguishable from one that could be used for producing a cloned child.

ourselves or others what we are doing. And we should not try to win the argument by definitional sleight of hand.

Here then are my reasons for believing that a ban that tried to block cloning-to-produce children while permitting cloning-for-biomedical research is a bad idea and for supporting a comprehensive ban on all human cloning.

1. Ineffective and counterproductive. If we want to prevent the development of anthrax bombs, we do best to block the production of anthrax spores, not just their transfer to a weapons delivery system. Similarly, if we mean to be fully serious about stopping the cloning of human children, we should try to stop the process before it starts, at the creation of the embryonic human clones, not merely rely on efforts to prevent their transfer to women for delivery. For a law (such as S. 303) that tried to prevent cloning babies by banning only implantation of cloned embryos would be ineffective and unenforceable. It would be difficult to know when the law had been violated; it would be impossible to enforce it once it had. Further, by endorsing cloning-for-research, such a law would in fact increase the likelihood of cloning-to-produce-children, by perfecting the procedure to practice it.

a. Permitting cloning for research will lead to improvement of cloning technique and increased success at getting cloned human embryos to the blastocyst stage, in the process making the whole practice safer. Once embryo-cloning techniques are thus perfected, people interested in cloning babies will be better able to succeed.
b. Once cloned embryos are produced and available in commercial laboratories, it will be very difficult to control what is done with them. As with the left-over embryos in the IVF clinics, cloned embryos produced for one purpose (research) could easily be used for another purpose (producing children).
c. Produced under conditions of industrial secrecy, they could be bought and sold without anyone's knowledge. Only under strict and transparent regulatory system of licensing, inventory, and reporting arrangements (not now included in S. 303) would we even have a guess as to the number and disposition of the cloned embryos produced.
d. Once available to medical practitioners of assisted reproduction, cloned embryos could be transferred to a woman's uterus without anyone's knowledge, protected by doctor-patient privacy and confidentiality.
e. Illicit "cloning pregnancies" would be impossible to detect.
f. Even if detected, there would be no enforceable legal remedy; the state could not and would not compel the abortion of the clone.

2. Ethically problematic. Allowing cloned embryos to be produced for biomedical research and/or stem cell extraction is morally highly problematic. It crosses several important moral boundaries, accelerating our slide down a slippery slope (or, more accurately, jumping us off an ethical cliff) into a dehumanizing world of genetic control of offspring and the routine use of nascent human life as a mere natural resource. In contrast, a ban on all human cloning is morally unproblematic.

a. The merely partial cloning ban proposed by S. 303 crosses a major moral boundary by endorsing the deliberate production of early human embryos for the sole purpose of research and exploitation, and requiring their necessary destruction. (This goes beyond the use of the spare embryos in the IVF clinics, each one of which was created solely for reproductive use but is now no longer needed and will likely die anyhow. Only yesterday, in the stem cell debate of 2001, many proponents of embryonic stem cell research, including some who are today sponsors of S. 303, made clear public statements opposing on moral grounds the creation of embryos specifically for research. Today they would cross that line without blinking. The slippery slope seems to be very steep.)

b. Cloned human embryos would be the first human embryos whose genetic makeup would be determined not by the chance union of egg and sperm but by deliberate human selection and design. When research cloning is seen in the context of growing powers of genetic screening and genetic manipulation of nascent human life, it becomes clear that saying 'yes' to creating cloned embryos, even for research, means saying 'yes,' at least in principle, to an ever-expanding genetic mastery of one generation over the next.

c. Use of cloned embryos in research, once allowed, will be impossible to limit. Arguments now used to justify creating cloned embryos to produce stem cells also justify growing embryos beyond the blastocyst stage. Today the demand is for stem cells; tomorrow it will be for embryonic and fetal organs. Experiments with cloned cow embryos implanted in a cow's uterus (Advanced Cell Technologies) already suggest that there may be greater therapeutic potential using differentiated tissues (e.g., kidney primordia) harvested from early fetuses than using undifferentiated stem cells taken from the 5-6 day old blastocyst stage. Should this prove correct, there will be great pressure to grow cloned human blastocysts to later stages, past 14 days—either in the uteruses (or other body cavities) of suitably prepared animal or human hosts or (eventually) using artificial placenta-like structures in the laboratory—in order to obtain the more useful tissues.

d. Combined with a legal prohibition on the implantation of cloned embryos (for the purpose of baby-making), permission to clone embryos for research creates a class of human embryos that it would be a federal felony <u>not</u> to destroy. Such a law <u>obliges</u> the state to enforce the destruction of nascent life, a troubling novelty.

e. In addition to the harm done to embryos, there is moral harm done to a society that comes to accept as normal the routinized production and use of early human life as a natural resource for our own benefit: we risk becoming desensitized, indifferent,

callous; we lose our awe and respect for the mystery and wonder of emerging new human life.

3. Inadequate regulation. Given the unique status and dangers related to the creation of cloned embryos, the limited regulatory provisions of S. 303 give too little oversight. They fall far short even of the regulatory recommendations of those members of the President's Council on Bioethics who were in favor of cloning-for-biomedical research.[4]

a. They do not clearly apply to privately funded research.
b. They do not provide mechanisms for keeping track of all cloned embryos produced in laboratories, nor do they establish standards or guidelines for the handling and use of cloned human embryos.
c. They are silent on whether cloned human embryos can be patented.
d. They are silent on putting human nuclei into animal eggs. (The definitions of "oocyte" and "nuclear transplantation" offered in the bill do not specify that the egg be a human egg.)
e. The prohibition on "valuable consideration" for egg donation is effectively undermined by permitting compensation for time, costs, and inconvenience, absent declaring who gets to define those things, or how much is too much to charge. As written, the loophole swallows the rule and egg-selling is allowed to continue (as it does today in obtaining "donor" eggs for assisted reproduction).
f. By applying only existing human subject protection regulations to research cloning, S. 303 protects egg and somatic cell donors, but says nothing about the treatment of the cloned embryo once it is created.

4. Unnecessary for Promoting Regenerative Medicine Research. The benefits of embryonic stem cell research (in both knowledge and potential therapy) do not necessarily require the creation of cloned embryos (or stem cells from cloned embryos). The putative benefits of cloning research are at best speculative, and it is unlikely to be the solution for the immune rejection problem. In contrast, a narrowly constructed yet complete ban on all human cloning would not interfere with stem cell research, adult or embryonic (using cells derived from non-cloned embryos).

a. The highly touted concept of "therapeutic cloning"—individualized, custom-made, rejection-proof cells derived from stem cells extracted from one's own embryonic clone—is not likely to succeed as an effective or practical form of regenerative medicine. Its alleged promise is vastly overrated, not to say spurious.

---

[4] See *Human Cloning and Human Dignity*, pp. 190, 209-211, 220-223.

(1) Cells derived in this way may not be rejection-proof. They will contain (antigenically significant) mitochondrial DNA, originating in the egg that received the somatic cell nucleus. They will therefore NOT be fully genetically identical to the patient donor of the nucleus. This non-identity could cause immune rejection of cells reintroduced into the donor as potential therapy. There is virtually no animal evidence of any sort indicating that stem cells taken from cloned animals will not be rejected or, for that matter, that they will be therapeutically effective in treating diseases (in animals). (A recent MIT study, published on-line in *Cell* and touted as the first success in therapeutic cloning, reports that the tailor-made stem cells were in fact attacked as foreign by the host that had supplied the somatic cell nucleus to produce the cloned embryo.)

(2) Stem cells derived from cloned embryos may be abnormal. Reprogramming of somatic nuclei introduced into oocytes is extremely difficult to achieve, and it generally results in numerous errors of gene expression. Such epigenetic "errors" could render stem cells derived from cloned embryos abnormal and hazardous for therapeutic use.

(3) "Therapeutic cloning" is impractical. It will require thousands of human eggs, a prohibitively costly business, especially at the beginning, as the success rate in getting clones to the blastocyst stage is very low. Also, therapy using individualized stem cells, produced in the laboratory via embryo cloning, would need to be scrutinized by the FDA, patient by patient, to make sure that nothing hazardous had been introduced in the process. (From the commercial point of view, far better to engineer rejection-proof stem cells that could be universally used with every patient; only one FDA approval would be needed). The verdict that "individualized therapeutic cloning" cannot be done on a large scale and is not commercially viable is the near unanimous judgment of the leading biotech companies; at a biotech conference last year on stem cell research NONE of the companies expressed any interest in pursuing somatic cell nuclear transfer as the means of overcoming the immune rejection problem.

b. There are other routes to solving the immune-rejection problem. Scientists are pursuing ways to engineer embryonic stem cells to make them rejection-proof in ALL recipients. Many new kinds of multipotent cells (found in the bone marrow, blood, fat, etc., of adults) have been transformed into nerve cells, bone cells, heart muscle cells, etc. If reintroduced into the patient from whose body they were first taken, these cells and tissues would not be rejected because they would contain only the patient's own DNA.

c. Cloning is not *essential* for basic research on selected diseases. If taken from patients with certain inherited diseases (e.g., juvenile diabetes), the multipotent adult precursor cells could be used to study the embryological development that leads to the diseases. It is not true that embryo cloning is the only way to obtain a library of stem cells that would permit such investigations.

d. Neither is it true that cloning of human embryos provides the only route to study the process of reprogramming of a specialized nucleus back to the unspecialized and totipotent state. Such studies can be carried out using somatic cell nuclear transfer

in animals, with animal oocytes and animal donor somatic nuclei. They have yet to be done.

In sum: Even if no single argument above is by itself decisive, their cumulative weight leads me to support a comprehensive ban on all human cloning, including the cloning of embryos for research. Such a ban is prudent, moral, and virtually cost-free. It is the only real ban on human cloning. In contrast, a ban only on implanting cloned embryos is imprudent and morally dubious, and would likely yield little benefit that cannot be obtained by other (morally unproblematic) means. Purporting to be a ban on reproductive cloning, it would in fact increase the chances that cloned human beings would be born, and sooner rather than later.

Opposition to human cloning-to-produce-children in America is overwhelming: the vast majority of our fellow citizens, including most scientists, would like to see it banned. Nearly every member of Congress has condemned it. Yet despite this near-unanimity, and despite the fact that bans on all human cloning are being enacted in many nations around the world, we have so far failed to give national public force to the people's strong ethical verdict. The failure of the last Congress to enact a ban on human cloning casts grave doubt on our ability to govern the unethical uses of biotechnology, even when it threatens things we hold dear. If Congress fails again to act this time around, human cloning will happen here, and we will have acquiesced in its arrival. It is my profound hope that Congress will rise to the occasion, and strike a blow in defense of human dignity.

Testimony of James Kelly
on Regenerative Medicine and Cloning
before the
Senate Judiciary Committee
March 19, 2003

Two years ago, while closely researching my own condition, I blindly accepted media reports claiming embryonic stem cells were our best hope to cure *other* conditions. When I realized the push for cloning was supported by companies that claimed they had no interest in pursuing the field (1), I wondered why. When I read media reports that sharply contrasted with information I had gathered from medical journals (2), I became concerned. When I read of my own condition being used to justify cloning (3), I began studying the issue in earnest. This is what I found:

- In embryonic stem cells derived from cloning, chromosomes transferred in the cloning process retain physical changes that accrue with age. These age-related changes are known to contribute to age-related disease (4,5).

  It is generally accepted that this physical change in chromosomes, called telomere deterioration, is a reliable indication of life span; the more rapid and serious the telomere deterioration, the shorter the expected life span. The creator of Dolly the sheep, Dr. Ian Wilmut, reported a marked shortening of telomeres in Dolly's chromosomes compared to those from non-cloned animals, and even suggested "the most likely explanation" for the physical deterioration observed in these animals "reflects that of the transferred nucleus. Full restoration of telomere length did not occur because these animals were produced without germline involvement (6)."

  Studies have shown that telomere restoration *does* occur in late-term fetal cows and newborn calves, but not in calf embryonic stem cells. The *Proceedings of the National Academy of Sciences* reports (7):

  "These results demonstrate that cloned embryos inherit genomic modifications acquired during the donor nuclei's in vivo and in vitro period but are subsequently reversed during development of the cloned animal."

  It is not known if Dolly's telomere defects were due to the type of somatic cell she was cloned from, or the difference in species between cows and sheep (8). Nor has research indicated how human telomere length will react to cloning. However, this issue provides one explanation why biotech companies and researchers are pushing to legalize cloning to produce late-term fetuses and newborn babies in more than one state.

  Since Dolly the sheep was cloned from the mammary gland cell of a six-year-old sheep, in essence her chromosome ends were already six years old, and therefore deteriorated more rapidly than those of non-cloned animals. In Dolly's case she died of a progressive lung infection normally seen in animals twice her age. (She was cloned from a six-year-old ewe and died when she was six.) An autopsy revealed she also suffered from cancer and arthritis (9).

- Investors are unwilling to invest in cloning (10), since its potential for leading to clinical treatments, if any, is considered decades away or, as a recent New York Times article concluded (11), "in the distant future."

  Scientist Janet Rowley is a pro-cloning member of the President's Council on Bioethics. In speaking of the therapeutic potential of cloned embryonic stem cells she recently cautioned, "I think it's not fair to say that the promise will not be realized, but I think that it is fair to say that the promise may take a very long time. And I just want to point out that we began the war on cancer in 1970 with the notion that it was all going to be over in 10 or 20 years and we're far from it (12)."

- Biotechnology corporate leaders believe its chances of success are "vanishingly small (1)."

- The public is being told that therapeutic cloning does *not* require the creation and killing of human embryos, when in fact that's exactly what it does.

- We've been led to believe that cloning's widespread and variable genetic defects pose no therapeutic risks. The truth is that researchers don't *know* how many genes are affected by cloning, or cloning's potential for mutation or aberrant imprinting during adult cell mitotic division, or the long term consequences of introducing such cells into adult organs.

  Dr Robert Marcus, Director of the East Anglia Bone Marrow Transplant Unit, explains the risks (13):

  "Any time you transfer genes within the cloning process, or change the genetic material within a cell, there may be defects introduced into a natural organ or species development. I think I would be quite cautious there."

  Unraveling the genetic riddle will be difficult, warns stem-cell researcher Joanna Maldonado-Saldivia of Cambridge University. "This work shows that lots of genes go wrong after cloning," she says. But so many are unidentified that it could take years to discover their functions (14).

  Davor Solter of the Max-Planck Institute agrees (15):

  "Misreprogrammed genes are like cockroaches. Where you see one there are likely to be many more under the surface."

- Embryonic stem cells derived from cloning are *not* expected to perfectly match the donor -- they may face rejection and require immune suppression.

  Dr. John Gearhart told the President's Council on Bioethics there is "no question" in his mind that embryonic stem cells derived from cloning "could be rejected (16). Absolutely." Dr. Irving Weissman explains (17):

  "I should say that when you put the nucleus in from a somatic cell, the mitochondria still come from the host (the egg)... And in mouse studies it is clear that those genetic differences

can lead to a mild but certainly effective transplant rejection and so immune suppression, mild though it is, will be required for that."

At MIT researchers tried to fix a genetic defect in a mouse with embryonic stem cells derived from cloning (18). Unexpectedly, the mouse refused to accept its own cloned cells. The researchers were so surprised they tried the test twice with the same result. To fix the problem they resorted to using *reproductive* cloning to create a *baby* mouse with the defect fixed. They then used its *adult* stem cells to fix the defect in the original mouse. In reporting this finding the researchers say:

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

Another study implanted a cloned embryo in a cow's womb. The fetus was later aborted and its fetal stem cells removed. These fetal cells were then implanted in the donor without apparent rejection (19). This test is being promoted as showing cloning *might* avoid rejection. However, neither study reports cloned *embryonic* stem cell acceptance by donors.

If further proof were needed, the above perspective certainly provides another reason why pro-Biotech legislation has been proposed in more than one state to permit the derivation and use of stem cells from cloned late-term fetuses and even newborn babies.

- If custom treatments from cloning *could* someday exist, they're expected by leading scientists to be too "astronomically" expensive (20).
- Australia's leading embryonic stem cell expert, Professor Alan Trounson, says the pace of stem-cell technology has been so rapid that therapeutic cloning is now unnecessary (21).

  "My view," he said, "is there are at least three or four other alternatives that are more attractive already."
- In citing clinical results using adult stem cells to repair human hearts, the Director of a prestigious German medical journal presents a truth that Americans are *not* being told (22):

  "The promises of unscrupulous embryo researchers, that clone without clear clinical goals and experiments, are insupportable. This remarkable proof has now given us a clear sign the Americans with their prohibitions are exactly right. The biotechnological revolution can take place without embryonic stem cells if the alternatives are developed."

Adult stem cells and cord blood have been used to cure 69 patients in France with sickle cell anemia (23). They've reversed multiple sclerosis in patients in Canada and China (24,25). In Germany, France, and the U.S. they've repaired the human heart (26,27,28). For my own condition, spinal cord injury, adult regenerative tissues are being clinically used in Portugal (29), Italy, Australia (30), and China. They've already been used to reverse paralysis in Portugal (31). In fact, with media attention focused on the threat of a "brain drain" if researchers are banned from cloning humans, we've totally overlooked the threat

of a "patient drain," since foreign doctors are successfully treating patients with adult regenerative treatments.

Besides the above cited applications, adult stem cells have also been used to safely and successfully induce remission in several cancers and improve patient conditions with Stroke (32), Parkinson's Disease (33), and Rheumatoid Arthritis (34). In mice, after drugs were used to remove the *cause* of type 1 Diabetes, the body's adult stem cells regenerated its missing islets (35). Others have used adult pancreatic stem cells to directly replace beta islets in diabetic mice, which then respond to glucose challenge, induce vascularization, and *completely* reverse insulin-dependence (36,37).

Recently, bone marrow stem cells were found to mature into insulin-secreting beta-islets in a conclusive test (38,39,40). Moreover, researchers have reported a flaw in previous embryonic stem cell studies for Diabetes. It appears that ES cells reported as producing insulin may in fact have absorbed and re-released the insulin from surrounding tissues (41).

A Medline search for every condition that stem cells are hoped to address finds that adult regenerative results far outstrip embryonic and fetal results with far fewer reports of adverse effects. The reason for this is simple. Adult stem cells are *designed* to regenerate organs in the adult body, whereas embryonic stem cells are made for the embryo.

In an admirably honest admission that speaks volumes, Dr Michael Good, Director of the Queensland Institute of Medical Research, has declared as a doctor and scientist that using embryonic stem cells poses more problems than adult stem cells and is unnecessary (42).

"The difficulty with using embryonic stem cells," Dr Good said, "is the tissue will be regarded as foreign and will be rejected by the body if the cells are not *exactly* matched to the patient. There are reports that prove that patients can donate their own adult stem cells, thereby dealing with the problem of the body rejecting the tissue."

He said research has also shown that the use of embryonic stems cells caused cancer growth in animals.

Dr. Good explained that supporting ES research would drain money away from effective research into adult stem cells. He also said a lot of money going into embryonic stem cell research came from drug companies which wanted to test the side effects of drugs on pure human tissue from embryos. (This may help explain the Pharmaceutical push in NJ for access to late term fetal and newborn clones.)

- Embryonic stem cells from *any* source are *not* considered by most scientists to be the optimal transplantation cell of choice (43). This is *another* truth America is not being told, which further explains why in New Jersey Science and Biotech are pushing for access to cloned late-term fetuses and newborn babies (44).

  Says the Director of Rutgers Neuroscience Center, Dr. Wise Young (45):

> "Dr. Carvey is expressing a growing consensus in the field that the most desirable cells for transplantation are cells that are far enough along the way to differentiating into desirable cells, such as neurons, insulin-secreting cells, radial glial or olfactory ensheathing glial cells, that they have a high likelihood of producing such cells. I recently heard a lecture by John Gearhart expressing the same goal, the differentiation of fetal stem cells to the point where they will produce a particular cell type predictably."

To summarize, embryonic stem cells derived from cloning:

- do not perfectly match the patient
- contain known and unknown genetic defects, as well as defective imprinting
- are expected to require immune suppression for immune-sensitive conditions
- retain the genetic age of the donor
- are *not* considered desirable for transplantation
- may be too expensive for patients to afford.

Regarding the likelihood that science will overcome just one of these issues (defective imprinting), Dolly's creator predicted in *Nature* (46):

"It should keep a lot of us in business for a long time."

Moreover, these flaws are in *addition* to critical defects already inherent in embryonic stem cells from *any* source. Regarding this point, The Institute for Science in Society, an international organization of 462 scientists from 57 countries, issued the statement (47):

"The risks of cancer, uncontrollable growth, genome instability and other hurdles make ES cells a bad investment in terms of finance as well as public health benefits."

The Institute adds that adult stem cells "are more likely to generate affordable therapies that can benefit everyone."

In other words, even if cloning's very real practical concerns *could* be overcome, including its need for female eggs and its expected exorbitant costs, and even if its rejection issues and genetic flaws *could* be addressed, it *still* would do nothing more than provide cells *known* to be genetically unstable, grow uncontrollably, and cause cancer (48).

Why then are millions of dollars, which could have been used to develop cures, instead being spent on a national campaign to convince Americans that therapeutic cloning offers their brightest hope for cures?

The ISIS offers one explanation:

"Commercial imperatives are the major impetus for ES cell research, much more so than for adult stem cells. There are more opportunities for patenting cells and cell lines as well as isolation procedures."

The Institute concludes:

"Scientists should stop manipulating public opinion to promote research that's both morally and scientifically indefensible. At the same time, governments need to invest our tax money in scientific research that can genuinely benefit the health of the nation, and not be misled by false promises of the next economic boom."

The exaggerated "promise" of therapeutic cloning is not a path to cures in our lifetimes, but a dangerous diversion away from cures. It is in *the interest* of cures that I urge you to support S. 245, the Brownback-Landrieu ban on all human cloning.

References:

1) Quoted in D. Gellene, Clone Profit? Unlikely *Los Angeles Times*, May 10th, 2002, Business Section
2) by Alex Dominguez, Adult stem cells may not be a cure-all *Associated Press*, March 13th, 2002
3) by Massie K. Santos, Human cloning not just around corner *Inquirer News Service* December 07, 2001
4) Cawthon RM; Smith KR; O'Brien E; Sivatchenko A; Kerber RA. Association between telomere length in blood and mortality in people aged 60 years or older. *Lancet* (England), Feb 1 2003
5) Boultwood J, Fidler C, Shepherd P, et al. Telomere length shortening is associated with disease evolution in chronic myelogenous leukemia. *Am J Hematol* (United States), May 1999
6) Shiels PG, Kind AJ, Campbell KH, et al. Analysis of telomere lengths in cloned sheep. *Nature* (England), May 27 1999
7) Betts D, Bordignon V, Hill J, et al. Reprogramming of telomerase activity and rebuilding of telomere length in cloned cattle. Proc Natl Acad Sci (United States), Jan 30 2001
8) Tian XC; Xu J; Yang X, Normal telomere lengths found in cloned cattle. *Nat Genet* Nov 2000
9) Whitfield, John "Obituary: Dolly the Sheep," *Nature Science Update*, [On-line], February 18, (2003)
10) by Luc Hatlestad, Double Fault: Why investors have little interest in cloning. *Red Herring Magazine*, April 1999
11) by Gina Kolata, The Promise of Therapeutic Cloning *New York Times*, January 5, 2003
12) Transcript, Meeting of the President's Council on Bioethics, April 25, 2002
13) by Erica Heilman, Keeping Pace with the News: Stem Cells Simplified *ABC News*, Aug 16th, 2002
14) by Tom Clark, Silence of the Clones, *Nature, Science Update* 11 March 2003
15) by Philip Cohen, Single gene failure explains cloning deaths *New Scientist* Online, 14 May 02
16) Transcript, Third Meeting, Meeting of the President's Council on Bioethics, Thursday, April 25, 2002
17) Transcript, Second Meeting, Meeting of the President's Council on Bioethics, February 13, 2002
18) William M. Rideout III, Konrad Hochedlinger, Michael Kyba, George Q. Daley, and Rudolf Jaenisch, Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy *Cell*, vol. 109 no. 1, pp. 17-27
19) Lanza, R.P., *et al.* 2002. Generation of histocompatible tissues using nuclear transplantation. *Nature Biotechnology* 20(July):689-696.
20) Peter Aldhous, "Can they rebuild us?", Nature, April 5, 2001, pp. 622-5
21) by Tom Noble, Stem-cell Cloning Not Needed, Says Scientist, The Age (Melbourne) July 29, 2002
22) Middeke M. [It can be done without embryonal stem cells!] *Dtsch Med Wochenschr* 2001 Aug 24;126(34-35):931

23) Bernaudin, F., *et al.* Results of myeloablative allogenic stem cell transplant (SCT) for severe sickle cell disease (SCD) in France. American Society of Hematology meeting. Dec. 8. 2002
24) By Ann Lukits, Stem cell technique shows promise as MS treatment Saturday, *The Kingston-Whig Standard* November 23, 2002
25) Ouyang J, Ni X, Chen B. [A preliminary result of treatment of progressive multiple sclerosis with autologous peripheral blood stem cell transplantation in China] Zhonghua Nei Ke Za Zhi 2001 Aug;40(8):550-2
26) Strauer BE, Brehm M, Zeus T, Gattermann N, Hernandez A, Sorg RV, Kogler G, Wernet P. [Intracoronary, human autologous stem cell transplantation for myocardial regeneration following myocardial infarction] Dtsch Med Wochenschr 2001 Aug 24;126(34-35):932-8
27) Pagani, FD., et al., Autologous Skeletal Myoblasts Transplanted to Ischemia-Damaged Myocardium in Humans *Journal of American College of Cardiology* Vol. 41, No. 5 2003
28) by Nicholas Wade, Doctors Use Bone Marrow Stem Cells to Repair a Heart *New York Times* 3/06/03
29) Dr. Carlos Lima, Human olfactory mucosa grafts in traumatic spinal cord injuries: a way to cure paralysis? *Brainland Neuroscience Information Center* March 13th, 2002
30) by Rachel Nowak, Nose cells could cure paralysis *New Scientist.com* 11 July 02
31) by Dave Parks, Nerves in nose may repair spinal cord injuries, *Birmingham News*, 12/08/02
32) Kondziolka D, Transplantation of cultured human neuronal cells for patients with stroke. *Neurology* 2000 Aug 22;55(4):565-9
33) Laurie Barclay, MD, Autologous Neural Stem Cells Improve PD Symptoms, *MedscapeWire* 4/10/02
34) Kim KC, Lee IH, Choi JH, Oh MR, Ahn MJ, Kim SY. Autologous stem cell transplantation in the treatment of refractory rheumatoid arthritis. *J Korean Med Sci* 2002 Feb;17(1):129-32
35) by William J. Cromie, Adult Stem Cells Effect a Cure (Diabetes) *Harvard University Gazette* August 16th, 2001
36) Ramiya VK; Maraist M; Arfors KE; Schatz DA; Peck AB; Cornelius JG, Reversal of insulin-dependent diabetes using islets generated in-vitro from pancreatic stem cells. *Nat Med* 2000 Mar;6(3):278-82
37) Peck AB, Cornelius JG, Chaudhari M, Shatz D, Ramiya VK., Use of in vitro-generated, stem cell-derived islets to cure type 1 diabetes: how close are we? *Ann N Y Acad Sci* 2002 Apr;958:59-68
38) A Ianus et al.; "In vivo derivation of glucose competent pancreatic endocrine cells from bone marrow without evidence of cell fusion" *Journal of Clinical Investigation* 111, 843-850; March 2003
39) VM Lee and M Stoffel; "Bone marrow: An extra-pancreatic hideout for the elusive pancreatic stem cell?"; *Journal Clinical Investigation* 111, 799-801; March 2003
40) by Nicholas Wade, Bone Marrow Harbors Cells That Can Fix The Pancreas *The New York Times*, March 15, 2003
41) Melton, D. et al., Insulin staining of ES cell progeny from insulin uptake. *Science* v299 17 Jan 03
42) by Natalie Gregg, Scientist critical of 'unnecessary' studies, (Brisbane) *Courier Mail*, March 13, 2003
43) Rush Presbyterian St. Luke's Medical Center, First Report of Stem Cell Signal of Intention to Become Specific Neuron; Cloned Cells Cure Parkinson's in Rat Model, *Science Daily*, May 13th, 2002
44) Excerpt from New Jersey S1909, 1/11/02, "As used in this section, 'cloning of a human being' means the replication of a human individual by cultivating a cell with genetic material *through* the egg, embryo, fetal and newborn stages into a new human individual."
45) Care/Cure.com., Wise Young, administrator, Posted May 10, 2002 02:36 PM May 10, 2002 02:36 PM
46) By Helen Pearson, Cause of sick clones contested *Nature*, Science Update Jan 11th 2002

47) Dr. Mae-Wan Ho, Why clone humans? ISIS Feature Article http://www.i-sis.org.uk/whyclone.php
48) S. Wakitani, K., et al., Embryonic stem cells injected into the mouse knee joint form teratomas and subsequently destroy the joint. *Rheumatology* 2003; 42: 162-165

from the office of

Senator Edward M. Kennedy

of Massachusetts

FOR IMMEDIATE RELEASE
March 19, 2003

CONTACT: Jim Manley / Stephanie Cutter
(202) 224-2633

STATEMENT OF SENATOR EDWARD M. KENNEDY AT THE JUDICIARY COMMITTEE HEARING ON CLONING

It's an honor to join my colleagues for this hearing on stem cell research. I especially commend our Chairman, Senator Orrin Hatch, and Senator Feinstein, for their leadership on this important issue.

Two weeks ago, in the name of banning cloning, the House has approved legislation that would halt life-saving research and even prohibit the importation of new miracle cures from abroad. The legislation that Senator Hatch and Senator Feinstein have proposed and that I strongly support offers a far better approach. It will outlaw human cloning, but protect needed medical research that could alleviate the suffering of millions of patients. The use of cloning to reproduce a child is improper and immoral – and our legislation will make it illegal. But it does so in a way that enables needed and promising research to continue as we seek cures for our most feared diseases.

Our opponents have tried to create a fog of fears and myths to confuse human cloning with medical research that uses the remarkable new technique of stem cell research. The distinction is clear. The abhorrent practice of human cloning would create babies that are exact copies of another person. Stem cell research, on the other hand, is used to seek cures for diseases that deprive people of their right to a healthy, happy and productive life.

Medicine must advance hand in hand with ethics. Our legislation applies strict ethical standards to this research. These protections guarantee strong ethical oversight, informed consent, and respect for the privacy of donors.

Congress has faced similar controversies in the past. In the 1970s, Congress rejected attempts to place unwarranted restrictions on new techniques in biotechnology. Countless Americans today benefit from the discoveries that would have been blocked if Congress had cut off this vital research. In the 1980s, Congress rejected attempts to outlaw in vitro fertilization. Because we supported medical progress then, countless citizens now know the joy of becoming a mother or father.

We must not allow misguided fears to deny patients the cures of tomorrow. Our legislation will protect cutting-edge avenues of medical research that offer the hope of good health to millions of our fellow citizens.

-30-

Senator Jon Kyl
Statement on Human Cloning
Senate Judiciary Committee
March 19, 2003

Mr. Chairman, thank you for holding this hearing. This is an important issue, and I am particularly appreciative of the effort I know you made to ensure that each of the panels was balanced.

We all know that this is an issue that arouses great passions, touching as it does on some of the most profound issues of morality and ethics. In discussing this issue, we are compelled to pause and reflect on the concerns of American men, women and children who suffer from terrible diseases and disabling conditions. I am pleased that the fourth panel will provide patient advocates the opportunity to speak for themselves.

This issue also raises the specter of a brave new world, one in which all moral considerations have been subordinated to unfettered scientific experimentation, profit, or some combination of the two.

The stated purpose of this hearing is to determine how to pursue ethical medical research without inviting that brave new world. I would humbly suggest that our effort to do so proceed within a set of guidelines that include the following.

- We should strive for clarity about the status of the entity produced by the somatic cell nuclear transfer (SCNT) process – and eschew semantic confusion. An admirably straightforward treatment of this question was provided by President Clinton's bioethics commission in its 1997 report on cloning. That report states:

  "The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term."

- Clarity is vitally important because without it, we may fail honestly to engage one of the most disturbing questions that has been raised in this debate: How would the law regard the cloned child?

  I am concerned that amidst some of the semantic hairsplitting that this debate tends to gets bogged down in, the suggestion has arisen that the embryo generated through the cloning process would not actually be a human being.

  Participants in this debate have even gone so far as to suggest that if an embryo is produced, implanted, and delivered through a process like that created Dolly the Sheep rather than conventional fertilization, then it is questionable whether that little boy or girl should be understood to be a human being.

  Such speculations quickly get us into very deep ethical waters. The corollary of the implied contention is that **if** the Raelians or someone else effected the birth of a child created through this process – then the child would not enjoy the

protection of the law and could be killed with impunity.

- The concerns about what would be entailed in enforcing a law that purports to distinguish between cloning for research and cloning for reproduction are very serious and troubling. The Department has advised Congress as follows:

  "The task of enforcing a ***general*** ban on human cloning ***for any purpose*** does ***not*** seem to pose insuperable challenges to law enforcement. Such a ban would clearly define the exact activity to be banned, which is the use of the procedure known as somatic cell nuclear transfer to produce human embryos.

  [On the other hand,] Enforcing a modified cloning ban would be problematic and pose certain law enforcement challenges.... [T]here does not seem to be any reliable means for determining the difference between a fertilized embryo and a cloned embryo... there would simply be no way for a prosecutor to prove that the implanted embryos were the ones which arose from cloning [and] ... any government-directed attempt to terminate a cloned embryo in utero would create ***problems enormous and complex***."

  Given our unique responsibility to ensure the good order of law enforcement operations in this country, I trust that we as a Committee, will not shrink from facing those "enormous and complex" problems squarely.

- I look forward to reviewing the testimony of scientists, including those who contend that the use of cloning technology will lead to important medical progress. That said, I have deep reservations about a logic that implies that the promised benefits of research can make it ethical – a logic that seems to be embedded in the official title of this hearing. Such a framework replaces actual ethics with guesswork, gives the scientific community an unwholesome incentive to inflate estimates of benefit, and truly does put us on a slippery slope to a world

in which the dignity of every human being is subordinated to an elite's assessment of "the greatest good for the greatest number."

Advocates of a cloning ban may not be able to "prove a negative" in the face of claims about the benefits of future cloning experimentation. But we can draw on the cautions that history provides. A decade ago, many in the scientific community were pressing for federal funding of research using tissue harvested from aborted fetuses. Many Members – including pro-life Members – joined that effort, and it was ultimately successful.

But once the ethical boundary was crossed, who noticed that the promised benefits failed to materialize? A *New York Times* article noted that a much-heralded effort to use fetal tissue to treat Parkinson's patients "not only failed to show an overall benefit, but also revealed a disastrous side effect" – in about fifteen percent of the patients, the fetal tissue implants triggered the production of "so much of a chemical that controls movement that the patients writhed and jerked uncontrollably."

I hope that colleagues and members of the general public will keep in mind that what we are being asked to do is trade the certain jettisoning of what until recently was an almost-universally recognized "stop sign" in bioethics for benefits that remain purely speculative, a trade-off that we might well live to regret.

- Finaly, I believe that we all must wrestle with the implications of a public policy that sanctions the manufacture of human embryos -- that is, living members of the human species -- for use as disposable research material. The fervent desire to cure the diseases that blight the lives of our friends, neighbors, and family members is a part of what makes us human, but it is not all that makes us human. I fear that if we allow ourselves to become accustomed to the use of human beings as research material, we will have allowed ourselves to become less human.

I trust that today's proceedings will provide illumination for us as we struggle with these and other important aspects of this vital issue.

U.S. SENATOR PATRICK LEAHY

CONTACT: David Carle, 202-224-3693 VERMONT

Statement Of Senator Patrick Leahy,
Ranking Democrat, Senate Judiciary Committee,
Hearing On
"Drawing The Line between Ethical Regenerative Medicine Research And Immoral Human Reproductive Cloning"
March 19, 2003

I am pleased the Senate Judiciary Committee is considering the scientific, moral, and ethical implications of cloning. In February, the House of Representatives passed legislation that would ban cloning technology for human reproductive and therapeutic research purposes. A similar bill has been introduced in the Senate by Senators Brownback and Landrieu.

This hearing will take up a bill that was introduced by Chairman Hatch and Senator Feinstein to ban cloning technology for human reproductive purposes but not for therapeutic research purposes. I look forward to hearing from today's witnesses on this challenging question. It is important for us to hear from experts on both sides of the issue so that we can fully understand the distinction between therapeutic and reproductive cloning technology.

I have spent a great deal of time giving this complex issue the serious deliberation it deserves, especially in light of recent claims by a religious sect that it cloned an infant. I am strongly opposed to the use of cloning techniques for the purpose of creating human beings. However, I do believe there are significant distinctions between human reproductive cloning and so-called "therapeutic cloning." The latter uses recombinant DNA techniques for research that could extend and enhance the lives of patients suffering from Alzheimer's disease, Parkinson's disease, diabetes, or physically crippling injuries. I do not believe Congress should prevent this promising research.

Again, I would like to thank the witnesses for coming today. I hope and expect that today's hearing will help us better understand this complicated issue.

#####

senator_leahy@leahy.senate.gov
http://leahy.senate.gov/

TESTIMONY ON THERAPEUTIC CLONING

Micheline M. Mathews-Roth, M.D.

I am Dr. Micheline Mathews-Roth. I am an associate professor of medicine at the Harvard Medical School, and a Physician at the Brigham and Women's Hospital: both institutions are in Boston, Massachusetts. I want to make it clear, however, that I am not speaking as a representative of either of these institutions, but as an individual physician and medical researcher. I do clinical and basic research on a rare genetic disease called erythropoietic protoporphyria (EPP). I developed what is the FDA-approved treatment for EPP (Annals N.Y. Acad. Science 1993; 691:127-138), and additionally, my collaborators and I have demonstrated that the mouse model of EPP can be cured by gene therapy of the bone marrow stem cells of these EPP mice (Nature Medicine 1999; 5:768-773).

The point of my testimony is to educate you by giving you the scientific information you need to know to understand exactly what is involved in therapeutic cloning, or as it is also called, research cloning, somatic cell nuclear transfer, or nuclear transplantation. The purpose of therapeutic cloning is to obtain embryonic stem cells to be developed into cells or tissues or organs to be used to treat a serious disease, such as Alzheimer's disease or diabetes or Parkinson's disease, that a particular patient has. Cloning is done by taking an oocyte (egg cell) from a female donor, and removing its nucleus. Then, a somatic cell (a body cell, not an egg or sperm cell) is obtained from the patient to be treated, and its nucleus is removed and is placed into that oocyte. The oocyte with its new nucleus, which has all 46 chromosomes, is the first cell, called a zygote, of the cloned individual. This zygote is then stimulated to start its growth and development. The cloned zygote's development is the same as that of a zygote produced by the union of egg and sperm by either sexual reproduction or by in-vitro fertilization (IVF) (see the "Information on Human Development" section and comparison table in the appendix of my written testimony, as well as the figure from the National Academy of Sciences publication on human cloning attached to the end of my testimony's text).

An important fact of embryology that is crucial for you to know is that each member of the human species indeed starts his or her existence as one cell, the zygote: and that this fact applies whether the zygote was formed by the union of egg and sperm in the mother's body or in a petri dish in the process of IVF, or by the processes of reproductive or therapeutic cloning. Again, look in the "Information on Human Development " section of the handout for the scientific references for this fact. **So, it is scientifically incorrect to say that a human life begins in the mother's womb - by the time the growing embryo arrives at the mother's womb to implant in it, including a cloned blastocyst, it is already 5 to 6 days old!** Again, check the "Information on Human Development" and "Timetable of Human Development" sections and the National Academy of Sciences figure of the handout for the scientific data on this.

There is an additional important scientific fact which must be remembered about embryonic stem cells, whether they are obtained from excess embryos produced by IVF or whether they are obtained from embryos made by therapeutic cloning: the only way to obtain these cells at the present time is to destroy - that is, to kill - a growing young human of 5 to 7 days of life, the age at which its "inner cell mass", the group of embryonic stem cells that the growing young human contains, can be removed. **To put it bluntly, in therapeutic cloning, a human being is made to start its life for the sole purpose of killing it when it gets to be 5 to 7 days old to obtain its useful parts, that is, its embryonic stem cells.**

I want to point out that there is an error in scientific terminology in the S-303 bill: there is no such thing as an "unfertilized blastocyst". You must realize that the somatic cell nucleus introduced into the enucleated oocyte in the process of cloning was formed by fertilization - when the sperm from the father of the nuclear donor fertilized the oocyte of the mother of the nuclear donor. That nucleus, as mentioned above, has its full component of 46 chromosomes, as does the nucleus of every

cell which will form when the cloned zygote starts to divide. If an oocyte is truly unfertilized, its nucleus will have only 23 chromosomes, and cannot divide - 46 chromosomes are necessary for normal cell division to occur. It should be obvious from this that a cloned baby or cloned cells for therapeutic cloning will indeed have two genetic parents - the mother and father of the nucleus donor. The clone is essentially the identical twin of the nuclear donor! There is a process called parthenogenesis, where either an oocyte or a sperm cell is stimulated to divide without being fertilized, but according to embryology textbooks, in the human species, only a few cell divisions would occur, because too many genetic defects would be present to allow full development: both a maternal and a paternal set of genes are needed for normal development in the human.

It should be obvious from the scientific data I have presented here, that producing embryonic stem cells from a blastocyst obtained from either therapeutic cloning or from excess IVF embryos results in the death of a very young human being, a "new genetically distinct human organism" (O'Rahilly and Muller). What we have to ask ourselves is: **do we as a society really want to allow the bringing into existence of many young humans for the sole purpose of killing them to obtain their useful parts, even for the laudable purpose of alleviating the suffering of other members of our species?** This is what sanctioning therapeutic cloning really means. And, it seems to me that doing this is a form of blatant discrimination - against very young humans - a vicious form of ageism, declaring that certain human beings are not worth protecting from deliberate killing..

Additionally, we have to remember that there is no guarantee that we will be able to master the process of directing embryonic stem cells from either cloned embryos or IVF embryos into developing into the kinds of differentiated cells or tissues we need for therapy without causing harm to the recipient of these cells or tissues: we are years away from achieving the goal of safe and effective embryonic stem cell therapy. The theoretical advantage of using cells and tissues derived from cloned embryonic stem cells is that there should be no immunological rejection of cells or tissues formed from them when these are transplanted into the nucleus donor to treat his or her disease, but this may not be completely true. Although by using the patient's own cells to produce the clone, one eliminates the problem of frank immunological rejection, immunological problems are not totally eliminated because of the presence of foreign mitochondria in the replacement tissue (i.e. the mitochondria of the enucleated oocyte, which will give rise to all the mitochondria in the cloned replacement cells or tissue). This can lead to some degree of immunological problems in the patient receiving the transplanted cloned cells or tissue, perhaps such as inducing autoimmune problems. Additionally, since many mutations occur in the early embryo in the first few days of life, a cloned embryo would not be exempt from developing these mutations, which would be transmitted to the inner mass cells (i.e. the embryonic stem cells). In normal intrauterine development, the majority of these defective blastocysts would be eliminated because they can't develop to implantation and beyond, but when development is stopped at 5 to 7 days, these early mutations are not eliminated. There is the possibility that these mutations may cause problems in the differentiated cells developed from the defective clone's embryonic stem cells. Also, reprogramming and imprinting errors developed in the early embryo would probably remain in the stem cells developed from that embryo, and may lead to future problems, perhaps malignancies, in the cells and tissues developed from them. And also the problem of teratoma (tumor) formation still exists. The bottom line is that much more research must be done in animal models (mouse and especially primate) to demonstrate the safety of transplanted cloned tissue, let alone its efficacy, before any human studies are even contemplated.

Now for some ethical considerations. Physicians are not supposed to kill human beings of <u>any</u> age. Trying to justify the killing of what we know are very young (5 to 7-day old) human beings, even for the very laudable purpose of trying to cure disease, is ethically unacceptable: a good end (successfully treating disease) never justifies using evil means (killing a young human to get its cells) to obtain the good end. Additionally, one cannot justify such deliberate killing of young humans by invoking the known fact that about 40% to 45% of zygotes never implant anyway.

In addition, researchers who develop new drugs or therapies are obliged to give sufficient and accurate information about these drugs or therapies to the patients who will receive them, so that the patients may give truly informed consent to receiving these therapies. This applies especially to pioneering treatments like cell and gene therapy (regenerative medicine). For patients receiving IVF embryo-derived or therapeutic cloning-derived stem cells, to give truly informed consent, these patients will need to be clearly informed that a very young human (and in the case of therapeutic cloning, their very young identical twin) will need to be killed to obtain the stem cells to be used in their treatment, even though these stem cells will be differentiated into specific cells, tissues or organs. If these facts are not made completely clear to the patients receiving either source of embryonic stem cell-derived cells, tissues or organs, then the researchers will have failed in their obligation to the patients to provide enough information for the patients to give truly informed consent. It is possible that some patients would not undergo the procedure if they know that killing a young human is involved, and once they find this out, they may be upset enough to consider bringing legal action against the researchers. Thus, it is to everyone's advantage that the complete truth about the derivation of stem cells - that is, the well-established scientific facts about the beginning of a life, and its necessary destruction to get stem cells - be given to potential patients, so that each can make a truly informed choice about whether they wish to receive cells or tissues which were obtained at the cost of another human's life. Regenerative medicine is certainly the wave of the future, but the scientific and medical establishment, as well as the government, has the obligation to allow only those therapeutic investigations to proceed which will not result in the deliberate killing of any human being of any age during the process of developing the therapeutic modalities, and which will not further jeopardize the health of the recipient of the generated cells, tissues or organs.

So are we denying treatment to our patients if we deny them the use of embryonic stem cells? Absolutely not - because there is good evidence that there are certain kinds of adult stem cells which are proving to be very versatile in being able to be transformed into the different kinds of tissues which are needed to treat serious diseases. Already there are many examples in the medical literature: in fact Dr. Weldon prepared a list of such papers. In one very exciting example, Dr. Catherine Verfaillie has discovered cells which are found in the bone marrow which she calls multipotent adult progenitor cells (MAPCs) which can be made to differentiate into cells of all three embryonic layers - endoderm, mesoderm and ectoderm. She finds these in human marrow, as well as in mouse marrow. She finds that they do not form teratomas, tumors which are commonly formed by embryonic stem cells, and suggests that since the MAPCs can divide extensively without loss of their potential to diferentiate into different tissues, they may be an ideal cell source for therapy of inherited or degenerative diseases (Nature 2002; 418:41-49; see also pages 1 and 25 of that issue). Another exciting recent study is that of Dr. Eliezer Huberman, who has found a cell from peripheral blood which is also expandable and can be differentiated into endothelial cells, nerve cells and liver cells (Proceedings of the National Academy of Sciences 2003;100:2426-2431). Neither of these cell types seem to undergo fusion with mature cells, which makes them very exciting for potential therapeutic use.

In summary, do we as a country really want to sanction the deliberate production of tiny bona-fide members of our human species for the only purpose of killing them to obtain their useful parts, in spite of the fact that using adult stem cells is also effective? Even if embryonic stem cell therapies were shown to work better than using adult stem cells, which I think is doubtful in view of the work by Verfaillie, Huberman and other scientists, it would not remove the fact that we are using an evil means, the killing of very young members of our species, to attain the good aim of curing disease. You, our ligislative leaders, had better think long and hard about this - do you really want to allow this atrocity to happen?

02/04/2003 17:10 BIO OUTBOUND → 2282258 NO.915 P02
FEB-04-2003 TUE 04:23 PM FAX NO. P. 02

February 5, 2003

The Honorable Dianne Feinstein
United States Senate
Washington, DC 20510

Dear Senator Feinstein:

As members of the religious community, we would like to commend you for your leadership on stem cell research. Your recognition of the great promise of stem cell research and your support for legislation that allows therapeutic cloning offer great hope for those suffering from juvenile diabetes, Alzheimer's disease, Parkinson's disease, spinal cord injuries, and other ailments.

This is a difficult issue for all of us, and we understand the complex decision you face in considering any legislation that involves human cloning. While it is imperative that we as a nation and as people of faith proceed with great caution, it is also important to do what we can to alleviate the suffering of others. Therefore, we believe that to ban this potentially life-saving research would be a mistake.

Like most, we are opposed to the practice of reproductive human cloning. A ban on this practice would be both welcome and appropriate. Therapeutic cloning, however, requires careful review. We are pleased that you considered this issue in its entirety and took into account the countless individuals who could be saved and whose pain could be alleviated by this medical research. We have a duty to do what we can to help our fellow man, and you have demonstrated your commitment to doing so through your leadership on this issue.

Sincerely,

Rev. Dr. Michael Bledsoe
Senior Pastor
Riverside Baptist Church
Adjunct Professor, Howard
University School of Divinity
Washington, DC

Rev. Dr. Joan Brown Campbell
Director of Religion
Chautauqua Institution
Chautauqua, NY

The Rev. Dr. George F. Regas
Rector Emeritus
All Saints Church
Pasadena, CA

Rev. Dr. J. Philip Wogaman
Professor of Christian Ethics Emeritus
Wesley Theological Seminary
Former Senior Minister
Foundry United Methodist Church
Washington, DC

TESTIMONY OF

THOMAS H. MURRAY, PH.D.

PRESIDENT, THE HASTINGS CENTER
GARRISON, NEW YORK

BEFORE THE

JUDICIARY COMMITTEE
UNITED STATES SENATE

MARCH 19, 2003

HEARING ON "PROMOTING ETHICAL REGENERATIVE MEDICINE RESEARCH AND PROHIBITING IMMORAL HUMAN REPRODUCTIVE CLONING"

I thank the Committee for the invitation to speak on the ethical issues of human cloning, including both reproductive cloning and the use of nuclear transplantation in research with human stem cells. My name is Thomas H. Murray, Ph.D. I am President of The Hastings Center, a non-profit, non-partisan research institute devoted to ethical issues in health and medicine, the life sciences, and the environment. Until it disappeared into the sunset in October 2001, I was a presidential appointee to the National Bioethics Advisory Commission. That body was asked to consider a broad range of issues in bioethics including human reproductive cloning and research on human stem cells. I had the honor and the awesome responsibility of participating in those deliberations. The United States Congress has the even more awesome responsibility of setting our nation's policy on these issues. I offer my remarks with gratitude and respect.

First I want to address reproductive cloning. In the six years since the birth of Dolly, the cloned sheep, was announced, the ethical case against reproductive cloning has grown stronger. The National Bioethics Advisory Commission concluded in its report on human cloning in June 1997: "...at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning." (p. iii) The scientific evidence on the dangers of reproductive cloning has progressed from informed speculation to hard evidence. Scientists are beginning to understand the specific and powerful obstacles against reproductive cloning in primates. Trying to create a child by cloning would be grossly unethical human experimentation.

The most sympathetic case for cloning to make a child is to try to bring back a child who died. The sad truth is that this is an illusion. For one thing, reproductive cloning works poorly when it works at all. Most cloned mammals die before or shortly after birth. Those that survive are almost certainly abnormal because of failures to reverse and redo epigenetic programming or other problems. If, despite the odds, a healthy child were born, it would be the same child only genetically; there is little reason to believe that this child would have the same personality, temperament, enthusiasms or interests as its progenitor. The child would live under a suffocating shroud of expectations that it would be just like the child who was lost. And the parents would learn that there are no technical fixes for grief. Grief is a lifelong affliction; it lies beyond the reach of science.

A law to ban human reproductive cloning would be useful. Not to deal with a plague of human clones; there is no such plague and despite the claims of would-be cloners, we can be virtually certain that there are no human clones alive or likely soon to be born—no healthy ones at least. We need the law to deny all legitimacy to that handful of entrepreneurs who are growing famous and wealthy with their ludicrous boasts, to protect gullible, desperate or hopelessly narcissistic people from exploitation, and, most of all, to prevent the almost certain harm befalling any child born through cloning. Such a law would be welcome by almost all Americans.

The ethics of nuclear transplantation in research with human stem cells presents a very different picture. In September 1999 the National Bioethics Advisory Commission issued its report, "Ethical Issues in Human Stem Cell Research." That report recommended federal

funding for research on human embryonic stem cells derived from embryos left over after in vitro fertilization, destined to be discarded, and donated for research. The Commission also proposed very stringent safeguards against commercialization and coercion.

It is important to note that the National Bioethics Advisory Commission consulted experts in theology from four great religious traditions: Roman Catholicism, Protestantism, Judaism, and Islam for its report on human cloning as well as for its stem cell report. In the stem cell report in particular we found a range of views within and among traditions. Some Catholic and some Protestant theologians opposed embryonic stem cell research, some argued that their tradition permitted it. NBAC considered only briefly the then-hypothetical possibility of combining nuclear transplantation with stem cells and did not make any specific recommendations concerning the matter. However, NBAC's other recommendations would not permit federal funding for embryos created by nuclear transfer. But NBAC noted the possibility that such research may take place with funds from other sources. The question before us was federal funding, not criminalizing a specific form of scientific research.

Dr. Kass can explain the reasons cited by the currently active President's Council on Bioethics in support of a moratorium on what they propose calling "cloning-for-biomedical-research," which they distinguish from "cloning-to-produce-children." I would be pleased to comment on those arguments should Committee members request.

The ethical arguments in favor of not criminalizing nuclear transfer in human stem cells are straightforward. The most compelling reason is that this research may contribute in time to the relief of suffering and the postponement of untimely death. Success is of course not certain; it is also possible that the greatest contributions to human health from research cloning will come from the basic research it will make possible as scientists create stem cell lines for an enormous variety of diseases, cell lines that will allow us to understand and, ultimately, treat or prevent those diseases. What is sometimes overlooked is the deep human truth that suffering and death afflicts families, not merely the individual. Our lives are entwined with the lives of others whom we love. Their suffering, their death, profoundly affects our own. When we minister to suffering, we minister not only to the individual but also to all of those who love and care for her or him. Anyone of us who has loved someone who suffered or died knows the truth of this.

A second argument appeals to our moral, legal and political traditions of freedom of speech and freedom of inquiry. Americans value the quest for new frontiers; today's explorers are more likely to wear white coats and inhabit laboratories than to paddle canoes or hike over mountain passes. Scientific inquiry is obliged to respect moral limits. That principle was resoundingly affirmed in the trials at Nuremburg and in our own nation's apology to the subjects of the Tuskegee syphilis study. But when we have no consensus that a form of research is ethically improper, the wiser course is to allow people to follow their individual consciences. This respects the value of freedom of inquiry without forcing people to violate their beliefs.

What reasons do people give for criminalizing nuclear transfer to create stem cells? This is a very important question: It is one thing to decide not to fund an activity because some Americans have moral objections to it. (If we applied that principle broadly, there would be no funding of research on blood transfusion or, for that matter, transfusions themselves, on the

grounds that Jehovah's Witnesses object to transfusions. The same would be true of all research using animals.) It is quite another to create a new federal crime for doing what the majority of Americans do not find inherently wrong—that is, work with very early human blastocysts.

We must acknowledge that morally thoughtful Americans are not of one mind on the moral status of four or six day-old blastocysts. In my book The Worth of a Child I posed a challenge: Imagine some new ethical argument or scientific fact that persuaded nearly everyone on one side of the embryo-as-person debate that they had been mistaken. The other side is right, they would admit. Can you imagine such an argument or fact? I cannot. Notice that I did not say which side came up with the persuasive new moral consideration. This is, I believe, not because people are impervious to logic, but because our beliefs about embryos are woven into a complex tapestry of other beliefs—about what it means to be a woman, a man, a child; about families; about the importance of being a nurturing parent. This tapestry of beliefs and commitments affects everything from our attitudes towards sex discrimination in employment to the importance of family leave and educational opportunities for women.

Respecting the diversity of beliefs about families, about women, men, children—and embryos—honors our most noble traditions. Where there is a clear and ringing consensus—as there is against cloning to create a child—let us act on it. Where there is profound and principled disagreement, let our laws respect that. Declining to fund such research can be an honorable choice and a wise public policy. Sending scientists to prison for ten years and subjecting them to fines of a million dollars or more devalues the ethical views of Americans for whom the possibility of alleviating suffering justifies research cloning.

There are important positive steps we can take now to control destructive uses of the technology. We can insist that all such research, whether publicly or privately funded, must be conducted according to the most stringent ethical standards. This would require legislation bringing such research under the so-called Common rule, 45CFR46 or the corresponding rules for research overseen by the FDA. We can enhance public accountability of the infertility industry by establishing stringent standards for procuring human eggs—now left to an essentially unregulated market. Let us take those steps now.

Thank you for this opportunity to testify and I look forward to responding to your questions.

January 13, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The National Venture Capital Association strongly supports the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*, sponsored by you, Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA), and Senator Tom Harkin (D-IA).

We understand the newly introduced bill would criminalize reproductive cloning while continuing to allow therapeutic cloning, which has the potential to treat life-threatening diseases, including spinal cord injury, Parkinson's disease, Alzheimer's disease, ALS, heart disease, diabetes, and cancer. The rigorous oversight provisions, including review by an ethics board, protections for research participants and large financial penalties for violations are a reasonable approach to creating a bright line test for all cell therapy—clearing the way for legitimate cell research and development of therapies to continue in the United States without the stigma that this behavior is unethical.

Promoting certainty in the area of cell research and therapy development is likely to increase commercial participation and venture support for these activities— a result that will hopefully speed successful development of treatments and encourage the participation of a vital component of the life science product development cycle that is largely missing from current cell therapy efforts.

NVCA appreciates your continued leadership on this issue as demonstrated through your sponsorship of this legislation to promote the development of better treatments and cures for the millions of Americans living with life-threatening diseases.

We look forward to working with you. If we can be of any assistance, please contact Nancy Saucier of my staff at 703/524-2549.

Sincerely,

Mark G. Heesen
President

1655 North Fort Myer Drive • Suite 850 • Arlington, Virginia 22209 • 703.524.2549 • Fax 703.524.3940 • www.nvca.org

RSRF

RETT SYNDROME RESEARCH FOUNDATION

...0 Devitt Drive
Cincinnati, OH 45246
513-874-3020 PHONE
513-874-2520 FAX

WWW.RSRF.ORG

TRUSTEES
PETER BAUM
MONICA COENRAADS
DENNIS A. EDER
CORY OLICKER HENKEL
ANNA LUZE
LAURIE MARCHESE
GORDON RICH
THOMAS SINCLAIR

OFFICERS
GORDON RICH
PRESIDENT
MONICA COENRAADS
VP RESEARCH
JEFF STAGNARO
TREASURER

SCIENTIFIC ADVISORY BOARD
...CHAEL R. HAYDEN,
..., PhD, FRSC (CHAIRMAN)
ADRIAN P. BIRD, PhD
MARC J. LANDE, PhD
WILLIAM C. MOBLEY, MD, PhD
LUIS F. PARADA, PhD
STEPHEN W. SCHERER, PhD
ROBERTO P. TUCHMAN, MD

NATIONAL INSTITUTES OF HEALTH LIAISON
ROBERT FINKELSTEIN, PhD

January 13, 2003

Senator Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The Rett Syndrome Research Foundation (RSRF) is a staunch supporter of the *Human Cloning Ban and Stem Cell Research Protection Act of 2003*, sponsored by you, Senator Dianne Feinstein (D-CA), Senator Arlen Specter (R-PA), Senator Ted Kennedy (D-MA), and Senator Tom Harkin (D-IA).

RSRF agrees that Congress should move swiftly to ban reproductive cloning. RSRF also concurs with the scientific community and the majority of Americans that therapeutic cloning and regenerative medicine should be allowed to proceed and given the opportunity to save lives.

Rett Syndrome is a devastating neurological disorder that robs baby girls of communication and motor skills. My own daughter, Chelsea age 6, is unable to walk, talk or use her hands. She is fed through a feeding tube, has difficulty breathing, seizures, gastrointestinal problems and more. Therapeutic cloning may help her and countless others lead a better life.

The Rett Syndrome Research Foundation is thankful for your continued support of biomedical research and for your courageous leadership in sponsoring this piece of legislation which instills hope and promise of a better life to millions of children and adults battling disease.

I look forward to helping you in any way possible

Sincerely,

Monica Coenraads

Monica Coenraads
VP of Research

/mc

SOCIETY FOR
WOMEN'S HEALTH RESEARCH

January 15, 2003

Senator Orrin Hatch
United States Senate
Washington, DC 20510

Dear Senator Hatch:

The Society for Women's Health Research strongly supports the "Human Cloning Ban and Stem Cell Research Protection Act of 2003 " the bill you and Senators Dianne Feinstein (D-CA), Arlen Specter (R-PA), Edward Kennedy (D-MA), and Tom Harkin (D-IA) recently introduced.

The bill protects therapeutic cloning research and provides strong safeguards against reproductive cloning, which the Society believes is unsafe and unethical. The legislation provides severe criminal and financial penalties for reproductive cloning and requires strict research oversight. The Society agrees with the Institute of Medicine (IOM) that any ban on reproductive cloning must not interfere with important areas of research such as therapeutic cloning. We believe that the "Human Cloning Ban and Stem Cell Research Protection Act of 2003" strikes an appropriate balance between the need to prevent the reproductive cloning of a human being and the need to protect life-saving therapeutic research.

As you may be aware, women live longer but not necessarily healthier lives than men. Many of the illnesses for which therapeutic cloning research shows such promise have a particularly strong impact on women. For example, cardiovascular disease is the number one killer of American women. Other afflictions that might be cured or alleviated through this research, such as Alzheimer's disease and stroke, affect women in disproportionately high numbers.

We thank you for your leadership in introducing the "Human Cloning Ban and Stem Cell Research Protection Act of 2003" to encourage medical breakthroughs to alleviate the suffering of countless individuals – men, women, and children - struggling with life-threatening and debilitating diseases.

Sincerely,

Roberta Biegel
Director of Government Relations

[redacted]

kirschfoundation

effecting change through strategic giving and advocacy

January 10, 2003

The Honorable Orrin Hatch
United States Senate
104 Hart Office Building
Washington, D.C. 20510

Dear Senator Hatch:

On behalf of the Steven and Michele Kirsch Foundation, I am writing to add our strong support for your sponsorship of legislation that would create a permanent ban on human reproductive cloning while permitting research involving somatic cell nuclear transfer (SCNT).

Since 2001, the Kirsch Foundation has been actively working to protect federal funding for embryonic stem cell research as well as scientists' ability to conduct SCNT research. We are opposed to human reproductive cloning, and also believe that it poses a distraction to the enormous medical potential of SCNT. As an advocate for medical research, the Foundation is deeply concerned about restricting scientists' ability to use this potentially life-saving tool.

The Foundation agrees with the scientific community, and a majority of Americans, in believing that SCNT research should be allowed to continue given its potential for developing cures for life-threatening diseases and conditions including Alzheimer's disease, diabetes, Parkinson's disease, cancer, heart disease, and spinal cord injury. In light of such medical promise, a permanent moratorium on the practice of human reproductive cloning – while protecting SCNT research – is clearly in the nation's best interest.

The Kirsch Foundation applauds your leadership in sponsoring legislation that ensures cures for devastating diseases continue to be developed.

Sincerely,

Susan E. Frank

Susan E. Frank
Director, Public Policy

Board of Directors
Steven T. Kirsch
Perry Olson
Harry J. Saal

Officers
Kathleen Gwynn
Peter deCourcy Hero

printed on recycled paper

Orthodox Union RCA

CLONING RESEARCH, JEWISH TRADITION & PUBLIC POLICY; A JOINT STATEMENT by the UNION of ORTHODOX JEWISH CONGREGATIONS of AMERICA and the RABBINICAL COUNCIL of AMERICA

Society today stands on the threshold of a new era in biomedical research. The wisdom granted to humans by our Creator has led to our greater understanding and knowledge of the building blocks of human life itself. Scientists revealed the existence and role of DNA and cellular science many years ago. Currently, scientists are not only able to describe the nature of cellular life, but manipulate it as well. We are now faced with the possibility of mastering the art of this manipulation to the point of being able to clone in research laboratories the cells that, in other circumstances, lead to fully developed human beings.

A debate has emerged in American society at large and among our elected leaders as to whether public policy should permit, encourage, restrict or ban the further conduct of this biomedical research. The issue is one with complex moral dimensions. On the one hand scientific research indicates that there is great life-saving potential in the results that can come from cloning research." On the other hand, we must be vigilant against any erosion of the value that society accords to human life.

Our Torah tradition places great value upon human life; we are taught in the opening chapters of Genesis that each human was created in God's image. After creating man and woman, God empowered them to enter a partnership with Him in the stewardship of the world. The Torah commands us to treat and cure the ill and to defeat disease wherever possible; to do this is to be the Creator's partner in safeguarding the created. The traditional Jewish perspective thus emphasizes that maximizing the potential to save and heal human lives is an integral part of valuing human life. Moreover, our tradition states that an embryo *in vitro* does not enjoy the full status of human-hood and its attendant protections. Thus, if cloning technology research advances our ability to heal humans with greater success, it ought to be pursued since it does not require or encourage the destruction of life in the process.

However, cloning research must not be pursued indiscriminately. We must be careful to distinguish between cloning for therapeutic purposes – which ought to be pursued, and cloning for reproductive purposes –

which we oppose. Thus, this research must be conducted under strict guidelines and with strict limitations to ensure that the research is indeed serving therapeutic purposes.

Consistent with this policy, we advocate that a fully funded and empowered oversight body comprised of scientists and ethicists be created to monitor this research. Relevant Executive-branch agencies and congressional committees should conduct periodic reviews as well. The oversight process should pay special attention to ensuring that the embryos used in this research are not brought to a point which constitutes human-hood.

We believe that the policy stated herein articulates the perspective of the Torah tradition and the community we represent and achieves the correct balance between pursuing new methods for saving human lives and maintaining the fundamental respect and sanctity of human life.

* This joint statement specifically addresses our view on the subject of cloning technology research. We have previously set forth our views on the related subject of stem cell research in a document which may be found at http://www.ou.org/public/Publib/cloning.htm

MORE...

- IPA Front Page
- OU.ORG Front Page

OU.ORG - YOUR GATEWAY TO THE JEWISH INTERNET

Union of Orthodox Jewish Congregations of America
Institute for Public Affairs

Main Office:
11 Broadway
New York, NY 10004
Phone: 212-613-8124 Fax: 212-564-9058
E-mail: ipa@ou.org

Washington Office:
800 Eighth Street N.W.
Washington, D.C. 20001
Tel: 202-513-6484 - Fax: 202-289-8938
E-mail: ipadc@ou.org

Prof. Richard Stone, Chairman
Nathan Diament, Director
Betty Ehrenberg, Director, International Affairs & Communal Relations

02/04/2003 17:10 BIO OUTBOUND → 2282258 NO.915 P03
FEB-04-2003 TUE 04:24 PM FAX NO. P. 06

Justice and Witness Ministries

A Covenanted Ministry of the United Church of Christ

Bernice Powell Jackson, Executive Minister

The Collegium of Officers
John H. Thomas
Office of General Ministries
Edith A. Guffey
Office of General Ministries
Bernice Powell Jackson
Justice and Witness Ministries
José A. Malayang
Local Church Ministries
Dale L. Bishop
Wider Church Ministries

Justice and Witness Ministry Teams
Economic Justice
Human Rights, Justice for Women and Transformation
Racial Justice

Public Life and Social Policy
110 Maryland Avenue
Washington, DC 20002
202.543.1517
fax 202.543.5994

Franklinton Center at Bricks
P.O. Box 220
Whitakers, NC 27891
252.437.1723

January 14, 2003

Senator William Frist
Senate Majority Leader
Washington, DC 20510

Senator Tom Daschle
Senate Minority Leader
Washington, DC 20510

Dear Senators Frist and Daschle:

The Senate is dealing with very complex issues concerning stem cell research and related issues of genetic engineering. In this moment when scientific potential is far ahead of experience, far ahead of informed ethical discussion, we understand that you have difficult moral and practical decisions to make in a context where there are many more questions than answers. I have prayed for each of you, and for other senators, and will continue to do so.

The United Church of Christ has addressed the issues of stem cell research and genetic engineering in resolutions from our General Synod, the most representative voice of our denomination. Those resolutions were based on decades of work by the UCC Science and Technology Working Group which was in regular communication and interaction with ecumenical colleagues. We don't pretend that we have issued the last word on these subjects, but you may find some of our contributions relevant as you work out your own positions.

In some ways, the "boiler plate" of caution may be our most important word. In the resolution of the 21st General Synod (1997) concerning The Cloning of Mammalian Species, the words of the 17th General Synod (1989) were recalled, stating that it is a time to be "cautious at present about procedures that would make genetic changes which humans would transmit to their offspring." The 21st General Synod went on to say that any changes in policy, such as the issues that are currently before the Senate, should only be pursued in the context of broad public discussion. We therefore counsel delay and urge the Senate to pursue a course that would create such broad public discussion. These are important matters and deserve full and careful attention.

Another important reason for delay and caution is that any human cloning aimed at producing living children would be based on research and methods that are preliminary and unsafe for human development. Though technological development is moving at a rapid pace, it seems unjustified to us to rush to explore human cloning aimed at live birth.

To create time for thoughtful ethical discussion **it is important that the Senate consider the regulation of private research and practice regarding human cloning.** We are pleased with both the substance and the application of ethical guidelines related to research on human genetics that are part of the National Institutes of Health. Those guidelines would serve as a good starting point for regulating private research.

The following basic points for the position of the General Synods of the United Church of Christ relating to research and practice concerning human genetics were developed in a series of resolutions from General Synods 8,14, 16, 17, 21, and 23 (2001). All are based in the understanding of the first creation story in Genesis that points to the responsibilities we have as the stewards of God's creation.

While the General Synods of the UCC believe that all life deserves respect, and that all human life deserves additional care and attention, **we distinguish between human life and the human person**. While this line can never be absolutely distinct, it is still an important guideline for ethical consideration. In the current discussions this leads us to the positions that stem cell research with embryonic stem cells could be allowed under certain conditions because of the potential for alleviating human diseases. Similarly, it leads us to the position that research on human pre-embryos (through the first 14 days of embryonic development) should be allowed for its potential to contribute to the overcoming of disease. One of the key conditions for such research is that all private research should be reviewed by the Institutional Review Boards of the National Institutes of Health.

Another key consideration of the General Synods is **support for research that holds promise for overcoming disease but great caution and resistance to human cloning aimed at producing designer children**. For starters, all public research money should be devoted to overcoming disease and no aid should be given to the wealthy who want to shape their offspring to personal or cultural standards. We believe that such designer children would be subjected to inappropriate social expectations and that the hope for shaping a child through genetic manipulation is both foolish and is not in accord with natural design of having two germ lines contributing to each person. However, should a human person be created through cloning, we insist that such a person should have full status as a human being.

While we emphasize the distinction between human life and the human person, we believe that **all human life deserves respect, even reverence.** We recognize that tens of thousands of frozen human pre-embryos exist in clinics around the U.S. and around the world. As a practical matter, very few will be given a chance to become a human person. Some of these pre-embryos could contribute to research that alleviates the diseases of human persons. In either case, attention should be given to creating respect for all human pre-embryos, including care and respect for the ending of their life-potential.

Finally, in considering all aspects and potentials of human genetic engineering, we believe that **the laws of the United States should consider the justice interests of all involved parties, that the privacy of those directly involved should be respected, and that any benefits of research shall be made available to all.**

Sincerely,

Pat Conover

Pat Conover
Legislative Director

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PRESIDENT

1111 Franklin Street
Oakland, California 94607-5200
Phone: (510) 987-9074
Fax: (510) 987-9086
http://www.ucop.edu

January 14, 2003

The Honorable Dianne Feinstein
United States Senate
331 Hart Senate Building
Washington, D.C. 20510

Dear Senator Feinstein:

I am writing to let you know the University of California (UC) supports "The Human Cloning Ban and Stem Cell Research Protection Act of 2003," which is a re-introduction of S.2439, a bill that you authored during the recently concluded 107th session of Congress. We appreciate your continuing leadership and efforts to enact this thoughtful legislation to ban human cloning and to help ensure ethical and potentially therapeutic nuclear transplantation research.

As you know, most Americans believe the ethical and moral implications of reproductive cloning are unacceptable, and scientific societies and research universities share this sentiment. The criminal and civil penalties provided in your bill are suitable disincentives to reproductive cloning.

Importantly, "The Human Cloning Ban and Stem Cell Research Protection Act of 2003" permits non-reproductive cloning research pursuant to closely regulated scientific and ethical standards. This research, utilizing somatic cell nuclear transfer to produce stem cells, holds much opportunity for preventing and alleviating human disease, disability, and premature death. In addition, your bill requires important protections for the safety and privacy of nuclear transplantation research participants, including informed consent, scientific board review of all protocols, and significant fines for ethics violations.

When UC and Stanford researchers made seminal recombinant DNA discoveries three decades ago, our nation weighed the risk and promise of this new science. Ultimately, recombinant DNA research proceeded under close and thoughtful regulation. At the same time, governments in Japan and Europe banned or inhibited this research. The result has been that the United States, and especially California, immediately gained dominance in the field of biotechnology worldwide, and both our country and the world have benefited since from the development of an array of medicines that have saved tens of thousands of lives.

Today, the U.S. is at a similar crossroads with respect to somatic cell nuclear transfer research. The enactment of "The Human Cloning Ban and Stem Cell Research Protection Act of 2003" will ensure our ability to lead the world in developing the medical breakthroughs that the nation expects from its investment in university research.

My colleagues and I appreciate your considering our views and your authoring this farsighted legislation.

Sincerely,

Richard C. Atkinson

Richard C. Atkinson
President

cc: The Honorable Barbara Boxer
The Honorable Orrin Hatch
The Honorable Edward Kennedy
The Honorable Arlen Specter
Provost King
Senior Vice President Darling
Assistant Vice President Sudduth

U.S. Senate Judiciary Committee
"Promoting Ethical Regenerative Medicine Research and Prohibiting Immoral Human Reproductive Cloning" Hearing
March 19, 2003

Testimony of Anton-Lewis Usala, MD
CEO and CSO, Ectocelle, Inc.
Clinical Professor and Medical /Administrative Director
Office for Regulatory Review of Clinical Trials (ORRCT)
East Carolina University

SLIDE 1

Destruction of specific cells results in many chronic disease states such as Type 1 Diabetes, Parkinson's Disease, and Spinal Cord Injury. Replacement of these tissues, with replacement of their specific function, would provide an effective cure for the disease state.

SLIDE 2

All cells within an individual contain the same DNA sequence. The DNA located on the chromosomes in the cells' nucleus selectively codes for different signals. Which signals are expressed depends on the cells environment, and determines the function of the cells. A differentiated heart cell has the same DNA template as a differentiated skin cell or brain cell. The cells differ only in which part of the DNA template is expressed, and this is determined by the microenvironment of the developing tissue.

Two recent theories to replace damaged tissue involve the use of transplanted human embryonic tissues, or tissues derived from cloned individuals. Neither of these sources of embryonic transplantation material has successfully resulted in recovery of clinical function in large animal studies, largely because appropriate communication with host tissues is not made.

SLIDE 3

Since cellular transplant material obtained from developing embryos, either foreign or cloned, must overcome the problem of appropriate integration into the transplant site in order to replace the function of the destroyed tissue, scientifically it may make more sense to induce the patient's own tissues to replicate at the desired site. If the patient's own tissue could be induced to regenerate at the desired site of injury, the communication and integration networks are mostly in place.

I would like to share with the committee the preliminary results of a product I developed while with my first biotechnology company. This product was designed to induce

regeneration of a specific kind of tissue in animal and human patients. My hypothesis was that exposing cells to an environmental structure similar to that present during natural embryogenesis, might induce the patient cells to behave as they did during embryogenesis, and induce explosive generation of tissue.

The scaffolding I invented was made from modified naturally occurring compounds, synthetically polymerized to give the desired structure. This product contained no cells, only structures for the patient's cells to bind to upon injection at the damaged site. If the hypothesis were correct, after exposing the patient's damaged tissue to this synthetic biopolymer, the patient's tissues would be induced to rapidly regenerate according to the direction of the patient's own DNA template.

The results I am about to show have been presented at several scientific meetings, and have recently been submitted to a peer-reviewed journal.

SLIDE 4

Shown is an example of the rapid wound healing induced in a dog that had naturally occurring diabetes and developed multiple full thickness skin ulcers. The dog had undergone multiple courses of antibiotics and surgical closure procedures, but the ulcers would not heal because of the chronic destruction of blood vessels commonly seen with long standing diabetes. After a one-time injection of the artificial embryonic scaffolding, the dog's wound's healed with regenerated tissue.

The new tissue resulting from exposure to the embryonic like matrix was determined to be structurally identical to non-wounded areas, without the usual scarring that is normally seen with healing lesions.

SLIDE 5

This photomicrograph shows the result of injecting the synthetic biopolymer into an 8 year-old dog's liver. After three weeks, the section of the liver was removed, and showed the apparent regeneration of embryonic tissue development within the mature dog liver cells.

Shown are cells that have the appearance of undifferentiated mesenchymal cells, apparently associated with differentiating fibroblasts and endothelial cells (the cells making up blood vessel walls). Finally, nucleated red blood cells, found in large quantities only during early fetogenesis, are found in the newly formed blood vessels, apparently differentiating from the endothelial cell lining of the blood vessel wall. This process only occurs during early fetogenesis, as red blood cells, without nuclei, are made in the bone marrow later in development. The interpretation of this slide was done by Dr. Ron Dudek, a medical embryologist.

SLIDE 6

Further large and small animal studies confirmed our finding, and a six patient feasibility study was reviewed by the Food and Drug Administration to examine the effect of a one-time injection in patients with chronic diabetic foot ulcers refractory to conventional therapy.

SLIDES 7-13

Within days of a one-time injection, all the patients experienced rapid diminution of ulcer size, with apparent regeneration of skin, blood vessels, and surrounding structures. Since the new tissue derived from the patients' own tissue, there was seamless integration with no evidence of rejection. Further study is required to determine if this particular product is safe and effective, but clearly the large animal and human patient studies suggest cellular transplantation is not necessarily required to replace damaged tissue.

SLIDE 14

Transplantation strategies, whether derived from foreign donors or cloned cells from the patient themselves, are clearly not the only approach to replace damaged tissues. Such transplantation strategies require destruction of the newly formed individual DNA template. Other avenues are further along in clinical trials, and should be considered as a first approach for study. Indeed, the patient's existing cells provide the most rationale source for fully integrating replacement tissues, as occurred during embryogenesis.

REFERENCES

Usala AL. Methods for increasing vascularization and promoting wound healing. US Patent #6,261,387; issued July 17, 2001.

Hansen M, Kurinczuk JJ, Bower C, and Webb S: The risk of major birth defects after intracytoplasmic sperm injection and in vitro fertilization. N Engl J Med. 2002 Mar 7;346(10):725-30.

Kikyo N, Wade PA, Gushin D, Ge H, and Wolffe AP: Active remodeling of somatic nuclei in egg cytoplasm by the nucleosomal ATPase ISWI.
Science. 2000 Sep 29;289(5488):2360-2.

Usala AL, Klann R, Bradfield J, Ray S et al: Rapid Induction of Vasculogenesis and Wound Healing Using a Novel Injectable Connective Tissue Matrix. Diabetes 49 (Supplement 1): Abstract 1664 PO, 2000.

Usala AL, Dudek R, Lacy S, Olson J, Penland S, Sutton J, Ziats NP, Hill RS: Induction of Fetal-Like Wound Repair Mechanisms *In Vivo* with a Novel Matrix Scaffolding. Diabetes 50:(Supplement 2)A488, #2048-PO, 2001.

Usala AL. On the Horizon: Current Research into Advanced Therapies for the Diabetic Foot Ulcer. Wound Management Symposium 2000, UNC Chapel Hill School of Medicine, Chapel Hill, NC, September 22, 2000.

Ravin AG, Olbrich KC, Usala AL, Levin LS, Klitzman B: Gel matrix manipulation of capsule vascularity surrounding submuscular implants in rats. J Biomed Mater Res (Appl Biomater) 58: 313-318, 2001.

Usala AL. Current Research and Future Products. Wound Management Symposium 2001, UNC Chapel Hill School of Medicine, Chapel Hill, NC, September 29, 2001.

Lacy SA, Penland SL, Sutton JS, Usala AL, Olson J, Harris G, Hill RS: Decreased Scarring of Surgical Wounds In Vivo Following Treatment with a Novel Biopolymer E-Matrix™. Engineering Tissue and Growth International Exposition, Pittsburgh PA, March 21,22, 2002.

Klann R, Lloyd W, Lacy, S, Sutton J, Usala A, Hill E. A novel hydrogel copolymer* reduces scar formation and increases TGF-3 gene expression. The 16th Annual Symposium on Advanced Wound Care and Medical Research Forum on Wound Repair, Oral Platform Presentation, 2002.

Marston W, Usala A, Hill RS, Mendes R, Minsley MA: Initial report of an injectable porcine collagen-derived matrix to stimulate healing of diabetic foot wounds in humans. Manuscript submitted. January, 2003.

SENATE JUDICIARY COMMITTEE

HEARING ON HUMAN CLONING

MARCH 19, 2003

Testimony by Harold Varmus, MD
President, Memorial Sloan-Kettering Cancer Center, New York City
Chair, The Joint Steering Committee for Public Policy

Thank you, Mr. Chairman, for inviting me to testify today.

I am Harold Varmus, President of the Memorial Sloan-Kettering Cancer Center in New York. Before assuming my current position in 2000, I served as Director of the National Institutes of Health for six years. I am also the Chair of the Joint Steering Committee for Public Policy, a coalition of nonprofit scientific societies representing 50,000 biomedical research scientists. In 1989, when I was on the faculty of the medical school at the University of California, San Francisco, I shared the Nobel Prize in Medicine for the discovery of cancer genes called oncogenes.

We are here today to discuss the contentious issues raised by the possibilities of human cloning. Two bills now before the Senate seek to insure that the nation behaves in an ethically appropriate manner in this new arena. Both bills would ban efforts to create cloned human beings, an appropriate prohibition given the unsafe nature of the procedure. However, one bill, by Senator Brownback and his colleagues, would set an unfortunate precedent: it would criminalize scientists, doctors, and patients who pursue the benefits of <u>some parts</u> of the technology involved in cloning, even if these steps were taken without any intention of making a cloned human being. The other bill, by you, Mr. Chairman, and your colleagues, would allow those benefits to be pursued, under the kinds of regulatory guidelines that have worked well for medical science in the past.

A brief science lesson: IVF versus cloning

Before returning to the legislation, let me briefly outline the science involved. It is useful to set the stage with the well-known and widely practiced procedure, in vitro fertilization (IVF; see Figure 1). In IVF, as in normal human reproduction, a single sperm fuses with (fertilizes) an egg, forming a cell that divides several times to produce an early embryo (called a blastocyst) in which cells are disordered and lack characteristics of specific organs or tissues. If the blastocyst is mechanically transferred into a uterus, a pregnancy may result; after a complex process of development, a child may ultimately be born. If, instead of implanting the blastocyst, its immature cells are dispersed and grown in a culture dish, they can continue to divide and can develop into a variety of tissue types under appropriate conditions. These so-called embryonic stem cells, the valuable by-products of IVF, have enormous potential to reveal fundamental truths about early human development, to assist drug development, and to be used as medical therapies for a wide range of human disorders.

Fortunately for the hundreds of thousands of families that now include children born as a result of IVF, this procedure was not banned or criminalized when introduced in the late 1970's, even though it was clear that many blastocysts would remain unused and eventually be discarded. Likewise, embryonic stem cells can be derived from blastocysts, without imposition of criminal penalties, as long as Federal funds are not used; some existing stem cells can even be studied with Federal funds with regulatory oversight.

Unlike IVF, which begins with the union of egg and sperm, cloning begins with the transfer of an intact nucleus from any cell in a single individual to an egg from which the nucleus has been removed (see Figure 2). In other words, it is an asexual process with all the genetic information in the progeny cell coming from one rather than two individuals. As experiments with many species of animal have shown, this procedure can, surprisingly, generate a blastocyst similar or identical to the one produced by fertilization. If the unfertilized blastocyst were transferred to a uterus, development into an infant could occur, although (judging from animal experiments) very inefficiently and usually imperfectly. If this blastocyst is dispersed into a culture dish, embryonic stem cells can be generated, studied, and used therapeutically, as they would be after IVF, with the advantage that the cells are freely transplantable to the individual who donated the nucleus.

A comparison of the legislative proposals

The bill proposed by Senator Brownback and his colleagues---and a similar measure proposed by Representative Weldon that was recently passed in the House of Representatives---would ban all of the steps shown in the second chart. The bill proposed by you, Mr. Chairman, and your colleagues would selectively and judiciously ban only the transfer of a cloned blastocyst into the uterus. Your legislation would preserve the right of American scientists to study early development with the immature clusters of cells in the blastocysts, thereby allowing them to seek new knowledge and new therapies that might benefit our citizens and others around the world.

Why am I and many others unhappy with the Brownback and Weldon bills? First, we are troubled by the precedent of imposing criminal penalties on scientists, doctors, and patients---even those patients who might return after treatments abroad. In the past, ethically sensitive science has been regulated by Federal guidelines (for instance, for work on recombinant DNA and gene therapy); by prohibitions on the use of Federal funds (for example, for embryo research); or by classification (as for military research). Criminalizing the science I have described is unnecessary, unjustified, and unprecedented. By imposing fines and imprisonment on those seeking knowledge to benefit society, it sends a signal that could undermine the confidence of the remarkable scientific enterprise we have built in this country.

Second, legislative solutions tend to be inflexible, so rapid changes in science make it a poor target for legislative control. The NIH and other government agencies have shown repeatedly that they are well-equipped to oversee the ethical conduct of research in a manner that is openly and swiftly responsive to new findings.

Third, advocates for the Brownback-Weldon bills have obscured the profound differences between studies of immature human cells in a culture dish and the full process required to make a cloned human being. There is no "slippery slope" here. The boundary between the two activities is broad and unambiguous. Federal rules and medical guidelines can easily delineate them. Under the bill proposed by Hatch et al, crossing that clear boundary, by trying to introduce the cells into a uterus, could lead to prosecution. And the

regulatory guidelines under your bill would require responsible government oversight, informed consent by cell donors, a fourteen day limit on the growth of early embryos, and a separation of IVF clinics from laboratories for research on nuclear transfer.

Finally, the draconian legislation proposed by Brownback, Weldon and their colleagues shows inadequate appreciation for the pace and difficulty---and for the long range promise---of science. We are just beginning to understand how a fertilized egg of any species develops into a mature organism. Embryonic stem cells derived from fertilized eggs and from nuclear transfer have enormous potential to tell us how the instructions for making an organism are laid down, how they can be reversed, and how we might reconstitute them---for example, to convert liver cells to nerve cells. If we pursue such studies, we will learn great truths, and later use those truths in ways that are now difficult to predict. And if we don't, someone else, somewhere else, surely will.

An historical perspective

This year's 50th anniversary of the discovery of the DNA double helix provides a vantage point for this discussion. In 1953 it was evident that DNA was the embodiment of genes and that the structure of DNA was of profound significance. But it was difficult to know what might be learned by studying it. Fortunately, no one seemed to be asking whether studies of human DNA might lead to ethically unacceptable methods or outcomes. But if there had been prohibitions on the study of DNA, we might not now, fifty years later, have a vaccine for hepatitis B virus, a drug to protect the bone marrow of cancer patients, tests to alert people to their risks of certain diseases, or a powerful new way to exonerate people who have been falsely imprisoned.

Mr. Chairman, as a result of recent advances in cell biology and rapid progress on the Human Genome Project, we have now arrived at the starting line in the race to understand how cells and organs really work. The problems are immensely difficult, but the potential benefits are extraordinarily great, for those who seek to understand biology or to help the disabled.

Tshis brings me to my final plea: Why should any Member of Congress wish to punish those who wish to learn---and to treat---when we have so much more to learn? And who has such moral standing that they would impose on our multi-ethnic, pluralistic society an ethical standard that only a minority would endorse?

Thank you for an opportunity to offer my views on these important subjects; I will be pleased to answer any questions that you and your Committee members may have.

Good Afternoon.

Thank you Chairman Hatch, Senator Leahy, and members of the Committee for giving me the opportunity me to testify before you today.

The potential of regenerative medicine is something that is important to my life. My name is Greg Wasson and I am here on behalf of the Coalition for the Advancement of Medical Research (CAMR). CAMR is comprised of universities, scientific and academic societies, patient's organizations, and other entities that are devoted to supporting stem cell research.

My task today is to speak for the millions of Americans living with MS, ALS, Parkinson's Disease, and many other illnesses, who believe in the promise of regenerative medicine, including therapeutic cloning.

I, along with the Coalition for the Advancement of Medical Research (CAMR), support every effort to criminalize and ban human reproductive cloning. It is unsafe and unethical. However, it is imperative that we protect therapeutic cloning. As a person living with Parkinson's disease, I know how urgently a cure is needed. Responsibly regulated regenerative medical research may one day provide better treatments and cures for a number of debilitating and presently incurable conditions.

Eight years ago, at age 43, I was diagnosed with Parkinson's disease. My fiancée, Ann Campbell, who is here with me today, was given the same diagnosis that same year at age

38. I was a lawyer in San Francisco. Ann was an editor and children's book author in New York City. Within five years we were both forced by our disease to retire on disability. Recently. I was also diagnosed with Diabetes, a disease that runs in my family.

Advocacy for a cure of our shared disease brought us together. Our hope is to restore our health so that we can enjoy the rest of our years together. Like millions of other Americans we need your help to make sure that our hope is not forsaken.

An estimated 1 million Americans have Parkinson's, a brain disorder that is presently incurable and the cause of which is unknown. Parkinson's is a progressive and degenerative disease that slowly robs its victims of dopamine, the neurotransmitter that enables us to initiate and regulate movement. Walking, breathing, speaking, swallowing, simply grasping an object, all depend on a sufficient supply of dopamine to transmit the impulses of the brain into action.

Cognitive functioning, thinking, is also impaired by Parkinson's. It is often cognitive impairment that forces people with Parkinson's to stop working. This was the case for both Ann and myself. We also live with the knowledge that 30% of all Parkinson's patients develop dementia, and that we are three times as likely as the general population to develop Alzheimer's.

After eight years, we have difficulty controlling symptoms such as tremor, stiffness, rigidity, gait, and balance, even though we take several different Parkinson's medications. Currently, I take about 25 pills per day just for Parkinson's, and must redose every 3 hours.

My medications, which cost about $11,000 per year including diabetes medications, allow me to sit here before you today. They allow me to speak and be understood. I am thankful for these medications. Without them, I would by not be unable to walk, feed or clothe myself. But my 25 Parkinson's pills every day do nothing to slow the progress of my disease. What you see when you look at me today is a medical marvel, but also an illusion - a "chemical costume" I must put on every 3 hours to create the impression of even imperfect health.

Parkinson's medications become less effective over time, which causes different problems for each patient. In my case, I now fluctuate "off" my medications without warning several times each day. An "off" fluctuation can leave me stranded at a mall, or in my living room, or at the movies. Although I still have very little tremor, balance is a serious problem, and I fall several times a day. My voice becomes monotone and is often too soft to hear. I often stutter when I speak, and my enunciation is mushy and indistinct. My face becomes masked and impassive. I shuffle with short, halting steps. I often drool and sometimes I choke on my food. The stiffness and rigidity of my body make it impossible to do the simplest tasks. For me, Parkinson's is all about one telling description of the disease – "poverty of movement."

And for both Ann and myself, the time will come when our medications fail us permanently and we will be totally functionally disabled. At that time we will leave the world that we all currently inhabit, and enter a twilight world of immobility, encased in our bodies as if in tombs, able to think but not speak, understand but not communicate. Eventually some complication of the disease will cause death, a death that may by then be welcome.

And we are not alone. Parkinson's is just one of a score of chronic diseases and conditions that are fatal at worst and leave their victims permanently disabled at best. These diseases and conditions affect more than 100 million Americans. Each of us here today has a loved one or friend who has a disease such as Alzheimer's, ALS, MS, Diabetes or Parkinson's. These are terrible illnesses with dire consequences for their victims.

In 2001 I worked on a stem cell petition with a number of persons suffering from ALS who became my friends. Now, two years later, most of them are dead. John Davis, an Alabama ALS victim and fellow advocate, once said of embryonic stem cell research, "this dog will hunt." He meant that such research had the potential to save countless lives, and he was right. But this research "will hunt" only if it is not leashed and muzzled. I believe that the same applies to SCNT.

We are not without hope. Regenerative medicine, including responsibly regulated therapeutic cloning, may lead to a cure or treatment for Parkinson's disease and a host of other diseases and conditions. As you have heard today in the scientific panel, human reproductive cloning and cloning for therapeutic medical purposes are not the same scientifically. They have entirely different objectives. The creation of stem cells through SCNT does not involve fertilization of egg by sperm. It is a process that occurs entirely in a petri dish. Cell division is caused by electrical or chemical stimulation rather than the natural joining of sperm and egg. The resulting ball, perhaps 100 cells the size of a pinhead, is neither a human life nor anything near it. The use of SCNT does not destroy human life – it is an attempt to restore human life.

Ann Campbell and I, along with millions of other Americans, are people - *living human beings* - with terrible diseases that will kill us unless cures are found. The willingness of some here to sacrifice these lives, placing less value on them than on a chemically produced, unfertilized mass of cells perhaps grown from one of our own hair follicles is the real crime, the real shame.

Compassion and common sense must prevail; ignoring the potential of therapeutic cloning would be a national tragedy and a huge mistake. But as with other scientific advances in history, a vocal and well-organized minority is trying to stop this research. Galileo, Columbus, and a South African doctor named Christian Barnard all held

scientific beliefs that frightened their contemporaries. But the earth *does* revolve around the sun, the earth *is* round, and today heart transplants are commonplace. Today the target is therapeutic cloning.

Opponents of stem cell research that employs therapeutic cloning have insisted that there are no studies showing its potential to treat disease. But numerous experts in the field, including witnesses who testified earlier today, have shown that this is not true.

Opponents have also argued that legalizing therapeutic cloning will open the floodgates to a black-market industry in reproductive cloning. The history of organ transplantation demonstrates that this concern is unwarranted. When organ transplantation was new, objections were raised that it would lead to black markets in harvested organs. This did not occur, and today organ transplantation is strictly and effectively regulated.

Senators, we believe that you understand and appreciate the enormity of the potential for saving human beings from fates such as Parkinson's, ALS, diabetes, and spinal cord injuries. We believe that, individually and collectively, you will make the choice to protect and to restore life. What greater legacy could any government leave its citizens?

And so, because we have hope and faith that this country will recognize the value of research into regenerative medicine, Ann and I are getting married this fall. On our wedding day, we will raise a glass to the promise of a new day when diseases like Parkinson's are simply a terrible memory.

In this committee, in the Senate, and in Congress, we place our highest hopes and trust.

Thank you for your time.

January 10, 2003

Senator Orrin G. Hatch
131 Russell Senate Office Building
Washington, DC 20510-4402

Dear Senator Hatch:

The University of Wisconsin-Madison has been a pioneering institution in the field of embryonic stem cell research – research with the promise and potential to diminish the suffering of millions afflicted with debilitating diseases. This potential is strongly linked to the possibilities of Somatic Cell Nuclear Transfer (SCNT) and research into other forms of therapeutic cloning. Thank you for sponsoring legislation that will help keep this research moving forward.

Sincerely,

John D. Wiley
Chancellor

CC: Senator Russell Feingold
Senator Herb Kohl

Office of the Chancellor
Bascom Hall University of Wisconsin–Madison 500 Lincoln Drive Madison, Wisconsin 53706-1380