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SCIENCE AND ETHICS OF HUMAN CLONING

HEARING

BEFORE THE

SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

JANUARY 29, 2003

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ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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SCIENCE AND ETHICS OF HUMAN CLONING

WEDNESDAY, JANUARY 29, 2003

U.S. SENATE,
SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:35 p.m. in room SR–253, Russell Senate Office Building, Hon. Sam Brownback, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. SAM BROWNBACK, U.S. SENATOR FROM KANSAS

Senator BROWNBACK. Good afternoon. We are glad to have everybody here. Thank you for joining us. The committee room will come to order.

This is the first hearing of the Commerce Science, Technology, and Space Subcommittee. We will have a number of them through this next 2 years. Senator Wyden chaired the Committee for the past year-and-a-half, did an excellent job, the working, ranking member.

I am looking forward to engaging in a number of different topics. This is the first up. It is a very timely topic, a very important topic for us to consider, to consider the issue of human cloning.

As I understand, we have—obviously, we have four members here. We are delighted to have all four of you here today. I understand from Senator Specter that he is really under a time crunch, and Senator Wyden and—oh, Senator Hatch is under the real time crunch, OK.

Senator HATCH. Mr. Chairman, I am conducting, or should be conducting, a hearing over in the Judiciary Committee on six judicial nominees, and it is a very hotly contested——

Senator BROWNBACK. If it would be OK with the other members, we would like to go——

Senator SPECTER. So am I, Mr. Chairman.

Senator BROWNBACK. If we could, let Orrin go first for a few minutes of his comments and then go ahead, and then you could be dismissed, if you would like, to chair the Judiciary Committee. And then we will go ahead with our opening statements after that, if that would be OK with the other Members of the Committee, or——

Senator SPECTER. If I might ask, Mr. Chairman, if I might be permitted to use just a couple of minutes when Senator Hatch finishes?

Senator BROWNBACK. That will be fine, and then we will go ahead with our opening statements here at that point. We will try to accommodate you on the hearing schedule that you are on. I know you have an important Judiciary Committee markup.

STATEMENT OF HON. ORRIN G. HATCH,
U.S. SENATOR FROM UTAH

Senator HATCH. Thank you so much, Mr. Chairman and Members of the Committee. That means a lot to me.

As you can imagine, this hearing is the first one, and it is a very tough hearing. But I did want to be with you today, and I want to commend you, Mr. Chairman and others on the Committee, for holding this hearing today.

And while it is no secret that we may differ somewhat on all of the matters under discussion today, I want to make sure that everybody knows that I am a great admirer, friend, and supporter of my friend from Kansas. And I appreciate his sincerity and his honesty in the way he serves, as well as all of you who serve on this Committee. As a fellow right-to-life Senator, I can tell you that I will miss you on the Judiciary Committee, Mr. Chairman.

I am here today, though, to speak to the Subcommittee about how to stop the offensive practice of human reproductive cloning while at the same time allowing vital biomedical research to go forward under strict moral and ethical guidelines and protections.

It is my hope that the 108th Congress will be able to come to agreement on some key matters. At the least, I hope we can pass legislation that will help derail the Raelians and the other fringe groups in their ill-advised attempt to clone human beings. I believe that there is virtual unanimity within Congress and among the public that society should prevent, through strong Federal criminal sanctions, attempts to interfere with the traditional means of reproduction in the form of this new form of asexual reproduction.

Let me briefly explain what reproductive cloning means, because some confusion about the facts may still persist. In normal reproduction, including in vitro fertilization, a female egg, with a full complement of 23 chromosomes, is united with a male sperm cell that also contains 23 chromosomes. The cell resulting from this union of the female and male reproductive cells contains the complete set of 46 chromosomes that each of the specialized cells in our body contain, except for reproductive cells like the sperm and egg. Through the process of sexual reproduction, each of us is the shared product of our parents' genetic material.

In contrast, through a technique still under development, it might be possible for some unscrupulous scientists to facilitate the birth of an asexually developed cloned baby. Here is how: Through the new technology of somatic cell nuclear transfer, it appears that it may one day be possible to remove the normal 23 chromosomes present in a human egg cell and replace them with the full complement of 46 chromosomes that are present in all normal human cells other than the egg and sperm cells. This nuclear transplantation takes place without the fertilization of the egg and without sperm.

If the cellular product of such nuclear transplantation were implanted in a woman's womb, it is theoretically possible that an

asexually reproduced person could be born. The unsubstantiated claims of Raelians notwithstanding, scientific experts tell us that it would be very difficult to succeed in bringing to birth a cloned human baby. After all, it took 377 failures before Dolly, the cloned sheep, was born.

At present, there is no unambiguous Federal law in the United States that prevents the birth of cloned human beings. The best way to stop reproductive cloning in its tracks in the United States is for Congress to pass a tough Federal criminal law banning reproductive cloning. That is something we could do today. And I believe that if our country took this action, many other nations would follow suit.

Now, I recognize that there are very heartfelt views on both sides of this issue, Mr. Chairman, and where I part company with the type of legislation that you and our right-to-life colleagues—Representative Dave Weldon, an advocate, of course—is on some important aspects of the new science of regenerative medicine and stem-cell research.

Regenerative medicine concerns itself with the study of healthy and diseased cells and tissues and the attempt to devise interventions to repair damaged, or prevent diseased cells and tissues. Perhaps the most promising avenue for regenerative medicine is the study of stem cells. Stem cells are those various flexible cells that appear to have the ability to transform themselves into the more than 200 types of specialized cells that form the tissues that comprise the human body. There is broad agreement that research into mature adult stem cells should proceed full speed ahead.

Please make no mistake about it, I am fully supportive of adult stem cell research. But let me hasten to add a word of caution. Many leading scientific experts tell us that this branch of stem cell research is not as promising as embryonic stem cell research at this time.

In addition to adult tissue cells, such as bone marrow cells, there are two other promising sources of stem cells. First, stem cells derived from embryos produced for, but no longer needed in, fertility treatment. Second, stem cells derived through the somatic cell nuclear transport process for research, not reproductive, purposes.

This first source, stem cells derived from the excess embryos left over from the in vitro fertilization process, is the type of embryonic stem cells that President Bush made eligible for limited Federal funding in the year 2001. Only those stem cells lines that were derived before the date of the President's speech on August 9th, 2001, qualified for Federal funding. Those embryos were formed in the laboratory of fertilization clinics. While these types of embryos were created in the laboratory, they all contained the normal 23 chromosomes from a woman's egg cell and 23 chromosomes from a male's sperm cell.

Now, I respect the fact that many hold the view that life begins at the moment the egg and sperm are united, even if this occurs outside the womb, in a laboratory. After many conversations with scientists, ethicists, patient advocates, and religious leaders, and many hours of thought, reflection, and prayer, I reached the conclusion that human life does not begin in the petri dish. I believe that human life requires and begins in a mother's nurturing womb.

In June of 2001, I wrote to President Bush and also to Secretary of Health and Human Services Tommy Thompson explaining my views on this matter and urging them to allow Federal funding of research on stem cell lines derived from the thousands of embryos left over in the in vitro fertilization process each year. While I would have preferred the President to have gone further in this area, I applauded the President for his decision to make a limited member of stem cells lines eligible for federally funded research.

I recognize the role that Dr. Leon Kass has played in acting as a trusted sounding board and advisor and helping the President reach a decision that was disappointing to many of my colleagues and friends in the right-to-life community, such as you, Mr. Chairman. Each year, thousands of laboratory-facilitated embryos no longer needed in the treatment of fertility are routinely discarded. Many, including many of us with a pro-life philosophy, do not understand why it is permissible, and has been accepted for many years, to destroy these spare embryos, but it is somehow improper and unethical to use these cells to benefit mankind.

Last fall, the Labor-HHS Appropriations Subcommittee held a hearing that shed light on some of the major deficiencies of the Administration's policy. And I commend the leadership of that subcommittee, and particularly the leadership of Senators Specter and Harkin for their long and distinguished record on this issue.

And, by the way, I do have a statement by Senator Feinstein that I would ask, through unanimous consent, be placed in the record immediately following my——

Senator BROWNBACK. Without objection.

Senator HATCH. While the number of eligible stem cell lines has grown from about 60 cells lines right after the President's speech to more than 70 cells lines, at the hearings, scientists pointed out that due to intellectual property restrictions and other issues such as logistics, the reality is that only about ten or so stem cell lines are practically available for research purposes.

All of these facts led me to conclude that I must support efforts to increase the number of stem cell lines derived from spare IVF embryos eligible for federally funded research. More stem cell lines are needed to reflect adequately the ethnic and gender composition of the public, and that is sorely lacking in the current stem cell lines. We must recognize the importance of making more stem cell lines available to government-funded researchers, because a great deal of basic biomedical research conducted in this country largely occurs through resources provided by the formidable 27-billion-dollar budget of the National Institutes of Health. Those who applaud the promise of adult stem cell research—although it is unjustifiably believed to be superior over embryonic stem cell research in the eyes of many experts—should at least acknowledge that whatever progress that has been made in this area was possible, in large part, by the 20-year head start in the Federal funding of this type of research.

I plan to work with Senators Specter, Harkin, and Feinstein, and others, to expand the number of embryonic stem cell lines eligible for Federal research funding by seeking greater use of spare embryos from IVF clinics.

In addition to increasing federally funded research on the sexually-produced spare IVF embryos, I favor continuing to permit research on whether stem cells may be derived through the somatic cell nuclear transfer process.

Let me repeat my opposition to any attempt to use nuclear transplantation to facilitate the birth of a cloned baby. If, on the other hand, nuclear transplantation can lead to another source of stem cells, I think we should take advantage of this technique, so long as we develop adequate ethical standards. Nuclear transplantation does not use a fertilized egg. And unless the asexually produced cell is implanted into a woman's womb, a baby cannot be born. I do not consider the laboratory-created product of nuclear transplantation, the unfertilized enucleated egg injected with a somatic cell nucleus, to be a person.

Frankly, I think even those who believe that life begins at conception, even if the unison of sperm and egg takes place in the lab, need to consider carefully whether the joinder of an enucleated egg with a somatic cell nucleus accompanied by chemical or electrical stimulation should fairly be thought of as the same process as conception. The man-made technology of nuclear transplantation is certainly a far cry from the natural world of birds and bees.

I believe that criminalizing any attempt to implant the product of nuclear transplantation into a woman's womb, together with the appropriate protections in areas such as informed consent, make it possible to conduct ethical stem cell research through the transfer—or through the technique of somatic cell nuclear transfer.

Scientists believe that there are unique advantages of using the DNA of one person, rather than the combined DNA of two parents, to study disease progression, and, in particular, the disease progression of a certain person. In addition, it may be possible to develop therapies that will be less likely to be rejected by the immune system if such therapies are derived from the patient's own DNA.

Forty-one American Nobel laureates have told Congress of their strong belief that the emerging science of nuclear transplantation offers great hope in combatting many currently life-threatening, but essentially untreatable diseases. We are talking about cancer, heart disease, diabetes, Alzheimer's, Parkinson's, multiple sclerosis, ALS, and so many more.

It is estimated that over 100 million Americans suffer from diseases that stem cell research may 1 day help cure or prevent. A critical feature of being pro-life, in my opinion, is helping the living. Helping those millions of American families struggling with the challenges of debilitating diseases is exactly what stem cell research with spare embryos from fertility treatment and from nuclear transplantation promises. It is my hope that Congress will enact legislation that will ban the birth of cloned babies, but will allow stem cell research through nuclear transplantation to go forward.

I am working with a bipartisan group of Senators, including Senators Specter, Harkin, Feinstein, and Kennedy, to craft such legislation, and we hope to introduce such legislation within the next few weeks.

Senator BROWNBACK. If we could wrap it up, we were trying to accommodate you to be able to get back to your committee.

Senator HATCH. You were wonderful and I certainly appreciate it; I am sorry to have taken this long. Let me just wrap it up.

Failure to act on legislation to ban the birth of cloned babies only emboldens such irresponsible groups such as the Raelians. Failure to enact legislation that sanctions nuclear transplantation research, accompanied by stringent ethical and moral safeguards, undermines America's role as a leader in biomedical research and may result in the potentially revolutionary fruits of this research as well as some of our leading researchers in moving offshore and away from the American public. I think that outcome should be avoided, for a simple reason—the patients are waiting.

And let me close by saying that for Kris Gulden, who testified before the Judiciary Committee 2 years ago and will speak to you today, and millions of others, the wait has already been too long.

Thank you, Mr. Chairman. I thank you for your great courtesy to me. And I will leave Senator Feinstein's statement.

Senator BROWNBACK. And her statement will be entered into the record.

[The prepared statement of Senator Hatch follows:]

PREPARED STATEMENT OF HON. ORRIN G. HATCH, U.S. SENATOR FROM UTAH

Thank you, Mr. Chairman.

I want to commend you for holding this hearing today.

While it is no secret that you and I do not see eye-to-eye on all of the matters under discussion today, I also want to be sure that it is no secret that I am a great admirer, friend, and supporter of my friend from Kansas.

As a fellow Right to Life Senator, I can tell you that I will miss you on the Judiciary Committee.

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At the least, I hope that we can pass legislation that will help derail the Raelians and other fringe groups in their ill-advised attempts to clone human beings.

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More stem cell lines are needed to adequately reflect the ethnic and gender composition of the public. We must recognize the importance of making more stem cells lines available to government funded researchers because a great deal of basic biomedical research conducted in this country largely occurs through the resources provided by the formidable $27 billion budget of the National Institutes of Health.

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A critical feature of being pro-life is helping the living. Helping those millions of American families struggling with the challenges of debilitating diseases is exactly what stem cell research with spare embryos from fertility treatment and from nuclear transplantation promises.

It is my hope that Congress will enact legislation that will ban the birth of cloned babies but will allow stem cell research through nuclear transplantation to go forward. I am working with a bipartisan group of Senators, including Senators Specter, Harkin, Feinstein and Kennedy, to draft such legislation and we hope to introduce such legislation in the next few weeks.

Failure to act on legislation to ban the birth of cloned babies only emboldens such irresponsible groups like the Raelians.

Failure to enact legislation that sanctions nuclear transplantation research accompanied by stringent ethical safeguards undermines America's role as a leader in biomedical research and may result in the potentially revolutionary fruits of this research—as well of some of our leading researchers—in moving off-shore and away from the American public. This outcome should be avoided for a simple reason—the patients are waiting.

Let me close by saying that for Kris Gulden—who testified before the Judiciary Committee two years ago and will speak to you today—and millions of others, the wait has already been too long.

[The prepared statement of Senator Feinstein follows:]

PREPARED STATEMENT OF HON. DIANNE FEINSTEIN,
U.S. SENATOR FROM CALIFORNIA

"The Senate Should Ban Human Cloning, But Permit Promising Medical Research to Continue"

Mr. Chairman, thank you for holding this hearing and inviting me to testify.

At the dawn of this new era in medicine, we have mapped the human genome, we have discovered drug therapies for cancer that work at the cellular level, and we are unlocking the promise of nuclear transplantation.

We are now poised between two choices.

We can continue under the current *status quo* with no regulations on cloning and with the certain knowledge that, sooner or later, we will be faced with reproductive cloning.

Or, we can simply and reflexively ban all cloning, including the valuable biomedical research field of somatic cell nuclear transplantation which may well lead to cures for diseases such as cancer, Parkinson's, and Alzheimer's afflicting tens of millions of people.

In my view, both of these choices are morally unacceptable.

I believe that we should adopt a balanced, common-sense approach to this issue: ban human cloning—that is, creating a whole-body, carbon copy of a human being—but permit valuable stem cell research to continue, with strong and strict regulatory oversight.

I will shortly be introducing legislation with Senators Hatch, Kennedy, Specter, Harkin, and others to do just that.

There is broad agreement across our society that human reproductive cloning should be prohibited. Such cloning is unsafe, immoral, and unacceptable.

Our bill bans human reproductive cloning.

Under our bill, anyone who even attempts to clone a human being will face a 10-year prison term and a minimum $1 million fine.

But there is also wide-scale support in our society to continue research that may yield cures, treatments, and diagnoses for many diseases and illnesses. And our bill allows this important research to continue.

Nuclear transplantation research has nothing to do with cloning humans. Rather, it has everything to do with saving lives and alleviating suffering.

Somatic cell nuclear transplantation is a technique that offers enormous potential for providing cures for diseases such as cancer, diabetes, cystic fibrosis, and heart disease as well as conditions such as spinal cord injuries, liver damage, arthritis, and burns.

For example, a blue-ribbon National Academies' Panel concluded that

> "Because of its considerable potential for developing new medical therapies for life-threatening diseases and advancing fundamental knowledge . . . biomedical research using nuclear transplantation to produce stem cells be permitted."

I believe that any bill to ban cloning should allow this valuable research to continue under strict safeguards to prevent abuse. The legislation that we will introduce will include such safeguards.

I am pleased that virtually every leading medical, scientific, and patients' advocacy group opposes legislation that would ban nuclear transplantation research and supports our approach.

These organizations include the American Medical Association, National Health Council, Parkinson's Action Network, Juvenile Diabetes Research Foundation, and Federation of American Societies for Experimental Biology, which represents over 600,000 medical researchers around the country.

In my view, it would be a great setback for millions of patients with catastrophic medical conditions to prohibit medical research that offers them the possibility of a cure.

These are real people, with real diseases and real suffering. They are the ones whose hopes would be dashed if we ban nuclear transplantation.

Let me read from a letter I received last year from Richard Avedon, the father of five-year-old Emma:

"Our five year old daughter suffers from Juvenile diabetes. We were lucky. We discovered her condition during a check-up when she was a year old. When the disease develops in infants, it's usually discovered only when the child lapses into a coma and is rushed to the emergency room, often in critical condition. Emma 's pancreas produces no insulin. On her belt, that she wears twenty-four hours a day, there is an insulin pump that is attached to her backside and that delivers insulin to her body through surgical tubing.

By pricking her finger for blood, as often as every two hours throughout the day and night, we determine her current level of blood sugar and then use the pump to adjust her insulin accordingly.

What we have learned about Emma's particular condition, referred to as 'brittle' or unpredictable diabetes, is that despite all our efforts to control the progressions of the disease and all the efforts she will make as she grows older, Emma can look forward to a lifetime of potential complications, including blindness, kidney failure, limb amputation and a substantially shortened life expectancy, unless a cure if found.

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

Thank you.

Senator BROWNBACK. Senator Specter, if you could give your brief comments so we could go to the opening statements here by the panel that is on the dais.

STATEMENT OF HON. ARLEN SPECTER, U.S. SENATOR FROM PENNSYLVANIA

Senator SPECTER. Mr. Chairman, I shall be very brief. I ask unanimous consent that my statement be made a part of the record.

Senator BROWNBACK. Without objection.

[The prepared statement of Senator Specter follows:]

PREPARED STATEMENT OF HON. ARLEN SPECTER,
U.S. SENATOR FROM PENNSYLVANIA

Mr. Chairman and Members of the Committee. Thank you for calling this hearing.

As we prepare to debate the cloning issue, I wanted to share with you what I have learned about stem cell research and cloning.

As Chairman of the Appropriations Subcommittee on Labor, HHS and Education, I have taken part in 14 hearings where scientists, patients and ethicists described the promise—and the challenges—associated with stem cell therapy and therapeutic cloning, or what some are calling "nuclear transplantation." As stem cell research progresses, one of the biggest challenges that we will face is finding a way to ensure that the patient's body does not reject the implanted stem cells. A way to do that is by giving the stem cells the DNA code of the patient, so that the cells will not be rejected. This would be accomplished by a technique commonly referred to as therapeutic cloning. However, for many Americans, mere mention of the word "cloning" conjures up grotesque images from a bad science-fiction movie: mad scientists, bubbling test tubes and row after row of zombie-like characters.

Evidently, those images were shared by members of the U.S. House of Representatives, who passed H.R. 2505, the Human Cloning Prohibition Act. Unfortunately, that legislation was written so broadly that it would also put a halt to promising research on therapies for a number of diseases that plague society.

The problem is that the word "cloning" is scientific shorthand for a complex process that can be used to achieve different ends—some bad and some good. But like any shorthand expression, its meaning is easily misunderstood by those who are unfamiliar with all the facts involved, the most important being that there are actually two types of cloning: reproductive cloning and therapeutic cloning. The difference between the two is like night and day. One serves no useful purpose and is ethically

and morally wrong. The other holds the potential to save lives and avoid human suffering.

Reproductive cloning involves the development of a full individual from a single body cell, the same process which Scottish scientists used in 1997 to create Dolly the sheep, and Texas scientists recently used to create CC the cat. All of us abhor human reproductive cloning and agree that it should be banned. To address this issue I, along with Senator Hatch and others, introduced S. 2439, a bill that provides criminal and civil penalties for any person who performs or attempts to perform human cloning.

Therapeutic cloning, on the other hand, refers to creating embryonic stem cells that are genetic matches to the patient for the purpose of repairing damaged and diseased tissue. In 1998, scientists first reported that embryonic stem cells have the ability to transform into any type of cell in the human body. If the scientists' theories are accurate, human embryonic stem cells, or tissues derived from them, could be transplanted to any part of the body to replace tissue that has been damaged by disease, injury or aging. It is this remarkable adaptability that leads scientists to believe that one day, stem cells could be the basis for an entire field of regenerative medicine.

As an example of the way this could work, let's say that a patient has heart damage resulting from a heart attack. The genetic material from one of his mature cells would be transplanted to an egg, which has been donated by a woman and had its own genetic material removed. This nuclear transplantation would create an entity that has never before existed in nature, but is related to a "pre-implantation embryo." This pre-implantation embryo, or "activated oocyte" as others have called it, is stimulated to divide in a Petri dish. After five to seven days, it would form a ball of about 100 cells called a blastocyst. At this stage, embryonic stem cells can be derived from within the blastocyst. These stem cells continue to divide in an undifferentiated state for an indefinite period of time. Stem cells, or heart tissue derived from these cells, would then be transplanted into the damaged heart of the patient where they would take up residence and work alongside the patient's original heart cells. Because the cells are the identical genetic match of the patient, no rejection would ever occur.

In 2001, President Bush announced his support for limited federally-sponsored embryonic stem cell research. While I prefer wider availability of stem cells than the President calls for, his compromise at least allows stem cell research to proceed. But scientists will never be able to explore the full potential of stem cells if legislation like H.R. 2505, the House-passed ban, is enacted into law.

Many say that we should ban medical research related to therapeutic cloning because it is unproven and may lead to unintended consequences. We have heard these arguments before, and we should heed the lessons learned. Twenty five years ago a debate raged regarding the potential of a new biotechnology called recombinant DNA. Members of Congress argued about whether to ban the use of this controversial technology completely, or to draft regulations that would allow scientists to move forward slowly. Many believed that the new technology could be used to cure diseases, and should therefore be fostered. Others believed that the technology was unproven, unsafe and would lead to Aldous Huxley's nightmarish vision of a *Brave New World,* and should therefore be banned completely. A debate was engaged whose conclusion was far from certain. In the end, the scientists identified ethical and safety guidelines and the Congress allowed them to create techniques using recombinant DNA. Today, this technology forms the backbone of an entire industry that has led to the development of recombinant vaccines, insulin for diabetics, drugs to fight AIDS, cancers, and many of our most debilitating diseases and afflictions. A ban on recombinant DNA 25 years ago would have resulted in the early deaths of hundreds of thousands, if not millions of Americans.

Today, we stand on the threshold of another era of scientific advances that, with the proper ethical guidelines, may revolutionize the way medicine is practiced. Dr. Bert Vogelstein, a prominent cancer researcher at Johns Hopkins University chaired a National Academies of Sciences Panel that investigated the potential of stem cells and nuclear transplantation to produce stem cells. Dr. Vogelstein's panel found that nuclear transplantation and stem cell-based therapies could be used to treat diseases and injuries that afflict over 100 million Americans. These maladies include cancer, diabetes, osteoporosis, cardiovascular diseases, autoimmune diseases, Alzheimer's disease, Parkinson's disease, burns, spinal-cord injuries and birth defects. Dr. Vogelstein estimates "that 170,000 Americans a year might be spared disease-related deaths through stem cell therapies." This is an astounding figure from an experienced cancer researcher.

Lest someone think our country's scientists have no moral compass, when news accounts first surfaced that some individuals planned to conduct human cloning ex-

periments, the prestigious National Academy of Sciences was quick to call for a legal ban on reproductive cloning. The Federation of American Societies for Experimental Biology, which represents over 60,000 of our nation's scientists, followed suit by emphatically denouncing human reproductive cloning. But both organizations were quick to make the distinction that, unlike reproductive cloning, therapeutic cloning holds enormous life-saving potential and should therefore be pursued.

Why is all this important? Because unless we take the time to understand the distinction between reproductive and therapeutic cloning, we risk losing one of the brightest hopes we have for treating and curing maladies like cancer, Alzheimer's, diabetes, spinal cord injury, and heart disease.

We must not tie the hands of our scientists. There are already reports of a "reverse brain drain," in which scientists are leaving the United States or choosing not to come here in the first place because of restrictions on stem cell, and now therapeutic cloning, research. More importantly, we risk delaying scientific and medical breakthroughs that can save lives.

We should ban human reproductive cloning, and the legislation that I and others have introduced will do so. But, before we close off the opportunity to save lives, we owe it to ourselves and future generations to look beyond the word cloning and engage in a substantive debate regarding regenerative therapies that could revolutionize the practice of medicine.

Senator SPECTER. Senator Hatch has outlined the issues very, very well, and I will just supplement with a couple of comments.

During my 23 years on the Senate Appropriations Subcommittee for Health and Human Services, I have promoted the funding for the National Institutes of Health, which has done remarkable work. When stem cells burst upon the scene in November 1998, in my capacity as chairman of that subcommittee, I convened the first of some 14 hearings on the subject.

I am totally opposed to human cloning. The word "cloning" has been used with reproductive cloning, which is a misnomer. It is really nuclear transplantation. There are enormous advances possible on the most dreaded maladies around. If the embryos could be used to produce life, that would be their highest use, and I would be all for it. But—and, Senator Hatch—and this is the only thing I will repeat—said he cannot understand why you should destroy embryos instead of using them. And I think that is the consideration, in a nutshell.

Last year, I took the lead in putting up $1 million—or the appropriations process did—for embryo adoption. And if there are enough people who are willing to adopt embryos, we ought to give them tax breaks. That would be the best use. But rather than discard them, let us use them. Let us work together to ban human cloning, but not mistake that it is not cloning when you talk about nuclear transplantation, which has the capacity to save many, many lives.

President Bush acknowledged the importance of stem cells on August the 9th in his famous speech where he authorized Federal funding for stem cell lines in existence at that time. Let us permit science to go forward.

That is three-and-a-half minutes, Mr. Chairman, and I thank you.

Senator BROWNBACK. Thank you, as well, Senator Specter.

Thank you all for coming today. We will have opening statements at this point in time. I wanted to accommodate other members. And we will get back to the rest of the panel, then, after that.

Today we will investigate the science and the ethics of human cloning. The world was stunned when a cult claimed to have pro-

duced the first live-born human clone over the Christmas holidays, and whether or not the Raelian claim of a live-born human clone is, in the end, proven to be true or false, we all know, at a minimum, that a live-born human clone is either already among us, or is, at least, a likely reality.

Of course, what the Raelians claim to have done is build on work that some in the biotech community are attempting to do. Work has already begun in biotechnology laboratories for the mass production of made-to-order human clones. Some want to begin cloning humans, some want—they just do not want anyone to call it that. Some who support human cloning would have society believe that there are two different types of cloning—so-called "reproductive cloning" and so-called "therapeutic cloning." Science, however, tells us that there is only one type of cloning, and, when successful, always results in the creation of a young human—initially a human embryo; eventually, a live birth. All cloning is reproductive, then, by nature. By that, I mean all human cloning produces another human life.

Now, so-called "therapeutic cloning" is the process by which an embryo is specially created for the directly intended purpose of subsequently killing it for its parts or for research purposes. Some proponents of human cloning claim that an embryo created in this manner will have cells that are a genetic match to the patient being cloned and, thus, would not be rejected by the patient's immune system. This claim is overstated, at best. In fact, there are some scientific reports that show the presence of mitochondria DNA in the donor egg can trigger an immune-response rejection in the patient being treated.

To describe the process of destructive human cloning as therapeutic when the intent is to create new human life that is destined for its virtual immediate destruction is certainly misleading. However one would like to describe the process of destructive cloning, it is certainly not therapeutic for the clone who has been created and then disemboweled for the purported benefit of its adult twin.

I, along with the President and the vast majority of Americans, do not believe that we should create human life just to destroy it. Yet that is exactly what is being proposed by those who support cloning in some circumstances. And however they might name the procedure—whether they call it "nuclear transplantation," "therapeutic cloning," "therapeutic cellular transfer," "DNA regenerative therapy," or some other name—it is simply human cloning.

Now, let us be clear, the Raelians and those interested in human cloning research seek to create human life through a process of human cloning that a vast majority of Americans clearly oppose. The threat presented to us by the Raelians is one that should refocus our attention on the immediacy of passing a permanent and comprehensive ban on all human cloning. The need for a permanent and comprehensive ban is pressing.

Six states have already passed laws that outlaw human cloning, and several more are beginning to follow suit. In fact, just yesterday the Indiana State Senate voted 47 to 3 to ban all human cloning.

Clearly, the Congress must address this issue during the 108th Congress. Later today, Senator Mary Landrieu and I, along with

several of our Senate colleagues, will introduce the Human Cloning Prohibition Act of 2003.

The President has already stated his unequivocal support for a permanent and comprehensive ban on all human cloning numerous times, including in his annual State of the Union Address just last night. And during the 107th Congress, the House voted, in an overwhelmingly bipartisan majority, to ban it.

The time for action in the Senate is now. Hopefully through this hearing, and with some of the hearings to come over the next several months, we will be able to better understand the implications of human cloning for our society.

And I would note, as some of you have noticed already, the whole issue is going to be in the definition of "What is a human clone?" Last night, when the President said he supported banning all human cloning, virtually everybody stood up and applauded. I thought that to be a very good sign. Then you find, "Well, what does the parsed word mean here? And when is a human clone a clone?" And that is the definition of what Senators Hatch and Specter were talking about, as well.

I hope we can focus in on human cloning—What is a human clone?—that we can ban that procedure and ban the creation of human clones, and I hope we can have a good discussion of that. This is not about embryonic stem cells from embryos that are currently in existence, as some have already testified. This is about the creation of a human clone, and it is primarily the issue of the creation of that human clone for research purposes. So hopefully we can have a good hearing and discussion on that point.

I now turn to the ranking member, Senator Wyden.

STATEMENT OF HON. RON WYDEN,
U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you, Mr. Chairman. I am certain we are going to have a good hearing, because you have always been very fair. I will tell you, having chaired this Subcommittee in the last Congress, and I wish I did not have to turn over the gavel right now, but I look forward to working with you. I know we are going to find common ground on a host of issues. I do not think there is a more exciting Subcommittee in the U.S. Senate than this one, and I wish you well.

Mr. Chairman and colleagues, first and foremost, with the hopes and aspirations of millions of suffering Americans, I just hope that Congress will follow the route of careful science here, rather than create roadblocks of resistance when our scientists try to come up with breakthrough cures.

I think it is especially important to reflect on another matter that we faced about 30 years ago, which has an awful lot of parallels to what we are dealing with today. In the late 1970's, when recombinant DNA technology was being developed, Congress was pushed then to consider a ban on all research in a field that was considered new and controversial. There was a debate, and much of the same set of questions we are faced with now was raised then. Fortunately, the research was allowed to go forward. It was done carefully. As I have suggested, therapeutic research must be done now, but the benefits have just been extraordinary. I will just

mention a few of them, a few of the 66 recombinant DNA products have helped tens of millions of patients worldwide—Humulin and Humalog serve human insulin, for over 4 million diabetes patients worldwide. Herceptin treats breast cancer, is now being treated in Phase 3 clinical trials. Epogen has been used since 1989 to fight anemia in kidney-dialysis patients. Endro works with the body's immune system to control inflammation. Pulmozyme has prevented childhood deaths from cystic fibrosis.

I think when you look at these kind of complicated scientific questions, where passions do run very high and people have differences of opinion, it is important to look at these historical models. I am convinced that making sure that we did not stop scientists in the 1970's was critical, the decisions we make about whether to stop or not stop scientists now is just as critical.

Last session, the Senate looked at two very different approaches to regulating yet another unfamiliar line of research. One of them would have banned reproductive cloning while allowing scientists to continue promising research on somatic cell nuclear transfer. The other approach would have been not only reproductive cloning, but also nuclear transfer and the importation of medical advances made through this research.

I favor the first approach. I think it is absolutely critical if we are to unlock the next generation of life-saving medical treatments. I hope that this Congress will not turn a blind eye to the therapeutic potential of the research that can lead to these breakthroughs.

I know that with strong differences of opinion, Chairman Brownback is going to handle a difficult issue fairly, and I look forward to working with him and our colleagues.

Senator BROWNBACK. Thank you, Senator Wyden.

Senator Ensign, would you have any opening comments?

STATEMENT OF HON. JOHN ENSIGN,
U.S. SENATOR FROM NEVADA

Senator ENSIGN. Just very briefly, Mr. Chairman.

I thank you for calling this hearing. I think in the bigger scope of things, I do not know that we could be dealing, as far as future is concerned, with a more important issue. It really does get to how we view ourselves as human beings. When we are starting to mess with the genetic makeup of people, the potential for evil is so great it is—it is almost unimaginable. And so this issue coming before us, it is so important that we deal with it, and we deal with it in a very logical, systematic manner, and we get as much scientific testimony as possible so that we know—we all know what we are dealing with.

There is a lot of confusion out there. I mean, it sounds so good to say "therapeutic cloning." I mean, you know, it is not reproductive cloning, it is therapeutic cloning. That is why, Mr. Chairman, when you mentioned how important it is going to be to have the definition of terms, just the difference between those two terms right there, it tells you, you know, whoever wins the battle of the definition will probably win this debate.

And so it is very important that we establish that cloning is cloning. Dolly was a clone. I think that everybody recognizes that

Dolly was a clone. Somatic cell nuclear transfer, that is the way Dolly was created. Everybody would recognize that that was a clone. A clone, as Senator Hatch was talking about, you would not define that as a clone, but that certainly, in my book, is a clone.

And so I think that it is important, as we get testimony, that we educate ourselves and we educate all of our colleagues about truly what we are dealing with here, because I really believe that this is one of the fundamental questions of our age, and future generations will be looking back at what we do now, depending on which direction we go.

So thank you very much for holding this hearing, and I look forward to the testimony of the witnesses.

Senator BROWNBACK. Thank you.

Senator Fitzgerald, do you have any comments?

STATEMENT OF HON. PETER FITZGERALD,
U.S. SENATOR FROM ILLINOIS

Senator FITZGERALD. Well, I just want to thank the Chairman for his leadership on the cloning issue, and I am proud to be a co-sponsor of your legislation.

And I want to welcome Representatives Toomey and Weldon to the Committee, and we will take—do some questions later.

Thank you.

Senator BROWNBACK. You both have been very patient. Congressman Weldon, I believe we will go with you first, if that is OK. And I very much appreciate both of you being here to testify here today.

Dave Weldon.

STATEMENT OF HON. DAVE WELDON,
U.S. REPRESENTATIVE FROM FLORIDA

Dr. WELDON. Thank you, Mr. Chairman, for the opportunity to testify.

It is critically important that the Senate act and enact a complete ban on human cloning. There is a huge bipartisan majority of Americans that want to see the procedure of human cloning banned, both for reproductive purposes and for experimental research. The failure to act is not only confusing and disappointing to the American people, but it also sends out a very wrong signal to the world community.

The United States remains the world's leader in the arenas of biomedical technology development and research, but, as well, in the areas of ethics involving the applications of these technologies. Many countries that have banned all human cloning remain amazed that the United States has not enacted a similar ban and that today in America, it remains legal to perform human cloning.

For this reason, I would like to confine my comments to the principal issue that is responsible for the failure of the Congress to act. All human cloning begins with the production of a cloned embryo. Reproductive cloning involves implanting a cloned embryo into a woman's uterus; while cloning research, therapeutic cloning, somatic cell nuclear transfer, nuclear transfer, or whatever you choose to call it, involves taking that same embryo, using it, and then destroying it after the cells have been extracted.

The question before us is whether we should ban human cloning at its beginning, or whether we should allow the creation of cloned embryos for experimental research and the inevitable implantation.

Many advocates for research cloning have advanced the notion that we need to allow it because of the so-called "potential" of therapeutic cloning. This potential has been based on speculation, exaggeration, and with no scientific facts. There are not even animal models to back up the claims that are promised. Cloning advocates say they need cloning to cure diseases. We were all promised, just last year, that embryonic stem cell research will cure all our ills. Now, a few months later, those same people are telling us that we need to accept human cloning experiments to address the tissue rejection issues.

I would like to remind you that transplant surgeon and now–Senate Majority Leader Frist made it clear on November 27th, 2001 in a Senate-floor speech that cloning does not resolve the tissue rejection issues. In fact, the real successes and advances being made are in the area of adult stem cells. Adult stem cells can be harvested from many areas of our body, such as the marrow, fat tissue, even the nose. There are no immune rejection issues with their use, no moral or ethical objections, and they have been used successfully in clinical practice for over 20 years to treat a host of serious conditions. Adult stem cells have been used successfully in over 45 human clinical trials, treated thousands with bone marrow transplants, and cured—cured a 59-year-old man of Parkinson's Disease. Furthermore, today's medical literature abounds with publications demonstrating successful new human clinical applications of adult stem cells.

Mr. Chairman, I still see patients, and I still read the medical journals. For the record, I submit a list of over 80 recent articles I was able to obtain from the medical literature demonstrating the successful use of human stem cells.

Senator BROWNBACK. Those will be submitted to the record without objection.*

Dr. WELDON. Researchers have found it very difficult to move embryo stem cells beyond the petri dish. Their robust tendency to duplicate and differentiate has shown them to be unstable in animal trials, with a tendency to form cancer-like tumors. Today, not only is there no example of embryo stem cells being used successfully to treat diseases in humans, there is not even a good animal model where this can be done.

What Senator Hatch and others are proposing we do is to go down the same path with cloned human embryos. Mr. Chairman, these are not minor issues. These are major issues, and there are obstacles we face—and the obstacles faced with embryo stem cells and cloned stem cells, we do not face with adult stem cells.

Both my bill and your bill, Mr. Chairman, allow unfettered, ongoing research in the fields of animal cloning. Cloning of animals is permissible under our legislation. Cloning of tissues is permissible. Cloning of DNA is permissible. Mr. Chairman, we do not allow drug companies to go out there and start experimenting on human subjects with their drugs until they have first demonstrated suc-

*The information referred to has been retained in Committee files.

cess in animal models. I think the gentleman from Nevada can testify to this. He is a former veterinarian.

Why some would want to skip this process and go directly to human cloning is beyond me. I say to these researchers, "Go out and conduct your animal experiments and then come back to us, and do not skip the process and start experimenting with humans." Too much is at stake.

If we pass anything short of the bill such as the one I have introduced, and the bill that you and Senator Landrieu would introduce, we will be forced to confront some very serious issues. If we go down the path Senator Hatch and Senator Specter have proposed, I think there are some very serious challenges that we will open up.

We will usher in an era where women will be exploited by experimental research cloning by corporations in order to get their eggs. Millions of women's eggs will be purchased for use in cloning experiments. This commodification of women is one of the reasons that leading feminists, like Judy Norsigian, have come out against research cloning. We have already seen the disturbing ads in college newspapers offering to pay women for their eggs for research. I find it hard to believe that some would embrace exposing women to serious—a serious medical procedure in order to harvest their eggs for these questionable experiments.

I would further assert that if the approach that Senator Hatch is advocating were allowed to move forward, eventually these companies will go to Central and South America and exploit poor women in Third World countries to get their eggs. The failure to approve our bill will allow there to be hundreds of labs all over the country creating cloned human embryos, which will ultimately usher in reproductive cloning. It will be impossible to police a reproductive cloning ban alone. The U.S. Department of Justice said so in testimony they presented to a House committee last year.

And, Mr. Chairman, I would like to introduce that testimony for the record in this Committee.

Senator BROWNBACK. Without objection.

[The information referred to follows:]

> Dr. WELDON. But you kind of leave the door open. That's the impression I get. You say, at this time, until there are better results in animals; I can't help but conclude that at least in your opinion and the position of many members of your professional association that you may come out ultimately in support of Dr. Zavos' position that we should allow reproductive cloning.
> Dr. COWAN. Yes, sir. It is a difficult position. Certainly, at this time though, we don't recommend it; but times can change. Times have changed for all of us, and we may very well see the position for reproductive cloning in the future. Rather than close this door, we would prefer to say, leave it open until we know more about it.

Dr. WELDON. Once cloned embryos are available in the laboratory, the implantation of a cloned human embryo into the womb of a surrogate mother would occur in the privacy of the doctor-patient relationship. Once implanted, what would the proponents of research cloning suggest we do? How could we possibly enforce their bill?

On May 15th, 2002, Dr. Bryan Cowan, representing the American Society for Reproductive Medicine, testified before the House that they opposed reproductive cloning at this time. I questioned

him, asking him whether his professional organization may come out ultimately in support of reproductive cloning, as Dr. Zanos Panos wants to do. He responded, and I quote, "Yes, sir, it's a difficult position." Their position is that when the safety issues are resolved, they want to engage in reproductive cloning. So research cloning will pave the way for reproductive cloning. Therefore, the only way to effectively stop this from occurring is to ban cloning from the start.

Finally, let me say that if we allow research cloning to be legal in the U.S., we are opening the door to a whole host of additional moral/ethical dilemmas. The artificial womb is currently under development, and it is possible now to place cloned embryos in an artificial womb environment and allow them to develop beyond the embryonic stage into the fetal stage of development.

Mr. Chairman, artificial wombs will be available in the near future. I will suggest to you that you will see these same people knocking on your door next year saying, "Please just let us grow these embryos for a few more weeks in the artificial womb so we can now get the differentiated cells." The question remains, How far will they go? To what age would they like to allow these cloned embryos to develop? How much do they want to exploit them?

Mr. Chairman, again, thank you for inviting me to be here, and I would be happy to answer any questions during the question period.

[The prepared statement of Dr. Weldon follows:]

PREPARED STATEMENT OF HON. DAVE WELDON,
U.S. REPRESENTATIVE FROM FLORIDA

Thank you for the opportunity to testify. It is critically important that the Senate enact a complete ban on human cloning. There is a huge bipartisan majority of Americans that want to see the procedure of human cloning banned, both for reproductive or experimental research purposes. The failure to act is not only confusing and disappointing to the American people, but it also sends out a very wrong message to the world.

The United States remains not only the world's leader in the arenas of biomedical technology development and research, but as well in the areas of the ethics involving the applications of these technologies. Many countries that have banned all human cloning remain amazed that the United States has not enacted a similar ban, and that today in America it remains legal to perform human cloning.

For this reason, I would like to confine my comments to the principle issue that is responsible for this failure to act. All human cloning begins with the production of a cloned embryo. Reproductive cloning involves implanting a cloned embryo into a women's uterus; while cloning research, therapeutic cloning, somatic cell nuclear transfer, nuclear transfer, or whatever you choose to call it, involves taking that same embryo and destroying it to take its cells rather than implanting it.

The question before us is whether we should ban human cloning at its beginning, or whether we should allow the creation of cloned human embryos for experimental research and the inevitable implantation.

Many advocates for research cloning have advanced the notion that we need to allow it because of the so-called potential of therapeutic cloning. This potential has been based on speculation, exaggeration and with no scientific facts. There are not even animal models to back up the claimed promises.

Cloning advocates say they need cloning to cure diseases. We were all promised just last year that embryonic stem cell research will cure all our ills. Now a few months later those same people are telling us that we need to accept human cloning experiments to address tissue rejection issues. I would like to remind you that transplant surgeon, and now Senate Majority Leader Frist, made it clear on November 27, 2001, in a Senate floor speech, that cloning does not resolve the tissue rejection issues.

In fact, the real successes and advances are being made in the area of adult stem cells. Adult stem cells can be harvested from many areas of your body such as the marrow, fat tissue, even your nose. There are no immune rejection issues with their use, no moral or ethical objections, and they have been used successfully in clinical practice for over twenty years to treat a host of serious conditions. Adult stem cells have been used successfully in over forty-five human clinical trials, treated thousands with bone marrow transplants, and cured a 59 year old man of Parkinson's disease.

Furthermore, today's medical literature abounds with publications demonstrating successful new human clinical applications of adult stem cells. Mr. Chairman, I still see patients and I still read the medical journals. For the record I submit a list of over 80 recent articles I was able to obtain from the medical literature demonstrating the successful use of adult stem cells.

Researchers have found it very difficult to move embryo stem cells beyond the petri dish. Their robust tendency to duplicate and differentiate has shown them to be unstable in animal trials with a tendency to form cancer like tumors. Today, not only is there no example of embryo stem cells being used successfully to treat disease in humans, there is not even a good animal model where this can be done. What Senator Hatch and others are proposing we do is to go down this same path with cloned human embryos. Mr. Chairman, these are not minor issues. These are major issues, and they are obstacles we do not face with adult stem cells.

Both my bill and your bill, Mr. Chairman, allow unfettered, ongoing research in the field of animal research in the area of cloning. Cloning of animals is permissible under our legislation Cloning of tissues is permissible. Cloning of DNA is permissible. Mr. Chairman we do not allow drug companies to go out there and start experimenting on human subjects with their drugs until they have first proven successes in animal models. Why some would want to skip this process with human cloning is beyond me. I say to the researchers, go out and conduct your animal experiments and then come back to us, but do not skip that process and start experimenting with humans. Too much is at stake.

If we pass anything short of the bill that Rep. Bart Stupak and I have introduced in the House, and the bill that you and Senator Mary Landrieu are introducing in the Senate, we will be forced to confront some very serious issues.

Absent our bill, we will usher in an era where women will be exploited by experimental research cloning corporations for their eggs. Millions of women's eggs will be purchased for use in cloning experiments. This commodification of women is one of the reasons that leading feminists like Judy Norsigian have come out against research cloning. We have already seen the disturbing ads in college newspapers offering to pay women for their eggs for research. I find it hard to believe that some would embrace exposing these women to serious medical procedures in order to harvest their eggs for experiments.

Second, the failure to approve our bill will allow there to be hundreds of labs all over the country creating cloned human embryos which will usher in reproductive cloning. It will be impossible to police reproductive cloning. The U.S. Department of Justice said so in testimony they presented in a House Committee last year. (Mr. Chairman I would like to submit their testimony for the record.) Once cloned embryos are available in the laboratory, the implantation of a cloned human embryo into the womb of a surrogate mother would occur in the privacy of the doctor-patient relationship. Once implanted, what would the proponents of research cloning suggest we do? How could they possibly enforce their bill?

On May 15, 2002 Dr. Bryan Cowan, representing the American Society for Reproductive Medicine, testified before the House that they opposed reproductive cloning "at this time." I questioned him asking whether his professional organization "may come out ultimately in support of Dr. Zavos' position that we should allow reproductive cloning." He responded, and I quote: "Yes, sir. It is a difficult position." Their position is that when the safety issues are resolved they want to engage in reproductive cloning. So, research cloning will pave the way for reproductive cloning. Therefore, the only way to effectively stop this from occurring is to ban cloning from the start.

Finally, let me say that, if we allow research cloning to be legal in the U.S., we are opening the door to a whole host of additional moral and ethical dilemmas. The artificial womb is currently under development and it is possible to place the cloned embryos in an artificial womb environment and allow them to develop beyond the embryonic stage well into the fetal stage of development.

Mr. Chairman, artificial wombs will be available in the near future. I'll suggest to you that you'll see these same people knocking on your door next year, saying please just let us grow these embryos for a few more weeks in the artificial womb so we can get the differentiated cells. The question remains, how far will they go,

to what age would they like to grow these smallest of humans in order to exploit them.

Senator BROWNBACK. Thank you, Dr. Weldon. I appreciate your testimony. Being a physician adds another level of credibility.

Senator Ensign, though, noted to me that he remains a veterinarian. You said he "was." But he remains a veterinarian.

Dr. WELDON. My deepest apologies, Doctor.

Senator BROWNBACK. Next, we have Congressman Patrick Toomey. He is a Congressman from Pennsylvania's 15th District, serving in the House of Representatives. We are glad to have you with us, Congressman Toomey.

STATEMENT OF HON. PATRICK J. TOOMEY, U.S. REPRESENTATIVE FROM PENNSYLVANIA

Mr. TOOMEY. Thank you, Mr. Chairman and Members of the Committee, for allowing me to testify today.

As you all know, during the last Congress, the House of Representatives overwhelming passed H.R. 2505, a bill introduced by my colleague from Florida, Dr. Weldon, which would ban all human cloning. As a strong supporter and one of the 265 House members who voted for this bill, I am here today to urge my Senate colleagues to do likewise. As the President stated last night, because no human life should be started or ended as the object of an experiment, I ask you to set a high standard for humanity and pass a law against all human cloning.

I am certainly very sympathetic to all those who suffer from incurable or chronic afflictions. I think we all are. And we are all committed to helping find cures. I understand the good intentions of those who advocate human cloning and the hope that research on these clones might yield cures for major illnesses. But for a variety of reasons, both technical and ethical, I believe it is wrong to pursue this approach.

On the technical level, although I am neither a doctor nor a scientist, the evidence suggests to me that cloned human embryos are not likely to yield cures for major illnesses. Hopes to the contrary are not well-founded and may be false hopes for the afflicted.

As just one example, according to Thomas Okarma, the chief executive officer of Geron Corporation, a leading bio-pharmaceutical company, quote, "The odds favoring success are vanishingly small, and the costs are daunting. It would take thousands of human eggs on an assembly line to produce a custom therapy for a single person. The process is a nonstarter, commercially," end quote.

Furthermore, as Dr. Weldon has explained, despite years of research with animal cloning, no successful treatment has been developed using cells derived from cloned embryos, for either animals or people.

The process that would be required to produce large supplies of cloned human embryos is, itself, ethically problematic. Super-ovulatory drugs are necessary for producing large supplies of eggs for harvesting. These drugs have been linked to an increased risk of ovarian cancer. In addition, this process inherently treats a woman's eggs as a commodity.

Supporters of human cloning for research purposes have proposed limitations that are both arbitrary and, I believe, unwork-

able. To avoid the dilemma of creating a cloned child, they would require that the cloned embryo be destroyed after a specified period of time. Some have suggested 14 days. Clearly, this is an arbitrary point in time. If scientists were to determine that the embryo would be of more scientific value after 21 days or 51 days, what rationale would keep the 14-day limit in force?

In addition, a specified deadline for experimenting upon and destroying a cloned human embryo would be almost impossible to enforce. The Justice Department concluded that, quote, "Enforcing a modified cloning ban would be problematic and pose certain law enforcement challenges that would be lessened with an outright ban on human cloning." The statement went on to say, "There does not seem to be any reliable means for determining the difference between a fertilized embryo and a cloned embryo," and concluded by stating that, "Once a pregnancy were established, any government-directed attempt to terminate a cloned embryo in utero would create problems enormous and complex." In other words, if a cloned human embryo were to be implanted and a viable pregnancy established, it would be virtually impossible to detect or differentiate from a routine pregnancy. And if detected, the only way to prevent the cloned child would be a forced abortion, which is obviously unacceptable to all of us.

As daunting as all of the technical challenges are, Mr. Chairman, perhaps the strongest arguments against human cloning are the ethical arguments. The process of transferring a somatic cell nucleus into an enucleated egg produces a human embryo that has the potential to be implanted in utero and developed to term. In other words, the embryo produced for the purpose of therapeutic cloning, as some would call it, is biologically indistinguishable from an embryo intended for reproduction. It is a human life—at a very early stage of development, of course, but entirely human, nevertheless.

Thus, creating cloned human embryos for research purposes means creating human life for the purpose of research and with the intent of destroying it. This commodification and exploitation strikes me as a profound undermining of our society's sense of human dignity. And in doing so, I believe it undermines our very humanity.

Mr. Chairman, I thank you for holding this hearing today. I thank you for your support for a ban on all human cloning, and I thank you for allowing me to testify this afternoon.

[The prepared statement of Mr. Toomey follows:]

PREPARED STATEMENT OF HON. PATRICK J. TOOMEY, U.S. REPRESENTATIVE FROM PENNSYLVANIA

Thank you, Mr. Chairman and Members of the Committee for allowing me the opportunity to testify today.

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I am certainly very sympathetic to all those who suffer from incurable or chronic afflictions—we all are—and we all are committed to helping to find cures. I under-

stand the good intentions of those who advocate human cloning in the hope that research on these clones might yield cures for major illnesses. But for a variety of reasons, both technical and ethical, I believe it is wrong to pursue this approach.

On the technical level, although I am neither a doctor nor a scientist, the evidence suggests to me that cloned human embryos are not likely to yield cures for major illnesses. Hopes to the contrary are not well founded, and may be false hopes for the afflicted.

According to Thomas Okarma, Chief Executive Officer of Geron Corporation, "The odds favoring success are vanishingly small, and the costs are daunting. It would take thousands of [human] eggs on an assembly line to produce a custom therapy for a single person. The process is a nonstarter, commercially."

Furthermore, despite years of research with animal cloning, no successful treatment has been developed using cells derived from cloned embryos for either animals or people.

The process that would be required to produce large supplies of cloned human embryos is itself ethically problematic. Superovulatory drugs are necessary for producing large supplies of eggs for harvesting. These drugs have been linked to an increased risk of ovarian cancer. In addition, this process inherently treats a woman's eggs as a commodity.

Supporters of human cloning for research purposes have proposed limitations that are both arbitrary and unworkable. To avoid the dilemma of creating a cloned child they would require the cloned embryo to be destroyed after a specified period of time—some have suggested 14 days. Clearly this is an arbitrary point in time. If scientists were to determine that the embryo would be more scientifically valuable after 21 days or 51 days, what rationale would keep the 14-day limit in force?

In addition, a specified deadline for experimenting upon and destroying a cloned human embryo would be almost impossible to enforce. A Justice Department statement concluded that "enforcing a modified cloning ban would be problematic and pose certain law enforcement challenges that would be lessened with an outright ban on human cloning." The same statement went on to say, "there does not seem to be any reliable means for determining the difference between a fertilized embryo and a cloned embryo" and concluded by stating "once a pregnancy were established, any government-directed attempt to terminate a cloned embryo in utero would create problems enormous and complex." In other words, if a cloned human embryo were to be implanted and a viable pregnancy established it would be virtually impossible to detect or differentiate from a routine pregnancy. And if detected, the only way to prevent a cloned child is a forced abortion, which is obviously unacceptable to all of us.

As daunting as all of the technical challenges are, perhaps the strongest arguments against human cloning are the ethical arguments. The process of transferring a somatic cell nucleus into an enucleated egg produces a human embryo that has the potential to be implanted in utero and developed to term. In other words, the embryo produced for the purpose of "therapeutic cloning" as some call it, is biologically indistinguishable from an embryo intended for reproduction. It is a human life-at a very early stage of development of course-but entirely human nevertheless. Thus creating cloned human embryos for research purposes means creating human life for the purpose of research with the intent of destroying it. This commodification and exploitation strikes me as a profound undermining of our society's sense of human dignity. And in doing so, it undermines our very humanity.

Mr. Chairman, I thank you for holding this hearing today, I thank you for your support for a ban on all human cloning and I thank you for allowing me to testify this afternoon.

Senator BROWNBACK. Thank you very much, and thank you for your patience, too, on the panel because you have been here quite a while sitting and waiting.

I have just a couple of questions. Dr. Weldon, you have looked at a lot of the research. I have had people in my office look at the research. One thing that I have noted was a number of the claims that were made that this was going to cure a number of diseases—Parkinson's, ALS, a whole host of diseases—are the same claims that were made about fetal tissue research, were the same claims that were made about embryonic stem cell research, are now being made about cloning. As a matter of fact, we have gone back to the actual debates and pulled statements from people.

And of course, we all want to cure these diseases. We want to see that take place. But what I have seen of the research, particularly on fetal tissue, which has now been going on about 10 years, those claims have not proven valid, that they were going to cure all of these ailments. Indeed, in some cases, the fetal tissue research has had terrible impact on the actual patient when it has been used.

And I wanted to just enter into the record this—I ran across last week—in Rheumatology Journal, embryonic stem cells injected into the mouse knee joint formed teratomas and subsequently destroyed the joint.

This is the first research paper I know of at this point in time on embryonic stem cells forming tumors and destroying the joint, which is something that we saw taking place in the fetal tissue research area.

And I want to enter this into the record and would ask you to comment on what you have seen in the fetal tissue and the embryonic stem cell scientific work to date.

[The information referred to follows:]

RHEUMATOLOGY 2003; 42: 162–165, *British Society for Rheumatology*

Embryonic stem cells injected into the mouse knee joint form teratomas and subsequently destroy the joint

S. Wakitani, K. Takaoka, T. Hattori [1], N. Miyazawa [2], T. Iwanaga [2], S. Takeda [2], T. K. Watanabe [2] and A. Tanigami [3], Department of Orthopaedic Surgery, Shinshu University School of Medicine, Matsumoto,

Objective. To determine whether the joint space is a suitable environment for embryonic stem (ES) cells to grow and form cartilage.

Method. We transplanted ES cells into the knee joint and a subcutaneous space of mice with severe combined immunodeficiency.

Results. Teratomas formed in both areas. Those in the joints grew and destroyed the joints. The incidence of cartilage formation was the same in the knee joint and subcutaneous space, but the ratio of cartilage to teratoma was higher in the knee joint than in the subcutaneous space. The teratomas were proved to have been derived from the transplanted ES cells by detection of the neomycin-resistance gene that had been transfected into the ES cells.

Conclusions. It is currently not possible to use ES cells to repair joint tissues. Further optimization of donor ES cells to differentiate as well as inhibit tumour growth may help to meet these challenges.

Dr. WELDON. Well, you really got to the heart of the issue. And let me just say, in response to this, before I say anything else, you know, I am a physician. I took care of hundreds of patients with Parkinson's Disease, paralysis, diabetes. Indeed, I had an uncle I was very close to, died of Parkinson's Disease. My father died of the complications of diabetes. And so I just want to set the record straight. I do not pursue this in a trivial fashion. If it were scientifically valid to make the claims that there are all these great promises of cloning, I would very, very seriously look at that.

The facts are the facts. And facts are stubborn things; but they are, nonetheless, the facts. There is no evidence in the scientific literature that cloning can actually be used, even in an animal model of any form of disease.

[1] Department of Orthopaedic Surgery, Osaka-Minami National Hospital, Kawachinagano and
[2] Otsuka GEN Research Institute, Otsuka Pharmaceutical Co. Ltd, Tokushima and
[3] Fujii Memorial Research Institute, Otsuka Pharmaceutical Co. Ltd, Otsu, Japan.

And might I also add that the way we went down this whole path was, you know, we got started with the embryo stem cell lines. And adult stem cells, mind you, they have been used for 20 years, and there are no rejection issues.

And as I said, I have got—I am introducing, for the record, 80—eighty—research articles using adult stem cells. And I broke it down by tabs. I have got adult stem cell successes for brain damage. I have got adult stem cell successes for cancer. I have got adult stem cell successes for cerebral palsy, adult stem cell successes for diabetes, adult stem cell successes for eye disease, adult stem cell successes for heart disease. I mean, it is not like, if you take the time and look at the medical literature, there is not a lot of evidence here.

There is zero using embryonic stem cells, zero—zero. Zero using embryonic stem cells in humans. Zero using cloned models in humans. For animal models, it is the same number.

I have been challenging scientists at NIH and all these institutions, "Show me your data that there's all this promise," and they have yet to do it. Occasionally you see these articles appearing where the claims are made. But then, when you actually stop and read the article—in the two—the two publications I have seen, when you actually read the research article, they were actually using adult stem cells, and they were trying to claim, in the press, that these were embryonic stem cells, or these were cloned stem cells.

And so, in my opinion, there are lots of technical problems, and I do not want to get too deep into the science here, but I would be very, very happy to do that. There are some real bona fide problems. And probably the biggest one is the one you touched on in the example you described where the embryo stem cells ate away the joint.

The cell biologists love embryo stem cells because they are very robust, so when you play with them in a petri dish and a test tube, they grow very, very nicely and they differentiate very easily into different cell lines. But that very property of growing robustly and differentiating easily makes them extremely problematic when you try to do clinical applications with them.

I am sorry for that very lengthy answer to your question.

Senator BROWNBACK. It is a good answer, and very knowledgeable. You have spent a lot of time on this.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman. I will be brief.

The first thing I would like to do, Mr. Chairman, is ask unanimous consent to enter into the record a set of letters from a whole host of scientific and medical organizations that are in support of therapeutic research, and make that part of the record.

Senator BROWNBACK. Without objection.*

Senator WYDEN. Gentlemen, thank you. And I know you both have spent a lot of time on this issue. And as I indicated in my opening statement, I know that views run passionately on this subject.

*The information referred to has been retained in Committee files.

And I think my question, and I have just one, would be for your, Mr. Toomey, on this question of, well, the science is not going anywhere and it is not going to produce any big gains—let me just read you a sentence from just one of the letters from physician and scientific groups that I am putting in the record today.

This is from the American Society of Hematology. It was written just a few days ago. And I will quote here. It says, "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."

Now, this is from a very renowned organization, a group of physicians who are considered leaders in the field. And my question to you is, when a group like this says that the research is very promising—and also in the letter, they talk about how important it is to have rigorous oversight and careful procedures to make sure that the work goes forward—why is it appropriate for the U.S. Congress to say that that research should not go forward when they are talking about the need for rigorous oversight, careful scientific procedures so as to not promote abuse? Why should the Congress not let the scientific research go forward when there are the kind of safeguards and—they are against human cloning, as I am, as well—why should that science not go forward, Congressman Toomey?

Mr. TOOMEY. Well, Senator, thank you for that. And the fact—the opinion of these physicians needs to be carefully considered. That is an important part of this discussion. But I think that their opinion does not—and even their hope for rigorous oversight—does not change some fundamental features here, some fundamental facts, and that is that the product, the pursuit of what they are advocating means creating human life with the intent to learn from it and then destroy it at some period of time. And that is very troubling, on an ethical level, for many of us, and I think it is quite appropriate for Congress to make a judgment as to whether or not that ethical consideration outweighs the potential, the possibility, that there may, although there may not, be medical benefits from this.

And we also have an obligation, I think, to weigh carefully whether it is really, truly possible to provide the oversight that they say they would like to see. As I cited in my testimony, I think there are some very serious technical hurdles that may not be possible to overcome, in terms of preventing the kinds of abuses that I think, and many of us think, would inevitably occur.

Senator WYDEN. I would also put into the record at this point, Mr. Chairman, a piece in *The Wall Street Journal,* by Virginia Postrel, that talks about why it would be a mistake to impede medical progress. She would certainly be considered a conservative, in terms of her political perspective, and she also talks about the need for rigorous oversight. She says, in response to what Congressman Toomey said, "The small possibility of reproductive cloning does not justify making nucleus transfer a crime," and goes on to say how virtually anything in science, and these are her words, "could be translated into evil at some point." But I think good people, like

you and Senator Brownback and I, can find ways to minimize that prospect.

And I thank you all. I know you are very sincere in your views and I look forward to working with you.

Thank you, Mr. Chairman.

Senator BROWNBACK. That will be entered into the record.

[The information referred to follows:]

The Wall Street Journal, December 5, 2001.

YES, DON'T IMPEDE MEDICAL PROGRESS

By Virginia Postrel

To many biologists, the recently announced creation of a cloned human embryo was no big deal. True, researchers at Advanced Cell Technology replaced the nucleus of a human egg with the genetic material of another person. And they got that cloned cell to start replicating. But their results were modest. It took 71 eggs to produce a single success, and in the best case, the embryo grew to only six cells before dying. That's not a revolution. It's an incremental step in understanding how early-stage cells develop.

And it's far from the 100 or so cells in a blastocyst, the hollow ball from which stem cells can be isolated. Scientists hope to coax embryonic stem cells into becoming specialized tissues such as nerve, muscle, or pancreatic islet cells. Therapeutic cloning, or nucleus transplantation, could make such treatments more effective.

In theory, it would work like this: Suppose I need new heart tissue or some insulin-secreting islet cells to counteract diabetes. You could take the nucleus from one of my cells, stick it in an egg cell from which the nucleus had been removed, let that develop into stem cells, and then trigger the stem cells to form the specific tissue needed. The new "cloned" tissue would be genetically mine and would not face rejection problems. It would function in my body as if it had grown there naturally, so I wouldn't face a lifetime of immunosuppressant drugs.

But all of that is a long way off. ACT and others in the field are still doing very basic research, not developing clinical therapies. Indeed, because of the difficulty of obtaining eggs, therapeutic cloning may ultimately prove impractical for clinical treatments. It could be more important as a technique for understanding cell development or studying the mutations that lead to cancer. We simply don't know right now. Science is about exploring the unknown and cannot offer guarantees.

Politics, however, feeds on fear, uncertainty, and doubt, and the word "cloning" arouses those emotions. While its scientific importance remains to be seen, ACT's announcement has rekindled the campaign to criminalize nucleus transplantation and any therapies derived from that process. Under a bill passed by the House and endorsed by the president, scientists who transfers a human nucleus into an egg cell would be subject to 10-year federal prison sentences and $1 million fines. So would anyone who imports therapies developed through such research in countries where it is legal, such as Britain. The bill represents an unprecedented attempt to criminalize basic biomedical research.

The legislation's backers consider the fear of cloning their best hope for stopping medical research that might lead to gene-level therapies. Opponents make three basic arguments for banning therapeutic cloning.

The first is that a fertilized egg is a person, entitled to full human rights. Taking stem cells out of a blastocyst is, in this view, no different from cutting the heart out of a baby. Hence, we hear fears of "embryo farming" for "spare parts."

This view treats microscopic cells with no past or present consciousness, no organs or tissues, as people. A vocal minority of Americans, of course, do find compelling the argument that a fertilized egg is someone who deserves protection from harm. That view animates the anti-abortion movement and exercises considerable influence in Republican politics.

But most Americans don't believe we should sacrifice the lives and well being of actual people to save cells. Human identity must rest on something more compelling than the right string of proteins in a petri dish, detectable only with high-tech equipment. We will never get a moral consensus that a single cell, or a clump of 100 cells, is a human being. That definition defies moral sense, rational argument, and several major religious traditions.

So cloning opponents add a second argument. If we allow therapeutic cloning, they say, some unscrupulous person will pretend to be doing cellular research but instead implant a cloned embryo in a woman's womb and produce a baby. At the

current stage of knowledge, using cloning to conceive a child would indeed be dangerous and unethical, with a high risk of serious birth defects. Anyone who cloned a baby today would rightly face, at the very least, the potential of an enormous malpractice judgment. There are good arguments for establishing a temporary moratorium on reproductive cloning.

But the small possibility of reproductive cloning does not justify making nucleus transfer a crime. Almost any science might conceivably be turned to evil purposes. This particular misuse is neither especially likely—cell biology labs are not set up to deliver fertility treatments—nor, in the long run, especially threatening.

Contrary to a lot of scary rhetoric, a healthy cloned infant would not be a moral nightmare, merely the not-quite-identical twin of an older person. (The fetal environment and egg cytoplasm create some genetic variations.) Certainly, some parents might have such a baby for bad reasons, to gratify their egos or to "replace" a child who died. But parents have been having children for bad reasons since time immemorial.

Just as likely, cloned babies would be the cherished children of couples who could not have biological offspring any other way. These children might bear an uncanny resemblance to their biological parents, but that, too, is not unprecedented. Like the "test tube babies" born of in vitro fertilization, cloned children need not be identifiable, much less freaks or outcasts.

Why worry so much about a few babies? Because, say opponents, even a single cloned infant puts us on the road to genetic dystopia, a combination of Brave New World and Nazi Germany. A cloned child's genetic makeup is too well known, goes the argument, and therefore transforms random reproduction into "manufacturing" that robs the child of his autonomy. This is where the attack broadens from nucleus transfer to human genetic engineering more generally. *An anti-therapeutic cloning petition,* circulated by the unlikely duo of conservative publisher William Kristol and arch-technophobe Jeremy Rifkin, concludes, "We are mindful of the tragic history of social eugenics movements in the first half of the 20th century, and are united in our opposition to any use of biotechnology for a commercial eugenics movement in the 21st century."

But the "eugenics" they attack has nothing to do with state-sponsored mass murder or forced sterilization. To the contrary, they are the ones who want the state to dictate the most private aspects of family life. They are the ones who want central authorities, rather than the choices of families and individuals, to determine our genetic future. They are the ones who demand that the government control the means of reproduction. They are the ones who measure the worth of human beings by the circumstances of their conception and the purity of their genetic makeup. They are the ones who say "natural" genes are the mark of true humanity.

Winners in the genetic lottery themselves, blessed with good health and unusual intelligence, they seek to deny future parents the chance to give their children an equally promising genetic start. In a despicable moral equivalency, they equate loving parents with Nazis.

Biomedicine does have the potential to alter the human experience. Indeed, it already has. Life expectancy has doubled worldwide in the past century. Childbirth is no longer a peril to mother and infant. Childhood is no longer a time for early death. The pervasive sense of mortality that down through the ages shaped art, religion, and culture has waned.

Our lives are different from our ancestors' in fundamental ways. We rarely remark on the change, however, because it occurred incrementally. That's how culture evolves and how science works. We should let the process continue.

Senator BROWNBACK. Any comment?

Senator Ensign?

Senator ENSIGN. Thanks, Mr. Chairman.

Just very briefly, for either one of you. The debate is whether or not this is cloning. When we are talking about—I talked about that briefly in my opening research—the various definitions that we talk about. And maybe start with you, Dr. Weldon. They are saying that they are not creating life and destroying it with therapeutic cloning. Could you just address that, from a technical standpoint?

Dr. WELDON. Yes, I would be very, very happy to do that. And you know, a lot of people are trying to put lipstick on the pig here, and——

[Laughter.]

Dr. WELDON.—you know, the—when people say things like that, I have to say to them, "Well, explain to me, then, why Dolly is not a sheep." From a—you know, my background, you know, I practiced medicine for 15 years before I came here. And my undergraduate degree, I did research in molecular genetics, and my degree was in biochemistry. And I tend to look at this from a biological perspective, OK? And when we take a nucleus out of one of your body cells and put it in a female egg and zap it with electricity and it starts to duplicate—from a biological perspective, that is a human embryo with the full potential, if there are no genetic defects in it, to fully develop into a twin, an identical twin, of you. And to try to say that this is not the creation of human life, that this is not cloning, that this is not this, and this is not that, is really trying to do damage control, in my opinion.

The overwhelming—notwithstanding the assertions of some professional societies that this is ethically and morally OK, the overwhelming opinion of the American people that—is that it is not and that it is very, very problematic.

And the point I have just been trying to stress over and over again is, Where is the data? You know? It is like, "Where's the beef?" You know? Show me the information that this has all the supposed promise that you claim.

And might I also add that in the bill that we passed in the House, and the bill the Senator introduced in the last term—and I assume it is going to read the same way—the animal research can move ahead unfettered. And if it really does show all the supposed promise, we can revisit this issue. But to allow this to move ahead with humans, in my opinion, will—exploiting women, what it would entail—I think it is extremely disturbing. And I do not——

Mr. TOOMEY. I would just add, very briefly, Senator, that I think that some folks are attempting to create a distinction that does not exist based on the intended application, but based on the intended use of the embryo that is being created. And it seems to me, as a matter of logic, that regardless of the intended application or intended use of the embryo, since it is biologically indistinguishable, a so-called therapeutic clone or a reproductive clone, I think that is a false distinction.

Dr. WELDON. Can I just add one important point, if I may, Mr. Chairman?

If the positions of Senators Specter and Hatch and others move forward, what I would predict, as a scientist, as a physician who has read the literature, there will be no therapeutic applications of this technology. But what has the potential to happen is the development of human laboratory models of disease.

You could have a situation where if you had a child with cystic fibrosis, you could clone that child, you could make dozens of embryos of that child, and then sell those embryos to research labs all over the country and allow those embryos to develop in the lab and study cystic fibrosis that way. And that is a potential application of all of this.

But other than that, I do not—I think it is highly likely there would ever be any clinical utility in this kind of research. And what I have just described, which is an eventual outcome if we do not ban this, I think is morally and ethically extremely objectionable,

to have biotechnology companies with shelves of human embryos representing all these different diseases that they are selling and making out of, and that these embryos are just going to be exploited in the lab and then thrown away when they are done.

And mind you, the place they will go next is beyond the embryonic stage into the fetal development stage. Who on earth would want to go through all the trouble of extracting stem cells and have to deal with all that manipulation of the stem cells when you could just drop it in some broth and it would develop into a fetus, and then you could just get the tissue that you want?

Senator ENSIGN. Well, Mr. Chairman, unfortunately, I have to excuse myself from the hearing. Just one last comment that I would like to make.

When you become a new physician, become a new veterinarian, one of the things that they teach is, "Above all, do no harm." And as you mentioned, animal cloning can go forward, animal research can go forward. I think that it would be very, very wise of us, as an institution, to ban all human cloning at this point.

Once again, it could—I do not think that we should ever legalize it, even if it—from a utilitarian point of view, that it turns out to be actually useful. I am skeptical whether it will be useful, but even if it does, it is still fundamental to me that creating human life just because can you utilize it devalues human life.

We should be in the business of making a moral statement that we value human life in America, that we value each individual, that fundamentally we were a nation that valued the individual because we felt that we were created and that we had certain inalienable rights in each individual. And I think that we should, as a nation, continue to value each individual instead of devaluing life by looking at us as purely utilitarian.

Thank you, Mr. Chairman.

Senator BROWNBACK. Thank you for that statement.

Senator Nelson, did you have any questions or comments?

STATEMENT OF HON. BILL NELSON,
U.S. SENATOR FROM FLORIDA

Senator NELSON. Thank you, Mr. Chairman.

I would love to have your opinion on the two procedures compared to each other, one in the production of stem cells from a fertilized egg, as well as the production of stem cells from the procedure known as SCNT.

Dr. WELDON. The embryonic stem cell issue first came up when—you know, there were all these fertility clinics, and many of them have leftover embryos, and it was Dr. Thompson back in 1998 who showed that you could extract stem cells from those embryos and that they divide robustly and they differentiate into other tissues.

The procedure involving somatic cell nuclear transfer is really—from a stem cell perspective, is not that different; it is just a difference in the source. You know, in SCNT, you are taking the egg, and, rather than uniting it with a sperm and getting a new, unique human individual, you are taking that egg, removing the nucleus that was in the egg, which is 23 chromosomes, and you are taking a cell from, say, your body or somebody else's body, taking the nu-

cleus out and putting it in there. But once it starts dividing, you get the same kind of stem cells out of it that have the same characteristics—not exactly; I mean, there are a whole bunch of huge biological and medical issues that separate the two. But I think, from the layperson's perspective, it is basically the same thing.

Senator NELSON. So for the process of producing stem cells, of which the President has approved a certain process of certain existing stem cells, those of which were derived from fertilized eggs, from an ethical standpoint, you do not see any difference in deriving stem cells from the procedure of SCNT, as opposed to the procedure through the fertilized egg.

Dr. WELDON. Oh, well, no, there is a huge difference. In the case of the fertilized egg, you are looking at a situation where a man and a woman, you know, came together and created that, had some babies, and then decided they did not want to use it, and so they turned it over for—either to be discarded or to be exploited for research purposes and then destroyed, which I think, morally and ethically, is a very different issue, from a moral and ethical perspective, from saying, "We're going to create these human embryos for the purpose of exploiting them and then destroying them." In the one situation, you had an embryo that was going to be destroyed anyway, and you are trying to take advantage of it for utilitarian purposes. In the other scenario, you are specifically creating these things to take advantage of them.

And my position—and you were not here when I gave my testimony earlier—is that this is unnecessary and unethical. Unethical, we can debate. The reason I say it is unnecessary—and I was showing this earlier—this is just the recent medical literature, in the last 12 or 14 months, on adult stem cells. Eighty-eight studies I have here. In humans, not in animals.

Senator NELSON. Do you—and Mr. Toomey, chime in—do you approve the method of extracting stem cells from the fertilized egg that you said that was going to be discarded anyway?

Dr. WELDON. Well, my personal position on this issue is that the eggs belong to the mother and father. OK? And that if they do not want to implant them in the mother—if they have had their family, they have their three or four kids—then they are presented the option to either adopt them out or give them over to research.

My position on embryo stem cells was always that I did not want to see it funded. The debate in this city was over the use of taxpayer dollars. Because when you extract a stem cell, you kill the embryo, there are many people who are pro-life who feel that our taxpayer dollars should not be going for that purpose, and I agree with that position. But I never took the position that I wanted to make that illegal.

What I would like to make illegal is the special creation of human embryos for the purpose of exploiting them and destroying them through the process of cloning.

Senator NELSON. At the end of the day, what I am trying to get at—and, Mr. Toomey, maybe you want to—if we find that there is promise in curing diseases through stem cells, then we have to get them some way. And as I understand the description here, there is one of two ways. There is either through the fertilized egg that you have just described, or there is through the procedure of SCNT.

So if you are trying to combat disease with a stem cell, part of the process which has been approved already by the President—what is the best way? And why do you feel that way? And obviously, it is a matter of ethics, as you have explained your feeling on the——

Mr. TOOMEY. I would just briefly suggest that there is, perhaps, a third way. There are the existing lines of stem cells, which are already in existence and for which research is continuing, with Federal funding, as you know.

It is my view that the question of what to do with the "leftover," if you will, embryos from in vitro fertilization does pose its own unique set of ethical questions that we need to wrestle with. But I share Dr. Weldon's view. That is a—it is a distinct case. It is a separate set of issues. And it is reasonable for us to separate them and address them separately.

Dr. WELDON. Can I just add to that? If there is—your body is teeming with stem cells, Bill. I mean, they are in your nose, they are in your skin, they are in your fat tissue, they are in your blood. And those stem cells are called adult stem cells, and those stem cells have been studied in human clinical trials and have been found useful in treating a whole host of medical conditions.

The debate is over using embryo stem cells. And you are right, there are two places you can get them. You can get them from fertilized eggs through sexual fertilization and through cloning. And those stem cells have been shown to be useful in zero clinical trials in humans. They have been shown to be useful in zero animal models in humans.

And so, to me, the promise is in using these adult stem cells. And why would we want to go down the path of allowing human cloning when the embryo stem cells are just really not proven to be very effective at all?

Senator NELSON. And of course, this is the beginning of a very interesting debate. My predecessor, Senator Connie Mack, is someone who has come to me and pleaded the case of allowing the SCNT procedure to proceed, because he is very convinced that it will have the result of a number of medical breakthroughs.

So thank you for your opinion.

Senator BROWNBACK. Thank you very much. You have been a very patient and excellent panel. We appreciate your coming here.

The next panel will be Dr. Leon Kass. He is a native of Chicago. Dr. Kass was educated at the University of Chicago, where he earned his BS and MD degrees, and at Harvard, where he took a Ph.D. in biochemistry. He then did research in molecular biology at the National Institute of Health, while serving the United States Public Health Service.

Shifting directions from doing science to thinking about its human meaning, he has been engaged for over 30 years with ethical and philosophical issues raised by biomedical advance and, more recently, with broader moral and cultural issues.

And I would note, as well, he is chairman of the President's Council on Bioethics, appointed by President George W. Bush.

Dr. Kass, we are delighted to have you. I think we intended initially to have you on the program by 3 o'clock, maybe a little earlier. We are a quarter to 4, so we are running right on time. Delighted to have you. The floor is yours.

STATEMENT OF DR. LEON R. KASS, CHAIRMAN, THE PRESIDENT'S COUNCIL ON BIOETHICS

Dr. KASS. Thank you very much, Mr. Chairman, Members of the Committee. On behalf of the President's Council on Bioethics, I want to thank you for this opportunity to present the council's findings and recommendations on the vexing subject of human cloning.

Senator BROWNBACK. Dr. Kass, pull that microphone down a little bit more forward, if you would.

Dr. KASS. Is that better?

Senator BROWNBACK. Yes, thank you.

Dr. KASS. Also speaking personally, as someone who has written on the subject of the ethics of human cloning for 35 years, I want to thank you, Senator Brownback, for your vision in recognizing the momentous choice now before us, and for your courage and for your leaderships in seeking effective means to protect us from a dangerous assault on human dignity.

For the first 6 months of the year 2002, the President's Council on Bioethics met to consider the moral, biomedical, and human significance of human cloning in order to advise President Bush on the subject. The council's report, "Human Cloning and Human Dignity and Ethical Inquiry," was issued last July. I am submitting, as part of my testimony, the executive summary of the report, and we have provided here today fresh copies of the report, which I hope will be distributed to all Members of the Committee.

Senator BROWNBACK. That will be made part of the record without objection.

Dr. KASS. Right. I want to summarize, to begin with, the findings of the report in five points.

First, the council sought to examine the subject of human cloning in full by considering the human goods that cloning might serve or endanger, not just whether the technique is today feasible or safe. We regard it as of prime importance to put cloning in its proper place, both in its relation to human procreation and also in the context of other biotechnical powers now gathering for manipulating the human body and mind.

Second, the council worked to develop fair and accurate terminology, a point that has turned out to be crucial, beginning with the idea of human cloning, itself. And if I could recommend anything—one single thing in the report, it is the chapter on terminology, which is unanimously approved by all members of the council whether they support cloning for biomedical research or not. That is the third chapter——

Senator BROWNBACK. Very good.

Dr. KASS.—and I think it would be very help to your deliberations.

Whatever the purpose for which human cloning is undertaken, the act that produces the genetic replica is the very first step in the process, the creation of an embryonic clone. Accordingly, the council has insisted that we what we mean by "human cloning" is the production of cloned human embryos, the earliest stage of developing human life.

This act of cloning may be undertaken with the intention of either transferring these embryos to a uterus in order to initiate a pregnancy, or taking them apart in order to obtain stem cells for

research. But whatever the purpose, it is the same act, and the results—and it results in the same initial product, a cloned human embryo.

In popular discussion, the first use has been called "reproductive cloning," the second, "therapeutic cloning," "research cloning," "nuclear transfer for stem cells." The council has rejected these terms and has—instead chose to call these uses, respectively, "cloning to produce children," or "cloning for biomedical research." The terms are accurate. They allow us to debate the moral questions without deciding them terminologically and without Orwellian speech.

The third point has to do with the ethics of cloning to produce children. The council unanimously held that cloning to produce children should be opposed both morally and legally. Not only is the technique demonstrably unsafe, but it can never be safely and ethically attempted. We oppose this practice, not only because it is unsafe, but because it would imperil the freedom and dignity of the cloned child, the cloning parents, and the entire society.

And in its report, the council also argues that by enabling parents for the first time to predetermine the entire genetic makeup of their children, we would be taking a major step toward turning procreation into manufacture.

Cloning to produce children would also confound family relations and personal identity, create new stresses between parents and offspring, and might open the door to a new eugenics where parents or society could replicate the genomes of individuals whom they deemed to be superior.

Fourth, the ethics of cloning for biomedical research. Here, the council was not of one mind, for the issue is complicated. On the one hand, we all acknowledge that the research offers the prospect, though entirely speculative at this moment, of gaining some valuable knowledge and treatments for many diseases. On the other hand, as the previous witnesses have already testified, this practice would require the exploitation and destruction of nascent human life created solely for the purpose of research and, by creating cloned embryos, would make the cloning of children that much more likely.

Individual council members weighed these moral concerns differently, yet all members of the council agreed that each side in this debate has something vital to defend, not only for itself, but for us all. All of us understand that we cannot afford to be casual about human suffering, to be cavalier regarding how we treat nascent human life, or to be indifferent about how we decide among the alternatives.

Finally, our recommendations. The majority of the council, myself included, recommended that no human cloning of any kind be permitted at this time. We proposed that Congress enact a ban on all attempts, both publicly and privately funded, at cloning to produce children and a 4-year Federal moratorium on human cloning for biomedical research, beginning with the act of the production of cloned human embryos.

We argued for this moratorium on a number of grounds. It would give us more time to debate whether we should cross this crucial moral boundary, that of creating cloned human life solely as a resource for research. It would allow time for other areas of stem cell

research, both adult and embryonic, to proceed and to find out whether they will live up to their promise. It would allow time for those who believe cloning for biomedical research can never be ethically pursued to make their case, and for those who disagree to design a responsible system of regulation and public oversight, which they have no incentive to design in the absence of some kind of temporary ban. Perhaps most important, the moratorium on all cloning offers us the only effective way to prevent cloning to produce children while this deliberation continues and while no regulatory system is in place.

Also, a national moratorium on cloning for research would allow the debate on the question of research on cloned embryos to be taken up in the larger context where it belongs, namely in the context of embryo research generally, and in the context of future possibilities of genetic engineering of human life.

Pending such debate, the majority of the council held that no law should now be enacted that approves or authorizes any cloning. A minority of the council recommended that we do proceed with such potentially valuable research, but only if and when significant regulations are in place, including Federal licensing of all cloning research, oversight that would keep track of the uses and fates of all cloned embryos produced, and strict limits on how long cloned embryos may be allowed to develop outside the body.

To this point, Mr. Chairman, I have merely summarized the report of the council, emphasizing what I take to be its major achievements and conclusions.

I would ask for a few minutes, if I might, to elaborate briefly the ethical objections to human cloning to produce children, because most people—many people think that the major objection is simply a matter of safety and, beyond that, it rests on irrational repugnance.

Senator BROWNBACK. Please take the time you need.

Dr. KASS. Thank you, sir.

In order of increasing seriousness, I offer four objections to human cloning to produce children. One, it involves unethical experimentation on the unborn. Two, it threatens identity and individuality. Three, it turns procreation into manufacture. And four, it means despotism over children and perversion of parenthood.

And I won't rehearse all these arguments. These are arguments made in the report, though I make them here in my own name. Let me just touch on the third and the fourth.

Human cloning would represent a giant step toward turning begetting into making, procreation into manufacture, a process that was already begun with in vitro fertilization and genetic testing of embryos. With cloning, not only is the process in hand, but the total genetic blueprint of the cloned individual is selected and determined by the human artisans. We are here making a—taking a major step into making man, himself, simply another one of the manmade things.

How does begetting differ from making? In natural procreation, human beings come together complementarily, male and female, to give existence to another being who is formed exactly as we were by what we are. But in clonal reproduction, and in the more advanced forms of manufacture to which it will lead, we give exist-

ence to a being, not by what we are, but by what we intend and design. As with any product of our making, no matter how excellent, the artificer stands above it, not as an equal, but as a superior, transcending it by his will and creative powers. In human cloning, scientists and prospective parents adopt a technocratic attitude toward human children. Human children become their artifacts, and such an arrangement would be profoundly dehumanizing, no matter how good the product.

Next and most important, the practice of cloning by nuclear transfer would enshrine and aggravate a profound and mischief-making misunderstanding of the meaning of having children and of the parent-child relation. When a couple normally chooses to procreate, the partners are saying yes to the emergence of a new life in its novelty, are saying yes not only to having a child, but also to having whatever child this child turns out to be. The genetic distinctiveness and independence of the child is a natural foreshadowing of the deep truth that this child has his own and never-before-enacted life to live. Though sprung from a past, children take an uncharted course into the future.

In contrast, overbearing parents take a step that contradicts this entire meaning of the open and forward-looking nature of procreation and parent-child relations. The child is given a genotype that has already lived, with the full expectation that this blueprint of a past life ought to be controlling of the life that is to come. A wanted child now means a child who exists precisely to fulfill parental wants. Cloning is thus inherently despotic, for it seeks to make one's children after one's own image, and their future according to one's will.

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 become objects of manipulation and products of will. The same concerns, I would submit, even more than the concerns about embryo destruction, should lead us also to oppose cloning for biomedical research.

And I would like to wind up with just two more minutes, if I might.

Senator BROWNBACK. Please.

Dr. KASS. All human cloning must be seen in the context of our growing powers over human reproduction augmented by new knowledge of the human genome. Science already permits us to screen human embryos in vitro for thousands of human genes, not only to find markers for dread diseases, but also soon genes responsible for other human traits, not just sex, height, or skin color, but even intelligence, temperament, or sexual orientation. Genetic selection of embryos is today a growing industry, and some experts hail assisted reproduction as the route, not to the treatment of infertility, but to finding genetically sound babies.

While directed genetic change of human embryos may be a long way off, it has already been accomplished in primates in the laboratory, and it would be naive to think that cloning children will be confined to infertile couples, or that cloning research would be confined to the study to disease.

Once we view this in this larger context, the production of cloned embryos for any purposes—for any purpose—marks a significant leap in transforming procreation into a form of manufacture. The embryo created by cloning would be the first human embryo to have its genetic identity selected in advance, the first embryo whose makeup is not the unpredictable result of uniting egg and sperm. It is precisely this genetic control that makes cloned embryos appealing and useful.

We should not be deceived. 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. Once cloned embryos exist in laboratories, the eugenic revolution will have begun. And of course, it will be virtually impossible to prevent them from being used to produce cloned babies.

The failure of the last Congress to enact a ban on human cloning, notwithstanding the widespread agreement across the country that it should be prohibited, casts grave doubt on our society's ability to govern the unethical uses of biotechnology even when it threatens things we hold dear. If Congress fails to act this time around, human cloning is likely to happen here, and we—"we"—will have acquiesced in its arrival.

It is my profound hope, Mr. Chairman, that Congress will rise to the occasion and strike a blow in the defense of human dignity.

[The prepared statement of Dr. Kass follows:]

PREPARED STATEMENT OF DR. LEON R. KASS, CHAIRMAN, THE PRESIDENT'S COUNCIL ON BIOETHICS

Mr. Chairman and Members of the Committee. My name is Leon R. Kass, and I appear before you as Chairman of the President's Council on Bioethics. On behalf of the Council, I wish to thank you for this opportunity to present the Council's findings and recommendations on the vexing subject of human cloning. I am also 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. In my own scholarship, I have been thinking and writing about the ethics of human cloning for thirty-five years. Thus, speaking personally, I would like to thank you, Senator Brownback, for your vision in recognizing the momentous choice now before us and for your courage and leadership in seeking effective means to protect us from a dangerous assault on human dignity.

For the first six months of last year, the President's Council on Bioethics met to consider the moral, biomedical, and human significance of human cloning, in order to advise President Bush on the subject. The Council's report, *Human Cloning and Human Dignity: An Ethical Inquiry*,[1] was issued in July, 2002; I am submitting the Executive Summary of the report as part of my written testimony.

I want to summarize the contents of the report in five points. First, the Council sought to examine the subject of human cloning in full by considering the human goods that cloning might serve or endanger—not just whether the technique is feasible or safe. We sought also to assess the impact of growing biotechnical powers over human life and their effect on human procreation, on the goals and limits of biomedical science, and on the meaning of the activity of healing. It is of prime importance to put cloning in its proper place, both humanly speaking and also in the context of other biotechnical powers now gathering for manipulating the human body and mind.

Second, the Council worked to develop fair and accurate terminology. Human cloning is a subject that has been bedeviled by confusing speech and manipulative speech. Our goal was to clarify the terminology that confounds this discussion, beginning with the idea of human cloning itself. Whatever the purpose for which human cloning is undertaken, the act that produces the genetic replica is the very

[1] U. S. Government Printing Office, 299 pp., 2002. A commercial paperback edition, *Human Cloning and Human Dignity: The Report of the President's Council on Bioethics*, 350 pp., was published in 2002 by Public Affairs.

first step in the process, the creation of an embryonic clone. Accordingly, the Council has insisted that what we mean by "human cloning" is the production of cloned human embryos, the earliest stage of developing human life. This act of cloning may be undertaken with the intention of either transferring these embryos to a uterus in order to initiate a pregnancy or taking them apart in order to obtain stem cells for research.

In popular discussion, the first use has been called "reproductive cloning" or just "cloning." The second has come to be called "therapeutic cloning," "research cloning," or "nuclear transfer for stem cell research." The Council, instead, chose to call these uses respectively "cloning-to-produce-children" or "cloning-for-biomedical-research." These terms are accurate. And they allow us to debate the moral questions without euphemistic distortion or Orwellian speech. Whether one favors or opposes cloning to produce children; whether one favors or opposes cloning for biomedical research, the Council insists that we must acknowledge that both uses of cloning begin with the same act, the production of cloned human embryos. [2]

The third point concerns the ethics of cloning-to-produce-children. Regarding cloning-to-produce-children, the Council is in agreement with majority opinion both in America and the Congress. The Council was unanimous, in fact, that cloning-to-produce-children should be opposed, both morally and legally. Not only is the technique demonstrably unsafe, but it can never be safely and ethically attempted. And the Council opposes this practice not only because it's unsafe, but because it would imperil the freedom and dignity of the cloned child, the cloning parents, and the entire society. In its report, the Council also argues that by enabling parents for the first time to predetermine the entire genetic makeup of their children, we would be taking a major step toward turning procreation into manufacture. Cloning-to-produce-children would also confound family relations and personal identity, create new stresses between parents and offspring, and might open the door to a new eugenics where parents or society could replicate the genomes of individuals whom they deem to be superior.

The fourth point concerns the ethics of cloning-for-biomedical-research. Here the Council, like the nation, was divided. On the one hand, we acknowledge that the research offers the prospect, though speculative at the moment, of gaining valuable knowledge and treatments for many diseases. On the other hand, this practice would require the exploitation and destruction of nascent human life created solely for the purpose of research.

Individual Council members weighed these moral concerns differently. Yet all members of the Council—and I am delighted about this—agreed that each side in this debate has something vital to defend, not only for itself but for all of us. Each side understood that we cannot afford to be casual about human suffering, to be cavalier regarding how we treat nascent human life, or to be indifferent about how we decide among the alternatives. Each side recognized that we must face up to the moral burden of either approving or disapproving this research: namely, on the one hand, that some who might be healed more rapidly might not be; and on the other hand, that we will become a society that creates and uses some lives in the service of others.

Finally, the Council offered two policy recommendations, a majority recommendation and a minority recommendation, each of them distinct from the most prominent legislative proposals considered in the last Congress. Both recommendations called for a permanent ban on cloning-to-produce-children, thus giving public force to the nation's strong ethical verdict against this practice. Where the Council differed was on how to approach cloning-for-biomedical-research.

A minority of the Council recommended that we proceed with such potentially valuable research, but only once significant regulations are in place, including federal licensing of all cloning research, oversight that (among other things) would keep track of the uses and fates of all cloned embryos produced, and strict limits on how long cloned embryos may be allowed to develop outside the body.

A majority of the Council, myself included, recommended that no human cloning of any kind be permitted at this time. We proposed that Congress enact a ban on all attempts—both publicly and privately funded—at cloning-to-produce-children,

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[2] Despite efforts to obscure this fact, this is true for what scientists have preferred to call "nuclear transfer to produce stem cells." The act of nuclear transfer does not directly produce stem cells. It produces, as a primary product, a cloned human embryo, which, once grown to the blastocyst stage (about 5–6 days), may then be dissected for its stem cells. It is not true, as Stanford University originally claimed when it recently announced its intention to do "nuclear transfer to produce stem cells" (= "cloning for biomedical research"), that the President's Council endorses this terminology or, moreover, approves the use of human cloning for this purpose.

and a four-year federal moratorium on human-cloning-for-biomedical-research, beginning with the act of the production of cloned human embryos.

We argued for this moratorium on a number of grounds. It would give us more time to debate whether we should cross this crucial moral boundary—that of creating human life solely as a resource for research. A moratorium would allow time for other areas of stem cell research, both adult and embryonic, to proceed. It would allow time for those who believe cloning-for-biomedical-research can never be ethically pursued to make their case, and for those who disagree to design a responsible system of regulation and public oversight.[3] And, perhaps most important, a moratorium on all cloning offers the only effective way to prevent cloning-to-produce-children while the deliberation continues and while no regulatory system is in place.

A national moratorium on cloning-for-biomedical-research would also allow the debate on the question of research on cloned embryos to be taken up in the larger context, where it belongs, in the context of embryo research generally, and in the context of the future possibilities of genetic engineering of human life. Pending such debate, the majority of the Council held that no law should now be enacted that approves or authorizes any human cloning.

To this point, I have summarized the report of the Council, emphasizing what I take to be its major achievements and conclusions. In what follows, I wish to elaborate the ethical objections to human cloning-to-produce-children. I do so because some people think that, beyond the issue of safety, the popular opposition to cloning children rests wholly on irrational feelings such as repugnance, while others, ignoring what it might mean to be a cloned child, focus exclusively on the desires and putative rights of the adults who would wish to practice cloning. Though all the points that follow are made in the Council report, I will be speaking here in my own name and formulating the arguments in my own manner.

In order of increasing seriousness, I offer four objections to human cloning-to-produce-children: (1) it involves unethical experimentation; (2) it threatens identity and individuality; (3) it turns procreation into manufacture; and (4) it means despotism over children and perversion of parenthood.

First, any attempt to clone a human being would constitute an unethical experiment upon the resulting child-to-be. As the animal experiments indicate, there are grave risks of mishaps and deformities, even to those clones that are born alive. Conducting the experiments in humans in efforts to make cloning safer would violate the ethical norms for experimenting with human subjects. Shall we just discard the defective children? Moreover, because of what cloning means, one cannot presume a future cloned child's consent to be a clone, even a healthy one. Thus, we cannot ethically even get to know whether or not human cloning is feasible.

Second, cloning creates serious issues of identity and individuality. The clone may experience concerns about his distinctive identity not only because he will be in genotype and appearance identical to another human being, but, in this case, because he may also be twin to the person who is his "father" or "mother"—if one can still call them that. What would be the psychic burdens of being the "child" or "parent" of your twin? What will happen when the adolescent clone of Mommy becomes the spitting image of the woman Daddy once fell in love with? In case of divorce, will Mommy still love the clone of Daddy, even though she can no longer stand the sight of Daddy himself? In addition, unlike "normal" identical twins, a cloned individual will be saddled with a genotype that has already lived. He will not be fully a surprise to the world: people are likely always to compare his performances in life with that of his alter ego. True, his nurture and circumstance will be different; genotype is not exactly destiny. But one must also expect parental efforts to shape this new life after the original—or at least to view the child with the original version always firmly in mind. For why else did they clone from the star basketball player, mathematician, and beauty queen—or even dear old Dad—in the first place?

Since the birth of Dolly, there has been a fair amount of doublespeak on the matter of genetic identity. Experts have rushed in to reassure the public that the clone would in no way be the same person or have any confusions about his identity: they are pleased to point out, as previously noted, that the clone of Mel Gibson would not be Mel Gibson. Fair enough. But genotype obviously matters plenty. That, after all, is the only reason to clone, whether human beings or sheep. The odds that clones of Shaquille O'Neal would play in the NBA are, I submit, infinitely greater than they are for clones of Danny DeVito.

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[3] The Council majority also believed, that, in the absence of a ban or temporary moratorium, scientists and industrial researchers who want no restriction or regulation of their activities, would have no incentive whatsoever to design a regulatory scheme of the sort favored by the Council's minority.

A cloned child is deliberately deprived of a normal bio-social identity. He or she has (at most) but one biological "parent"; the usually sad situation of the "single-parent child" is here purposely planned, and with a vengeance. In the case of self-cloning, the "offspring" is, in addition, one's twin: The dreaded result of incest—to be parent to one's sibling—is here brought about deliberately, albeit without any act of coitus. Moreover, all other relationships will be confounded: what will father, grandfather, aunt, cousin, or sister mean, and who will bear what ties and burdens? To this it is no answer to say that our society, with its high incidence of broken families and non-marital childbearing, already confuses kinship and responsibility for children, unless one also wants to argue that this, for children, is a preferable state of affairs.

Third, human cloning would represent a giant step toward turning begetting into making, procreation into manufacture (literally, something "handmade"), a process already begun with in vitro fertilization and genetic testing of embryos. With cloning, not only is the process in hand, but the total genetic blueprint of the cloned individual is selected and determined by the human artisans. To be sure, subsequent development is still according to natural processes; and the resulting children will be recognizably human. But we here would be taking a major step into making man himself simply another one of the man-made things.

How does begetting differ from making? In natural procreation, human beings come together, complementarily male and female, to give existence to another being who is formed, exactly as we were, by what we are—living, hence perishable, hence aspiringly erotic, hence procreative human beings. But in clonal reproduction, and in the more advanced forms of manufacture to which it will lead, we give existence to a being not by what we are but by what we intend and design. As with any product of our making, no matter how excellent, the artificer stands above it, not as an equal but as a superior, transcending it by his will and creative prowess. In human cloning, scientists and prospective "parents" adopt a technocratic attitude toward human children: human children become their artifacts. Such an arrangement is profoundly dehumanizing, no matter how good the product.

Mass-scale cloning of the same individual makes the point vividly; but the violation of human equality, freedom, and dignity is present even in a single planned clone. And procreation dehumanized into manufacture is further degraded by commodification, a virtually inescapable result of allowing baby-making to proceed under the banner of commerce.

Finally, and perhaps most important, the practice of human cloning by nuclear transfer—like other anticipated forms of genetically engineering the next generation—would enshrine and aggravate a profound and mischief-making misunderstanding of the meaning of having children and of the parent-child relationship. When a couple normally chooses to procreate, the partners are saying yes to the emergence of new life in its novelty, are saying yes not only to having a child but also to having whatever child this child turns out to be. In accepting our finitude and opening ourselves to our replacement, we tacitly confess the limits of our control. Embracing the future by procreating means precisely that we are relinquishing our grip, in the very activity of taking up our own share in what we hope will be the immortality of human life and the human species. This means that our children are not our children: they are not our property, they are not our possessions. Neither are they supposed to live our lives for us, nor anyone else's life but their own. To be sure, we seek to guide them on their way, imparting to them not just life, but nurture, love, and a way of life. To be sure, they bear our hopes that they will surpass us in goodness and happiness, enabling us in small measure to transcend our own limitations. But their genetic distinctiveness and independence are the natural foreshadowing of the deep truth that they have their own and never-before-enacted life to live. Though sprung from a past, they take an uncharted course into the future.

Much mischief is already done by parents who try to live vicariously through their children. Children are sometimes compelled to fulfill the broken dreams of unhappy parents. But whereas most parents normally have hopes for their children, cloning parents will have *expectations*. In cloning, such overbearing parents will have taken at the start a decisive step that contradicts the entire meaning of the open and forward-looking nature of parent-child relations. The child is given a genotype that has already lived, with full expectation that this blueprint of a past life ought to be controlling of the life that is to come. A wanted child now means a child who exists precisely to fulfill parental wants. Cloning is thus inherently despotic, for it seeks to make one's children after one's own image (or an image of one's choosing) and their future according to one's will.

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 become objects of manipulation and products of will. We rightly worry about this threat when we oppose cloning-to-produce-children, yet the same concerns (even more than concerns about embryo destruction) should lead us also to oppose cloning-for-biomedical-research.

All human cloning must be seen in the context of our growing powers over human reproduction augmented by new knowledge of the human genome. Science already permits us to screen human embryos in vitro for thousands of human genes: not only to find markers for dread diseases, but also soon genes responsible for other human traits; not just sex, height, or skin color but even intelligence, temperament, or sexual orientation. Genetic selection of embryos is today a growing industry. Some experts hail assisted reproduction as the route to genetically sound babies. While directed genetic change of human embryos (even for therapeutic purposes) may be a long way off, it has been accomplished in primates in the laboratory. It would be naive to believe that cloning children will be confined to infertile couples or that cloning research will be confined to studies of disease.

Viewed in this larger context, the production of cloned embryos for *any* purpose marks a significant leap in transforming procreation into a form of manufacture. The embryo created by cloning would be the first human embryo to have its genetic identity selected in advance, the first embryo whose makeup is not the unpredictable result of uniting sperm and egg. It is precisely this genetic control that makes cloned embryos appealing and useful. But we should not be deceived: 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. Once cloned human embryos exist in laboratories, the eugenic revolution will have begun. And, of course, it will be virtually impossible to prevent them from being used to produce cloned babies.

Opposition to human cloning-to-produce-children is practically unanimous in America: 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.

Excerpted from: The President's Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry* (Washington, D.C.: Government Printing Office, 2002): xxi–xxxix.

Executive Summary

For the past five years, the prospect of human cloning has been the subject of considerable public attention and sharp moral debate, both in the United States and around the world. Since the announcement in February 1997 of the first successful cloning of a mammal (Dolly the sheep), several other species of mammals have been cloned. Although a cloned human child has yet to be born, and although the animal experiments have had low rates of success, the production of functioning mammalian cloned offspring suggests that the eventual cloning of humans must be considered a serious possibility.

In November 2001, American researchers claimed to have produced the first cloned human embryos, though they reportedly reached only a six-cell stage before they stopped dividing and died. In addition, several fertility specialists, both here and abroad, have announced their intention to clone human beings. The United States Congress has twice taken up the matter, in 1998 and again in 2001–2002, with the House of Representatives in July 2001 passing a strict ban on all human cloning, including the production of cloned human embryos. As of this writing, several cloning-related bills are under consideration in the Senate. Many other nations have banned human cloning, and the United Nations is considering an international convention on the subject. Finally, two major national reports have been issued on human reproductive cloning, one by the National Bioethics Advisory Commission (NBAC) in 1997, the other by the National Academy of Sciences (NAS) in January 2002. Both the NBAC and the NAS reports called for further consideration of the ethical and social questions raised by cloning.

The debate over human cloning became further complicated in 1998 when researchers were able, for the first time, to isolate human embryonic stem cells. Many scientists believe that these versatile cells, capable of becoming any type of cell in

the body, hold great promise for understanding and treating many chronic diseases and conditions. Some scientists also believe that stem cells derived from *cloned* human embryos, produced explicitly for such research, might prove uniquely useful for studying many genetic diseases and devising novel therapies. Public reaction to the prospect of cloning-for-biomedical-research has been mixed: some Americans support it for its medical promise; others oppose it because it requires the exploitation and destruction of nascent human life, which would be created solely for research purposes.

Human Cloning: What Is at Stake?

The intense attention given to human cloning in both its potential uses, for reproduction as well as for research, strongly suggests that people do not regard it as just another new technology. Instead, we see it as something quite different, something that touches fundamental aspects of our humanity. The notion of cloning raises issues about identity and individuality, the meaning of having children, the difference between procreation and manufacture, and the relationship between the generations. It also raises new questions about the manipulation of some human beings for the benefit of others, the freedom and value of biomedical inquiry, our obligation to heal the sick (and its limits), and the respect and protection owed to nascent human life.

Finally, the legislative debates over human cloning raise large questions about the relationship between science and society, especially about whether society can or should exercise ethical and prudential control over biomedical technology and the conduct of biomedical research. Rarely has such a seemingly small innovation raised such big questions.

The Inquiry: Our Point of Departure

As Members of the President's Council on Bioethics, we have taken up the larger ethical and social inquiry called for in the NBAC and NAS reports, with the aim of advancing public understanding and informing public policy on the matter. We have attempted to consider human cloning (both for producing children and for biomedical research) within its larger human, technological, and ethical contexts, rather than to view it as an isolated technical development. We focus first on the broad human goods that it may serve as well as threaten, rather than on the immediate impact of the technique itself. By our broad approach, our starting on the plane of human goods, and our open spirit of inquiry, we hope to contribute to a richer and deeper understanding of what human cloning means, how we should think about it, and what we should do about it.

On some matters discussed in this report, Members of the Council are not of one mind. Rather than bury these differences in search of a spurious consensus, we have sought to present all views fully and fairly, while recording our agreements as well as our genuine diversity of perspectives, including our differences on the final recommendations to be made. By this means, we hope to help policymakers and the general public appreciate more thoroughly the difficulty of the issues and the competing goods that are at stake.

Fair and Accurate Terminology

There is today much confusion about the terms used to discuss human cloning, regarding both the activity involved and the entities that result. The Council stresses the importance of striving not only for accuracy but also for fairness, especially because the choice of terms can decisively affect the way questions are posed, and hence how answers are given. We have sought terminology that most accurately conveys the descriptive reality of the matter, in order that the moral arguments can then proceed on the merits. We have resisted the temptation to solve the moral questions by artful redefinition or by denying to some morally crucial element a name that makes clear that there is a moral question to be faced.

On the basis of (1) a careful analysis of the act of cloning, and its relation to the means by which it is accomplished and the purposes it may serve, and (2) an extensive critical examination of alternative terminologies, the Council has adopted the following definitions for the most important terms in the matter of human cloning:

- *Cloning:* A form of reproduction in which offspring result not from the chance union of egg and sperm (sexual reproduction) but from the deliberate replication of the genetic makeup of another single individual (asexual reproduction).
- *Human cloning:* 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. It would be accomplished by introducing the nuclear material of a human somatic cell (donor) into an oocyte (egg) whose own nucleus has been removed or inactivated, yielding a product that has a

human genetic constitution virtually identical to the donor of the somatic cell. (This procedure is known as "somatic cell nuclear transfer," or SCNT). We have declined to use the terms "reproductive cloning" and "therapeutic cloning." We have chosen instead to use the following designations:

- *Cloning-to-produce-children:* Production of a cloned human embryo, formed for the (proximate) purpose of initiating a pregnancy, with the (ultimate) goal of producing a child who will be genetically virtually identical to a currently existing or previously existing individual.
- *Cloning-for-biomedical-research:* Production of a cloned human embryo, formed for the (proximate) purpose of using it in research or for extracting its stem cells, with the (ultimate) goals of gaining scientific knowledge of normal and abnormal development and of developing cures for human diseases.
- *Cloned human embryo:* (a) A human embryo resulting from the nuclear transfer process (as contrasted with a human embryo arising from the union of egg and sperm). (b) The immediate (and developing) product of the initial act of cloning, accomplished by successful SCNT, whether used subsequently in attempts to produce children or in biomedical research.

Scientific Background

Cloning research and stem cell research are being actively investigated and the state of the science is changing rapidly; significant new developments could change some of the interpretations in our report. At present, however, a few general points may be highlighted.

- *The technique of cloning*. The following steps have been used to produce live offspring in the mammalian species that have been successfully cloned. Obtain an egg cell from a female of a mammalian species. Remove its nuclear DNA, to produce an enucleated egg. Insert the nucleus of a donor adult cell into the enucleated egg, to produce a reconstructed egg. Activate the reconstructed egg with chemicals or electric current, to stimulate it to commence cell division. Sustain development of the cloned embryo to a suitable stage in vitro, and then transfer it to the uterus of a female host that has been suitably prepared to receive it. Bring to live birth a cloned animal that is genetically virtually identical (except for the mitochondrial DNA) to the animal that donated the adult cell nucleus.
- *Animal cloning: low success rates, high morbidity*. At least seven species of mammals (none of them primates) have been successfully cloned to produce live births. Yet the production of live cloned offspring is rare and the failure rate is high: more than 90 percent of attempts to initiate a clonal pregnancy do not result in successful live birth. Moreover, the live-born cloned animals suffer high rates of deformity and disability, both at birth and later on. Some biologists attribute these failures to errors or incompleteness of epigenetic reprogramming of the somatic cell nucleus.
- *Attempts at human cloning*. At this writing, it is uncertain whether anyone has attempted cloning-to-produce-children (although at least one physician is now claiming to have initiated several active clonal pregnancies, and others are reportedly working on it). We do not know whether a transferred cloned human embryo can progress all the way to live birth.
- *Stem cell research*. Human embryonic stem cells have been isolated from embryos (produced by IVF) at the blastocyst stage or from the germinal tissue of fetuses. Human adult stem (or multipotent) cells have been isolated from a variety of tissues. Such cell populations can be differentiated in vitro into a number of different cell types, and are currently being studied intensely for their possible uses in regenerative medicine. Most scientists working in the field believe that stem cells (both embryonic and adult) hold great promise as routes toward cures and treatments for many human diseases and disabilities. All stem cell research is at a very early stage, and it is too soon to tell which approaches will prove most useful, and for which diseases.
- *The transplant rejection problem*. To be effective as long-term treatments, cell transplantation therapies will have to overcome the immune rejection problem. Cells and tissues derived from *adult* stem cells and returned to the patient from whom they were taken would not be subject (at least in principle) to immune rejection.
- *Stem cells from cloned embryos*. Human embryonic stem cell preparations could potentially be produced by using somatic cell nuclear transfer to produce a cloned human embryo, and then taking it apart at the blastocyst stage and isolating stem cells. These stem cells would be genetically virtually identical to

cells from the nucleus donor, and thus could potentially be of great value in biomedical research. Very little work of this sort has been done to date in animals, and there are as yet no published reports of cloned *human* embryos grown to the blastocyst stage. Although the promise of such research is at this time unknown, most researchers believe it will yield very useful and important knowledge, pointing toward new therapies and offering one of several possible routes to circumvent the immune rejection problem. Although some experimental results in animals are indeed encouraging, they also demonstrate some tendency even of cloned stem cells to stimulate an immune response.

- *The fate of embryos used in research*. All extractions of stem cells from human embryos, cloned or not, involve the destruction of these embryos.

The Ethics of Cloning-to-Produce-Children

Two separate national-level reports on human cloning (NBAC, 1997; NAS, 2002) concluded that attempts to clone a human being would be unethical at this time due to safety concerns and the likelihood of harm to those involved. The Council concurs in this conclusion. But we have extended the work of these distinguished bodies by undertaking a broad ethical examination of the merits of, and difficulties with, cloning-to-produce-children.

Cloning-to-produce-children might serve several purposes. It might allow infertile couples or others to have genetically-related children; permit couples at risk of conceiving a child with a genetic disease to avoid having an afflicted child; allow the bearing of a child who could become an ideal transplant donor for a particular patient in need; enable a parent to keep a living connection with a dead or dying child or spouse; or enable individuals or society to try to "replicate" individuals of great talent or beauty. These purposes have been defended by appeals to the goods of freedom, existence (as opposed to nonexistence), and well-being—all vitally important ideals.

A major weakness in these arguments supporting cloning-to-produce-children is that they overemphasize the freedom, desires, and control of parents, and pay insufficient attention to the well-being of the cloned child-to-be. The Council holds that, once the child-to-be is carefully considered, these arguments are not sufficient to overcome the powerful case against engaging in cloning-to-produce-children.

First, cloning-to-produce-children would violate the principles of the ethics of human research. Given the high rates of morbidity and mortality in the cloning of other mammals, we believe that cloning-to-produce-children would be extremely unsafe, and that attempts to produce a cloned child would be highly unethical. Indeed, our moral analysis of this matter leads us to conclude that this is not, as is sometimes implied, a merely temporary objection, easily removed by the improvement of technique. We offer reasons for believing that the safety risks might be enduring, and offer arguments in support of a strong conclusion: that conducting experiments in an effort to make cloning-to-produce-children less dangerous would itself be an unacceptable violation of the norms of research ethics. *There seems to be no ethical way to try to discover whether cloning-to-produce-children can become safe, now or in the future*.

If carefully considered, the concerns about safety also begin to reveal the ethical principles that should guide a broader assessment of cloning-to-produce-children: the principles of freedom, equality, and human dignity. To appreciate the broader human significance of cloning-to-produce-children, one needs first to reflect on the meaning of having children; the meaning of asexual, as opposed to sexual, reproduction; the importance of origins and genetic endowment for identity and sense of self; the meaning of exercising greater human control over the processes and "products" of human reproduction; and the difference between begetting and making. Reflecting on these topics, the Council has identified five categories of concern regarding cloning-to-produce-children. (Different Council Members give varying moral weight to these different concerns.)

- *Problems of identity and individuality*. Cloned children may experience serious problems of identity both because each will be genetically virtually identical to a human being who has already lived and because the expectations for their lives may be shadowed by constant comparisons to the life of the "original."
- *Concerns regarding manufacture*. Cloned children would be the first human beings whose entire genetic makeup is selected in advance. They might come to be considered more like products of a designed manufacturing process than "gifts" whom their parents are prepared to accept as they are. Such an attitude toward children could also contribute to increased commercialization and industrialization of human procreation.

- *The prospect of a new eugenics*. Cloning, if successful, might serve the ends of privately pursued eugenic enhancement, either by avoiding the genetic defects that may arise when human reproduction is left to chance, or by preserving and perpetuating outstanding genetic traits, including the possibility, someday in the future, of using cloning to perpetuate genetically engineered enhancements.
- *Troubled family relations*. By confounding and transgressing the natural boundaries between generations, cloning could strain the social ties between them. Fathers could become "twin brothers" to their "sons"; mothers could give birth to their genetic twins; and grandparents would also be the "genetic parents" of their grandchildren. Genetic relation to only one parent might produce special difficulties for family life.
- *Effects on society*. Cloning-to-produce-children would affect not only the direct participants but also the entire society that allows or supports this activity. Even if practiced on a small scale, it could affect the way society looks at children and set a precedent for future nontherapeutic interventions into the human genetic endowment or novel forms of control by one generation over the next. In the absence of wisdom regarding these matters, prudence dictates caution and restraint.

Conclusion: For some or all of these reasons, the Council is in full agreement that cloning-to-produce-children is not only unsafe but also morally unacceptable, and ought not to be attempted.

The Ethics of Cloning-for-Biomedical-Research

Ethical assessment of cloning-for-biomedical-research is far more vexing. On the one hand, such research could lead to important knowledge about human embryological development and gene action, both normal and abnormal, ultimately resulting in treatments and cures for many dreaded illnesses and disabilities. On the other hand, the research is morally controversial because it involves the deliberate production, use, and ultimate destruction of cloned human embryos, and because the cloned embryos produced for research are no different from those that could be implanted in attempts to produce cloned children. The difficulty is compounded by what are, for now, unanswerable questions as to whether the research will in fact yield the benefits hoped for, and whether other promising and morally nonproblematic approaches might yield comparable benefits. The Council, reflecting the differences of opinion in American society, is divided regarding the ethics of research involving (cloned) embryos. *Yet we agree that all parties to the debate have concerns vital to defend, vital not only to themselves but to all of us. No human being and no society can afford to be callous to the needs of suffering humanity, or cavalier about the treatment of nascent human life, or indifferent to the social effects of adopting one course of action rather than another.*

To make clear to all what is at stake in the decision, Council Members have presented, as strongly as possible, the competing ethical cases for and against cloning-for-biomedical-research in the form of first-person attempts at moral suasion. Each case has tried to address what is owed to suffering humanity, to the human embryo, and to the broader society. Within each case, supporters of the position in question speak only for themselves, and not for the Council as a whole.

A. The Moral Case for Cloning-for-Biomedical-Research

The moral case for cloning-for-biomedical-research rests on our obligation to try to relieve human suffering, an obligation that falls most powerfully on medical practitioners and biomedical researchers. We who support cloning-for-biomedical-research all agree that it may offer uniquely useful ways of investigating and possibly treating many chronic debilitating diseases and disabilities, providing aid and relief to millions. We also believe that the moral objections to this research are outweighed by the great good that may come from it. Up to this point, we who support this research all agree. But we differ among ourselves regarding the weight of the moral objections, owing to differences about the moral status of the cloned embryo. These differences of opinion are sufficient to warrant distinguishing two different moral positions within the moral case for cloning-for-biomedical-research:

Position Number One. Most Council Members who favor cloning-for-biomedical-research do so with serious moral concerns. Speaking only for ourselves, we acknowledge the following difficulties, but think that they can be addressed by setting proper boundaries.

- *Intermediate moral status*. While we take seriously concerns about the treatment of nascent human life, we believe there are sound moral reasons for not regarding the embryo in its earliest stages as the moral equivalent of a human person. We believe the embryo has a developing and intermediate moral worth

that commands our special respect, but that it is morally permissible to use early-stage cloned human embryos in important research under strict regulation.

- *Deliberate creation for use*. We believe that concerns over the problem of deliberate creation of cloned embryos for use in research have merit, but when properly understood should not preclude cloning-for-biomedical-research. These embryos would not be "created for destruction," but for use in the service of life and medicine. They would be destroyed in the service of a great good, and this should not be obscured.
- *Going too far*. We acknowledge the concern that some researchers might seek to develop cloned embryos beyond the blastocyst stage, and for those of us who believe that the cloned embryo has a developing and intermediate moral status, this is a very real worry. We approve, therefore, only of research on cloned embryos that is strictly limited to the first fourteen days of development—a point near when the primitive streak is formed and before organ differentiation occurs.
- *Other moral hazards*. We believe that concerns about the exploitation of women and about the risk that cloning-for-biomedical-research could lead to cloning-to-produce-children can be adequately addressed by appropriate rules and regulations. These concerns need not frighten us into abandoning an important avenue of research.

Position Number Two. A few Council Members who favor cloning-for-biomedical-research do not share all the ethical qualms expressed above. Speaking only for ourselves, we hold that this research, at least for the purposes presently contemplated, presents no special moral problems, and therefore should be endorsed with enthusiasm as a potential new means of gaining knowledge to serve humankind. Because we accord no special moral status to the early-stage cloned embryo and believe it should be treated essentially like all other human cells, we believe that the moral issues involved in this research are no different from those that accompany any biomedical research. What is required is the usual commitment to high standards for the quality of research, scientific integrity, and the need to obtain informed consent from donors of the eggs and somatic cells used in nuclear transfer.

B. The Moral Case against Cloning-for-Biomedical-Research

The moral case against cloning-for-biomedical-research acknowledges the possibility—though purely speculative at the moment—that medical benefits might come from this particular avenue of experimentation. But we believe it is morally wrong to exploit and destroy developing human life, even for good reasons, and that it is unwise to open the door to the many undesirable consequences that are likely to result from this research. We find it disquieting, even somewhat ignoble, to treat what are in fact seeds of the next generation as mere raw material for satisfying the needs of our own. Only for very serious reasons should progress toward increased knowledge and medical advances be slowed. But we believe that in this case such reasons are apparent.

- *Moral status of the cloned embryo*. We hold that the case for treating the early-stage embryo as simply the moral equivalent of all other human cells (Position Number Two, above) is simply mistaken: it denies the continuous history of human individuals from the embryonic to fetal to infant stages of existence; it misunderstands the meaning of potentiality; and it ignores the hazardous moral precedent that the routinized creation, use, and destruction of nascent human life would establish. We hold that the case for according the human embryo "intermediate and developing moral status" (Position Number One, above) is also unconvincing, for reasons both biological and moral. Attempts to ground the limited measure of respect owed to a maturing embryo in certain of its developmental features do not succeed, and the invoking of a "special respect" owed to nascent human life seems to have little or no operative meaning if cloned embryos may be created in bulk and used routinely with impunity. If from one perspective the view that the embryo seems to amount to little may invite a weakening of our respect, from another perspective its seeming insignificance should awaken in us a sense of shared humanity and a special obligation to protect it.
- *The exploitation of developing human life*. To engage in cloning-for-biomedical-research requires the irreversible crossing of a very significant moral boundary: the creation of human life expressly and exclusively for the purpose of its use in research, research that necessarily involves its deliberate destruction. If we permit this research to proceed, we will effectively be endorsing the complete

transformation of nascent human life into nothing more than a resource or a tool. Doing so would coarsen our moral sensibilities and make us a different society: one less humble toward that which we cannot fully understand, less willing to extend the boundaries of human respect ever outward, and more willing to transgress moral boundaries once it appears to be in our own interests to do so.

- *Moral harm to society*. Even those who are uncertain about the precise moral status of the human embryo have sound ethical-prudential reasons to oppose cloning-for-biomedical-research. Giving moral approval to such research risks significant moral harm to our society by (1) crossing the boundary from sexual to asexual reproduction, thus approving in principle the genetic manipulation and control of nascent human life; (2) opening the door to other moral hazards, such as cloning-to-produce-children or research on later-stage human embryos and fetuses; and (3) potentially putting the federal government in the novel and unsavory position of mandating the destruction of nascent human life. Because we are concerned not only with the fate of the cloned embryos but also with where this research will lead our society, we think prudence requires us not to engage in this research.
- *What we owe the suffering*. We are certainly not deaf to the voices of suffering patients; after all, each of us already shares or will share in the hardships of mortal life. We and our loved ones are all patients or potential patients. But we are not only patients, and easing suffering is not our only moral obligation. As much as we wish to alleviate suffering now and to leave our children a world where suffering can be more effectively relieved, we also want to leave them a world in which we and they want to live—a world that honors moral limits, that respects all life whether strong or weak, and that refuses to secure the good of some human beings by sacrificing the lives of others.

Public Policy Options

The Council recognizes the challenges and risks of moving from moral assessment to public policy. Reflections on the "social contract" between science and society highlight both the importance of scientific freedom and the need for boundaries. We note that other countries often treat human cloning in the context of a broad area of biomedical technology, at the intersection of reproductive technology, embryo research, and genetics, while the public policy debate in the United States has treated cloning largely on its own. We recognize the special difficulty in formulating sound public policy in this area, given that the two ethically distinct matters—cloning-to-produce-children and cloning-for-biomedical-research—will be mutually affected or implicated in any attempts to legislate about either. Nevertheless, our ethical and policy analysis leads us to the conclusion that some deliberate public policy at the federal level is needed in the area of human cloning.

We reviewed the following seven possible policy options and considered their relative strengths and weaknesses: (1) Professional self-regulation but no federal legislative action ("self-regulation"); (2) A ban on cloning-to-produce-children, with neither endorsement nor restriction of cloning-for-biomedical-research ("ban plus silence"); (3) A ban on cloning-to-produce-children, with regulation of the use of cloned embryos for biomedical research ("ban plus regulation"); (4) Governmental regulation, with no legislative prohibitions ("regulation of both"); (5) A ban on all human cloning, whether to produce children or for biomedical research ("ban on both"); (6) A ban on cloning-to-produce-children, with a moratorium or temporary ban on cloning-for-biomedical-research ("ban plus moratorium"); or (7) A moratorium or temporary ban on all human cloning, whether to produce children or for biomedical research ("moratorium on both").

The Council's Policy Recommendations

Having considered the benefits and drawbacks of each of these options, and taken into account our discussions and reflections throughout this report, the Council recommends two possible policy alternatives, each supported by a portion of the Members.

Majority Recommendation: Ten Members of the Council recommend *a ban on cloning-to-produce-children combined with a four-year moratorium on cloning-for-biomedical-research. We also call for a federal review of current and projected practices of human embryo research, pre-implantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to recommending and shaping ethically sound policies for the entire field*. Speaking only for ourselves, those of us who support this recommendation do so for some or all of the following reasons:

- By permanently banning cloning-to-produce-children, this policy gives force to the strong ethical verdict against cloning-to-produce-children, unanimous in this Council (and in Congress) and widely supported by the American people. And by enacting a four-year moratorium on the creation of cloned embryos, it establishes an additional safeguard not afforded by policies that would allow the production of cloned embryos to proceed without delay.
- It calls for and provides time for further democratic deliberation about cloning-for-biomedical research, a subject about which the nation is divided and where there remains great uncertainty. A national discourse on this subject has not yet taken place in full, and a moratorium, by making it impossible for either side to cling to the status-quo, would force both to make their full case before the public. By banning all cloning for a time, it allows us to seek moral consensus on whether or not we should cross a major moral boundary (creating nascent cloned human life solely for research) and prevents our crossing it without deliberate decision. It would afford time for scientific evidence, now sorely lacking, to be gathered—from animal models and other avenues of human research—that might give us a better sense of whether cloning-for-biomedical-research would work as promised, and whether other morally nonproblematic approaches might be available. It would promote a fuller and better-informed public debate. And it would show respect for the deep moral concerns of the large number of Americans who have serious ethical objections to this research.
- Some of us hold that cloning-for-biomedical-research can never be ethically pursued, and endorse a moratorium to enable us to continue to make our case in a democratic way. Others of us support the moratorium because it would provide the time and incentive required to develop a system of national regulation that might come into use if, at the end of the four-year period, the moratorium were not reinstated or made permanent. Such a system could not be developed overnight, and therefore even those who support the research but want it regulated should see that at the very least a pause is required. In the absence of a moratorium, few proponents of the research would have much incentive to institute an effective regulatory system. Moreover, the very process of proposing such regulations would clarify the moral and prudential judgments involved in deciding whether and how to proceed with this research.
- A moratorium on cloning-for-biomedical-research would enable us to consider this activity in the larger context of research and technology in the areas of developmental biology, embryo research, and genetics, and to pursue a more comprehensive federal regulatory system for setting and executing policy in the entire area.
- Finally, we believe that a moratorium, rather than a lasting ban, signals a high regard for the value of biomedical research and an enduring concern for patients and families whose suffering such research may help alleviate. It would reaffirm the principle that science can progress while upholding the community's moral norms, and would therefore reaffirm the community's moral support for science and biomedical technology.

The decision before us is of great importance. Creating cloned embryos for *any* purpose requires crossing a major moral boundary, with grave risks and likely harms, and once we cross it there will be no turning back. Our society should take the time to make a judgment that is well-informed and morally sound, respectful of strongly held views, and representative of the priorities and principles of the American people. We believe this ban-plus-moratorium proposal offers the best means of achieving these goals.

This position is supported by Council Members Rebecca S. Dresser, Francis Fukuyama, Robert P. George, Mary Ann Glendon, Alfonso Gómez-Lobo, William B. Hurlbut, Leon R. Kass, Charles Krauthammer, Paul McHugh, and Gilbert C. Meilaender.

Minority Recommendation: Seven Members of the Council recommend *a ban on cloning-to-produce-children, with regulation of the use of cloned embryos for biomedical research.* Speaking only for ourselves, those of us who support this recommendation do so for some or all of the following reasons:

- By permanently banning cloning-to-produce-children, this policy gives force to the strong ethical verdict against cloning-to-produce-children, unanimous in this Council (and in Congress) and widely supported by the American people. We believe that a ban on the transfer of cloned embryos to a woman's uterus would be a sufficient and effective legal safeguard against the practice.
- *It approves cloning-for-biomedical-research and permits it to proceed without substantial delay.* This is the most important advantage of this proposal. The

research shows great promise, and its actual value can only be determined by allowing it to go forward now. Regardless of how much time we allow it, no amount of experimentation with animal models can provide the needed understanding of *human* diseases. The special benefits from working with stem cells from *cloned* human embryos cannot be obtained using embryos obtained by IVF. We believe this research could provide relief to millions of Americans, and that the government should therefore support it, within sensible limits imposed by regulation.

- It would establish, *as a condition of proceeding*, the necessary regulatory protections to avoid abuses and misuses of cloned embryos. These regulations might touch on the secure handling of embryos, licensing and prior review of research projects, the protection of egg donors, and the provision of equal access to benefits.
- Some of us also believe that mechanisms to regulate cloning-for-biomedical-research should be part of a larger regulatory program governing all research involving human embryos, and that the federal government should initiate a review of present and projected practices of human embryo research, with the aim of establishing reasonable policies on the matter.

Permitting cloning-for-biomedical-research now, while governing it through a prudent and sensible regulatory regime, is the most appropriate way to allow important research to proceed while insuring that abuses are prevented. We believe that the legitimate concerns about human cloning expressed throughout this report are sufficiently addressed by this ban-plus-regulation proposal, and that the nation should affirm and support the responsible effort to find treatments and cures that might help many who are suffering.

This position is supported by Council Members Elizabeth H. Blackburn, Daniel W. Foster, Michael S. Gazzaniga, William F. May, Janet D. Rowley, Michael J. Sandel, and James Q. Wilson.

Senator BROWNBACK. Thank you very much, Dr. Kass. That was a very profound statement, and I appreciate your thoughtfulness over the past 30 years on this topic and your willingness to serve the country at this time as we go through this.

I want to get the definition accurate. And you have stated it in your testimony, but I want to cover it one more time so that we are clear on it.

The SCNT, somatic cell nuclear transfer, as frequently people refer to human cloning, by your definition—by the board—the President's Council on Bioethics—you deemed that to be human cloning. Is that correct?

Dr. KASS. Cloning for biomedical research. It is cloning, because the act that produces the clone—the only act that produces the genetic replica—is the very first act.

Senator BROWNBACK. Past that, you are just letting it grow.

Dr. KASS. Past that, you let it grow. You let it grow up to about 5 days, when it is a ball of about a hundred cells, and it is at that point that your two different intentions decide whether you are going to try to produce a child with it or whether you are going to use it for biomedical research.

Somatic cell nuclear transfer is the name of the technique. It does not really name the act. The name of the act is the production of a cloned human embryo. That is why you did it, because that is what you want.

Senator BROWNBACK. OK. But as far as you are concerned, as the President's Bioethics Council, the process of SCNT is human cloning. Now, it is either for reproductive or biomedical research, but it is the process of human cloning. Is that correct?

Dr. KASS. SCNT is the "how" human cloning is done, yes. It is——

Senator BROWNBACK. OK.

Dr. KASS.—it is human cloning, exactly.

Senator BROWNBACK. Because I think one of the things that has been the big struggle in this debate is the debate about the term. And you have put it—and you have defined that term here, and I think it is important that we have that out there, about what is human cloning and what is not human cloning.

Dr. KASS. I think if—you are holding the text of the Council's cloning report in front of you—and I can refer you and colleagues later—page 54 has the conclusion of the terminological discussion. "Human cloning (what it is)" is "the asexual production of a new human organism that is, at all stages of development—that is, beginning at the first one—genetically virtually identical to the existing one. "How it is done" is by somatic cell nuclear transfer. And "why it is done" will either be to produce children, or to—for biomedical research.

Senator BROWNBACK. OK. I think that is a good way of putting it. What it is—but SCNT is just simply how——

Dr. KASS. It is just the——

Senator BROWNBACK.—it is done.

Dr. KASS.—it is just the technique.

Senator BROWNBACK. The technique——

Dr. KASS. Right.

Senator BROWNBACK.—for doing it. And that was the process used for Dolly.

Dr. KASS. That was the process used for Dolly. And when people say "somatic cell nuclear transfer to produce stem cells," you do not produce stem cells directly by somatic cell nuclear transfer; you produce an embryo, which you then have to grow up and then you get the stem cells out.

So the primary product of the technique of somatic cell nuclear transfer is an embryo. It is a cloned embryo. And if it is in the human species, it is a cloned human embryo.

Senator BROWNBACK. OK. And this is the same process that is being used now not only in Dolly, but in cats—well, what all has this been used—this same process been used in?

Dr. KASS. It has been used successfully in, I think, eight or nine mammalian species—sheep, cows, pigs, cats, mice, rats, goats. I have left out one or another, but——

Senator BROWNBACK. And if the Raelians——

Dr. KASS. By the way, the rate of success in some of these other species now goes up. It is no longer one in 277, as with Dolly.

Senator BROWNBACK. What is it now?

Dr. KASS. I do not have the latest data, but it is up to 4–5 percent in mice and the technique is being perfected by by practice.

Senator BROWNBACK. So that that one in nearly 300 is going down to—substantially as people learn more and are able to perfect the technique.

Dr. KASS. Yes.

Senator BROWNBACK. Now, the technique that the Raelians would have used if they did produce a human would be this SCNT procedure?

Dr. KASS. As—I assume so. With the Raelians, I think all bets are off, but——

[Laughter.]

Dr. KASS.—if—but, yes.

Senator BROWNBACK. Now, if—one of the things that you argued, as I understand it, is that if you allow this technique to develop, the SCNT technique of developing an embryo—and now we are past the issue of whether it is a human clone, but of developing that—but you just do it in research purposes, it is going to be very hard to hold that as a research topic, that you have created a human clone just for research purposes, that that is going to move on forward.

Dr. KASS. Well, I think it will in two ways, Senator. First, as Dr. Weldon, I think, has already amply testified, the belief that one can effectively establish a ban on only the transfer of such embryos to initiate a pregnancy is, I think, very problematic. If these are—if these embryos are produced commercially in laboratories under protection of industrial secrecy, no one will know what is being done with them. They could be bought and sold with impunity. They could be—find their way, just as the embryos now in in vitro clinics produced for one purpose, namely the treatment for infertility, now wind up in laboratories. So the same embryo produced originally for research could wind up in an infertility clinic and, under the privacy of the doctor-patient relationship, be used to produce a baby.

And as Dr. Weldon has pointed out, clonal pregnancy would be hard to find. A clonal pregnancy does not look any different from any other, and there would be no enforceable remedy should it be discovered.

So once the cloned embryos exist and once one gets a lot of practice at perfecting this technique, it will hasten the day that cloning for baby-making will arrive, and I do not think an effective ban could be erected in the way in which Senators Specter and Hatch and Feinstein and Kennedy think it can be.

But second, more importantly, if the justification for creating these embryos is that we need these embryos in order to pursue knowledge of disease and remedies for diseases and disabilities, that principle knows no limit at the five- to 6-day-old blastocyst stage. Already there has been one experiment with cloning of animals in which a cloned embryo—a cloned cow embryo—was put back into the cow's uterus, grown up to a couple of months, and then aborted, and that fetus had its kidney tissues removed.

And as, again, Dr. Weldon said, differentiated tissue, is much more valuable than stem cells, which are much harder to handle and the potential that some of them would remain undifferentiated and cause tumors would persist.

I am not sure about artificial uteruses, but one could put human embryos into pig uteruses and grow them up to much more valuable stages than they are at five or 6 days. And one can well expect that if we start down this road and the potential of differentiated tissue turns out to be realized, there will be great pressures to push all the way down.

Senator BROWNBACK. Because there has been no boundary really drawn that has any significance in——

Dr. KASS. There has no boundary that has any significance here at all, Senator.

Senator BROWNBACK.—and I also—I mean, I just—as Senator Ensign was saying, there is a profound issue here of human dignity, which I know you have written and thought about for a number of years. But just—when you start to research on humans, that is a profound issue and a place that we have crossed over of saying that humans can be used by other humans.

Dr. KASS. No, indeed. I think it is—a year ago, people were saying that—in the summer of 2001, people were saying, "Look, these embryos are going to die anyhow. Why should their death not be redeemed by putting them to use for the benefit of others? But no, it would be unthinkable to create them specially for research purposes." But within 6 months, we now have a call to say, "It's all right. Since there's really no difference between taking the ones that are spare and killing them and actually creating embryos explicitly for use, why don't we go the next step down the road?"

In addition to the harm that is potentially done to these little embryos, we have to think about the harm that is done to us as a society for coming to regard nascent human life as a natural resource for our own benefit. You do not have to think that the embryo—the 5-day-old embryo—is a person—and I am an agnostic on this question; I just do not know enough to know—but you do not have to think that it is a person to be very disquieted by what it would mean to start to instrumentalize and commercialize and turn nascent human life into a natural resource and treat it as if it were something to be mined so that you and I and our children could be benefited. This is a cost. This is a deep cost.

And I should say, by the way, that it is—there are—to disentangle this question from the stem cell question, which I hope we could, to some extent, disentangle—you were very careful in your bill, and Dr. Weldon in his, to limit this to cloning, not to regular stem cell research.

Many, many countries around the world, an increasing number, have banned all human cloning—not just cloning to produce children, but cloning for biomedical research—even some of them that permit research on in vitro embryonic stem cells—to proceed—Australia, South Korea, Norway. The Canadian Government is now hearing, in the third reading, a bill that will allow embryonic stem cell research but would ban all human cloning.

Cloning is different because it is—in addition to embryo destruction, this is genetic manipulation.

Senator BROWNBACK. Very good.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman, and thank you, Dr. Kass. I know you have done considerable work in this field, and I think you know I have an interest in this, as well, stemming from having authored the fertility clinic legislation, which is still the only Federal law on the books now with respect to fertility.

My first question, I just want to be clear on one point. The U.S. Senate, by my calculus, is going to have a vote on the floor of the Senate before too long on an outright ban on cloning for biomedical research. That is what the vote is going to be. Now, you are the chairman of the President's Council on Bioethics. My assessment is that a majority of the President's Council on Bioethics does not

now support an outright ban on human cloning—or, excuse me, on cloning research. Is that correct?

Dr. KASS. It is a close call, Senator. On one way of reading the evidence, I think you are right. That table that has been—is—you are pointing to is a table which—is a table which reports the views of the individuals if the—if the question were on that issue alone. It is a subtle point.

The question is—if the question was only what—would we approve or disapprove cloning for biomedical research, seven were in favor of allowing it to go forward, but only under very severe restrictions; seven were in favor of banning it; and three were in favor of a—would be in favor of a moratorium. There is no—there is no specific count in there on what people think with respect to the packaged bill, where, for reasons that have something to do with the likelihood of increasing the risk of cloning to produce children, from allowing that research to go forward, where the count would be. That was on the ethics of the matter, not on the final question.

I think the only thing you can go on with respect to the final opinion is that at least the majority, ten to seven, favors a ban, permanent ban, on cloning to produce children and says that there should be no human cloning of any sort at this time, at least for 4 years.

Senator WYDEN. I just want to make it clear that I think when you read this, and I would like to make this—it is part of the President's Council on Bioethics Report, Mr. Chairman, July 2002, at page 202—it is very clear to me that a majority of the President's Council does not support an outright ban. Dr. Kass has made a point to put it in the context that he thinks is appropriate.

Dr. KASS. Senator, could I just ask you—just to read the—the paragraph before it indicates it is—the restriction. I will just refer you to point (e), and it has got the stipulations.

Senator WYDEN. Fair enough.

Doctor, recently several important congressional supporters of an outright ban have made an important change with respect to their proposal, and they have indicated that they now are willing to allow the importation of products from SCNT research coming from overseas. Now, in my view, this just undermines a basic proposition of the supporters of the ban's case. They have been saying again and again this is not going to produce any great scientific dividends, and yet now they have made this major change, I gather to pick up support. Is this change not an admission that there are potential medical breakthroughs and they want to get the products from overseas?

Dr. KASS. Three points. First of all, you could read that entirely the other way; there being some great doubt as to whether there are going to be any benefits, there is no point to stand in the way of importing them. Second, I think the—I think that the provision was a piece of—I had better be careful—I think it was a misguided provision of the previous law. I think it was—I think—sufficient unto the day.

The important thing is not to aid and abet immoral research. And if you regard this as immoral research, sufficient unto the day

is not allow the immediate products, which is to say the cloned embryos, to be made somewhere else and then used here.

Senator WYDEN. But that is exactly what they are doing. To me, it makes a mockery out of the exercise.

Dr. KASS. No, no—I am sorry, I do not—I have not seen the new text, Senator. I do not think—I think the importation provision of the last—of the bill that passed the House was not about the immediate product, but it had to do with even any kind of derivative drugs or things like that that someone might someplace produce. And it seemed to me—it would seem to be—to say that you would, 50 years from now, or a hundred years from now, not import a drug that might, in fact, aid juvenile diabetes because it came from a cell line that, 50 years earlier, had been created from a cloned embryo would not be regarded as somehow having been complicit in or aided and abetted in or encouraged the original evil. So I do not think that provision was necessary.

I am happy to—if it is really going out, I am happy to see that this provision is out. And I do not think it is an undermining of the principle that—that led people to oppose it.

Look, the most important thing that would be—to me, is something like this. You want to stop cloning to produce children. What is the most effective way to do that? What is the only effective way to do that? You stop that process before it starts.

Now, as Dr. Weldon said, if it should turn out, after extensive work in animals, about which I think we have to remain very skeptical—if after decades—and it is going to take decades to produce any evidence—they show us that there is a unique benefit, "a unique benefit," from stem cells from cloned embryos, we can revisit this question.

Senator WYDEN. Well——

Dr. KASS. But for the time being—for the time being, we are opening Pandora's box in the direction of genetic manipulation of nascent life, we are allowing the creation and the perfection of techniques of cloned embryos with the hope that we can then somehow stand in the way of keeping cloned babies from being—for what? For a pipe dream.

Senator WYDEN. Well——

Dr. KASS. For a pipe dream.

Senator WYDEN. You are saying "revisit it," and all of these suffering Americans say they cannot afford to wait. All of those with Parkinson's and Alzheimer's and other diseases want to see the Federal Government get behind them. They want to see the Federal Government go out and push as hard as it possibly can to find these cures. I have enormous respect for you—and I would like, if I could, Mr. Chairman, to ask about one other question that Dr. Kass is familiar with, in terms of in vitro. I think to have someone like yourself say, "We can revisit it sometime down the road," when people like myself, will meet you more than halfway with respect to safeguards—there is no debating the need for the safeguards, and there is no debating the fact that we are going to support a ban on human cloning—but with that ban, plus the safeguards, to tell all of those who are suffering that they should have to wait and we can revisit it some other time, I think is very unfortunate.

Dr. KASS. Senator, I am glad for the opportunity to respond, if I might.

Look, I do not think I take second place in the concern for the needs of suffering humanity. I trained as a physician. I also have personal reasons—I will not recite the details—but most of these dread diseases that are talked about have been in my family, are in my family. I know about them.

But there are—first of all, one runs a terrible risk of cruelly exploiting the needs and wishes of patients with the promise that the cures are just around the corner. We do not know—I grant you, we do not know which line of research is going to produce which benefits for which diseases. And I think that a fair-minded person will say not just adult stem cells, but embryonic stem cells should be tried. I am in favor of that.

Senator WYDEN. OK.

Dr. KASS. But—but, we will also set certain kinds of limits around things that, if we release those limits, lives would be saved. We do not allow the buying and selling of organs for transplantation, even though lives might be saved if we allowed that to open up.

Similarly, it seems to me—look, we have the example of other kinds of countries. They are going ahead with embryonic stem cell research, they are going ahead with adult stem cell research. But they, for their own good reasons—and the European Parliament, by a huge margin—called for a ban on all human cloning. Cloning.

The chances that you are going to get something out of the cloned embryos for research, as opposed to ordinary embryos for research, that is going to help these people I think are very small—show me the data first. It is going to be decades before you will have any, if at all.

Senator WYDEN. One last question. I appreciate the Chairman's indulgence.

Again, with so much of this having parallels to debates we had years ago, I am curious about the differences you see between this and IVF, the in vitro research in the 1970's. In the New England Journal of Medicine article back in the 1970's, you talked at that time about how there is no ethical way to proceed with in vitro fertilization research. But, to your credit, you did not call for a ban on all governmental research. You said, "Let's have the profession do internal oversight and scrutiny"—intraprofessional scrutiny, as you called it. And of course, there have been enormous gains, several hundred thousand babies born in the United States. Parents who carry genetic diseases are better able to avoid passing it along to their children.

Given the fact that we were careful then not to ban that research—why would we not say the same thing now with respect to therapeutic research that I and others want to do? What is different?

We have almost exactly the same concerns. We are in agreement that there are certainly potentials for abuse, in terms of the most egregious cases, human cloning. There is tremendous unanimity in the Congress on human cloning and the potential abuse. What is different now that requires this outright ban that is different from what we faced in the 1970's, when, to your credit, you and other

leaders, recognizing there was potential, said, "Let's make sure there's vigorous oversight," but did not ban it by government?

Dr. KASS. I think the difference, Senator—there are a number of differences. I am not sure I can collect them all here. And I—you know, with permission, if—when I formulate my thoughts——

Senator WYDEN. Of course.

Dr. KASS.—more carefully, I will send them in. But a couple of differences are striking.

Nobody knew before the first in vitro experiments were done whether that was going to be safe or not. And only recently are we beginning, in fact, to discover that maybe there are certain problems after hundreds of thousands of babies born. But the difference is, as I indicated, there, the child that is produced and the research that was taking place, although it paved the way for this—and in my early writings, one of the reasons I worried about that was that it was going to lead us down the road in the direction of ever-greater intervention, ever-greater genetic manipulation and the like—the difference there is that you are mixing an egg and a sperm, and the product is a product of chance.

Here, you have got the deliberate genetic manipulation and the creation of an embryo that is a genetic copy of another one. We are now crossing a border, both in the direction of cloning children as well as acquiring the technologies to intervene, to exercise growing genetic control over the next generation. That is different.

As long as you have got a—as long as you are mixing egg and sperm, it is out of the body, but it is still sex. Here, you have got intervention into the genotype, and that is a major watershed, and we should not cross it doing business as usual. If we are going to cross it, it should only be after there are powerful reasons which say we must cross it.

It is not enough in something like this to say "it could cure something." This is a major watershed. This is a major watershed. And the burden of proof, it seems to me, lies on those who say we should abandon our restrictions at this point. Show us why it is necessary, rather than say, "Why not?"

Now, scientists do not like any restrictions. And it is dangerous to interfere with basic research. But this is not just basic research; this is an action.

Senator BROWNBACK. And if we could move onto the next panel so we can wrap up.

Dr. Kass, thank you very much——

Dr. KASS. Thank you very much.

Senator BROWNBACK.—for your very clear testimony and service to the country. Appreciate it.

The final panel will be Dr. Anton–Lewis Usala, who is the medical and administrative director, Office of Regulatory Review of Clinical Trials, East Carolina University, and also serves as CEO and CSO of Ectosella, Incorporated; and Ms. Kris Gulden, who is a member of the Alexandria Virginia Police Department and received several awards for her law enforcement work. In addition, she won the Women's Triathlon Gold Medal in August 1996 at the Biennial Police Olympics in Salt Lake City. She was paralyzed after her bicycle was tragically struck from behind by a motor vehicle, leaving her with severe spinal cord injury. And both of these

individuals are with us today to be able to testify and illuminate us on the issue of human cloning.

Dr. Usala, thank you very much. You are first up. And please give us your testimony.

Dr. USALA. I am going to see if we can get the PowerPoint presentation to actually work, Senator.

Senator BROWNBACK. All right.

(Pause.)

Senator BROWNBACK. If you need to move that so you can see it, that would be just fine. If it is going to take you some time, we could go to Ms. Gulden's——

Dr. USALA. That would be great.

Senator BROWNBACK.—testimony. Would you mind going ahead of Dr. Usala?

Ms. GULDEN. Not at all.

Senator BROWNBACK. That would facilitate him.

Ms. Gulden, thank you very much for joining us here today.

STATEMENT OF KRIS GULDEN, COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH

Ms. GULDEN. Thank you, Senator Brownback.

I would like to testify this afternoon about the issue of somatic cell nuclear transfer, commonly referred to as "therapeutic cloning." My name is Kris Gulden, and I'm here on behalf of the Coalition for the Advancement of Medical Research.

The coalition is composed of more than 75 patient organizations, universities, scientific societies, foundations, and other entities advocating for the advancement of breakthrough research and technologies in the field of regenerative medicine. The goal, of course, is to cure disease and alleviate human suffering. Today, I consider myself the voice of hope for the millions of Americans who may benefit from this research.

Along with the Coalition for the Advancement of Medical Research, the National Academies of Science, 41 Nobel laureates, and the vast majority of the American public, I support a ban on human reproductive cloning. However, it is important that we protect important areas of medical research that offer hope to so many of our citizens.

As a person living with paralysis caused by a spinal cord injury, I know how urgently a cure is needed. I do not expect a cure tomorrow or even next year. But we may have before us our greatest chance to cure diseases like ALS, Alzheimer's, Parkinson's, cancer, diabetes, and even paralysis resulting from spinal cord injury.

Everything about my life changed on May 26th, 1998, when I began a bicycle ride that I never completed. I started my ride as a 31-year-old triathlete. I was employed as a police officer in Alexandria, Virginia. I had been on my bike for an hour when I was struck from behind by a motor vehicle. In addition to a traumatic brain injury and numerous broken bones, I bruised and displaced my spinal cord at the T4 level.

As a result of that accident, I have been forced to surrender my career as a public servant, robbed of the hobbies that sustained me, and left unable to perform some of the daily personal freedoms that able-bodied people take for granted. It should not be difficult to un-

derstand why I feel so passionately about furthering research into nuclear transplantation, a technique that has been called "the most promising advance in the history of medicine."

Within a few months of my injury, I had regained enough strength in my legs that I was able to walk with a rolling walker. However, a rare complication of a spinal cord injury, a disease called syringomyelia, has caused me to lose considerable function. I have not, though, lost hope. I ride a stationary bike that uses electrical stimulation to power my leg muscles 3 days a week for an hour at a time. I take therapeutic horseback-riding lessons, use a Nordic–Track-like device for standing and additional aerobic exercise, and I spend a month in Miami each year going through biofeedback training. The biofeedback shows that my brain is sending signals out to my leg muscles. This is evidence that my spinal cord is still healing.

I am doing my part, even 5 years post-injury, to maximize my potential for a return of function. But I cannot do it alone. With help from medical researchers who are exploring new technologies, there exists a possibility that I will not be forever reliant on this wheelchair.

I understand that the word "cloning" causes many people to imagine the worst-possible abuses. But there is a critical difference between cloning to make a baby, reproductive cloning, and therapeutic cloning techniques to create stem cells. While I am not a scientist, I am aware of the process of therapeutic cloning.

Dr. Joanne Baufman, executive vice president of the American Society for Human Genetics, is with us today and will answer questions pertaining to the science.

As a layperson, though, I find it unconscionable that the U.S. Congress would choose to prohibit this research knowing that it could lead to cures and therapies for many devastating diseases and disabilities.

I recognize that no area of research, be it adult stem cells, embryonic stem cells, or nuclear transplantation, comes with a guarantee. But they should all continue.

Although I did not include this in my written testimony, I would like to remind you that on September 25th, 2002, at a Senate Labor, Health and Human Services, Education, and Related Agencies hearing, Dr. Elliott Sarahuni, director of the National Institutes of Health, said, quote, "NIH continues to believe that research on both embryonic stem cells and adult stem cells must be pursued simultaneously in order to learn as much as possible about the potential of these cells to treat human disease," end of quote.

To me, the creation of embryonic stem cells through nuclear transplantation is a reasonable step in the quest to free people from the inescapable medical conditions with which they live. For me, the only escape from paralysis occurs when I dream. In my dreams, I still walk, I run, I play basketball, and I wear the uniform of the Alexandria Police Department. When the sun rises each morning, it brings reality with it. I rise to the sight of a wheelchair. Yet I rise with the hope that maybe this will be the morning I can move my legs.

On behalf of the Coalition for the Advancement of Medical Research, the countless Americans who stand to benefit from thera-

peutic cloning, and the friends and family members who love them, I am asking you to please carefully consider our futures as you deliberate this issue.

Thank you very much.

[The prepared statement of Ms. Gulden follows:]

PREPARED STATEMENT OF KRIS GULDEN, COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH

Good afternoon Senator Brownback and Members of the Committee. Thank you for the opportunity to testify today on the value of somatic cell nuclear transfer (SCNT), commonly referred to as therapeutic cloning. My name is Kris Gulden, and I am here on behalf of the Coalition for the Advancement of Medical Research. [1] The Coalition is comprised of more than 75 patient organizations, universities, scientific societies, foundations, and other entities advocating for the advancement of breakthrough research and technologies in regenerative medicine in order to cure disease and alleviate suffering. Today, I consider myself the voice of hope for the millions of Americans who may benefit from therapeutic cloning.

Along with the Coalition for the Advancement of Medical Research, the National Academies of Science, 41 Nobel laureates, and the vast majority of the American public, I support a ban on human reproductive cloning. However, it is imperative that we protect important areas of medical research that offer hope to so many of our citizens. As a person living with paralysis caused by a spinal cord injury, I know how urgently a cure is needed. I do not expect a cure tomorrow, or even next year, but we may have before us our greatest chance to cure diseases like ALS, Alzheimer's, Parkinson's, cancer, diabetes, and even paralysis resulting from spinal cord injury. I do not intend to overstate the promise of the research, but you can't overstate the hope that it offers people like me.

Everything about my life changed on May 26, 1998, when I began a bicycle ride that I never completed. I started my ride as a 31 year-old triathlete. I was employed as a police officer in Alexandria, Virginia. I'd been on my bike for an hour when I was struck from behind by a motor vehicle. In addition to a traumatic brain injury, four broken vertebrae, two broken ribs, a broken breastbone and clavicle, I bruised and displaced my spinal cord at the T4 level. As a result of that accident, I have been forced to surrender my career as a public servant, robbed of the hobbies that sustained me, and left unable to perform some of the daily, personal freedoms that able-bodied people take for granted. It should not be difficult to understand why I feel so passionately about furthering research into nuclear transplantation—a technique that has been called the most promising advance in the history of medicine.

Within a few months of my injury, I began to follow research that was being conducted at the Miami Project to Cure Paralysis. At about the same time, I was experiencing tremendous healing and discovered that I could move my legs. I rapidly progressed to walking with the rolling walker. However, a rare complication of a spinal cord injury—a disease called syringomyelia, has caused me to lose considerable function. I have not, though, lost hope.

I ride a stationary bike that uses electrical stimulation to power my legs three days a week, for an hour at a time. I take therapeutic horseback riding lessons, use a Nordic track—like device for standing and additional aerobic exercise, and I spend a month each year doing biofeedback in Miami. The biofeedback shows that my brain is sending signals out to my leg muscles. My spinal cord is still healing. My commitment to getting out of this wheelchair is unwavering. I am doing my part—even five years post-injury, to maximize my potential for return of function. But I can't do it alone. I need medical researchers to continue exploring new technologies that could forever rid me of my wheelchair.

Five years ago, I was excited when I learned about the restorative potential of Schwann cells that were being studied in Miami. When stem cells were isolated—especially embryonic stem cells, I became even more convinced that there would be a medical breakthrough to help me reclaim the life I left behind. Now we're talking about nuclear transplantation—a technique to create embryonic stem cells that could be used to treat a myriad of diseases and disabilities. With each additional discovery, my hopes soar. In the five years since my injury, I've come to accept that

[1] The Coalition is comprised of nationally-recognized patient organizations, universities, scientific societies, foundations, and individuals with life-threatening illnesses and disorders, advocating for the advancement of breakthrough research and technologies in regenerative medicine—including stem cell research and somatic cell nuclear transfer—in order to cure disease and alleviate suffering.

scientists are making progress, and that the question of a cure is no longer a matter of "if", but "when".

I understand that the word "cloning" causes many people to imagine the worst possible abuses. But there is a critical difference between cloning to produce a baby—reproductive cloning—and therapeutic cloning techniques to create stem cells. While I am not a scientist, I am aware of the process of therapeutic cloning. It is unconscionable to me that the United States Congress would choose to prohibit research that could lead to cures and treatments for many devastating diseases and disabilities.

I recognize that none of these areas of research—adult stem cells, embryonic stem cells, and nuclear transplantation—comes with a guarantee, but they should all continue. I also understand that the limited potential of adult stem cells makes working with embryonic stem cells preferable. One may argue that there are already existing lines of embryonic stem cells available for research. But that number is dwindling. The creation of embryonic stem cells through nuclear transplantation seems to me a reasonable step in the quest to free people from the inescapable medical conditions with which they live.

For me, the only escape from paralysis is to dream. In my dreams, I still walk. I run, I play basketball, and I wear the uniform of the Alexandria Police Department. When the sun rises each morning, it brings reality with it. I rise to the sight of a wheelchair, yet I rise with the hope that maybe this will be the morning I can move my legs.

Please don't take away the hope of countless Americans who could benefit from therapeutic cloning and the family members and friends who love them and care for them. On behalf of the Coalition for the Advancement of Medical Research I again thank the Committee for its deliberations and for the opportunity to speak to this issue.

Senator BROWNBACK. Thank you very much, and thank you for your powerful and passionate testimony.

Dr. Usala, are we ready to go?

Dr. USALA. We are up and going, Senator, thank you.

Senator BROWNBACK. Thank you.

STATEMENT OF DR. ANTON-LEWIS USALA, MEDICAL AND ADMINISTRATIVE DIRECTOR, OFFICE OF REGULATORY REVIEW OF CLINICAL TRIALS, EAST CAROLINA UNIVERSITY

Dr. USALA. Destruction of specific cells results in many chronic disease states, such as type-one 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 diseased state.

Two theories to replace damaged tissue involve the use of transplanted human embryonic tissues or tissues derived from cloned individuals. Tissues obtained from donor human embryos have different DNA than the recipient patient and will, thus be rejected as foreign material by the patient; while tissue obtained from cloned human embryos have the same DNA as the patient and, thus, would theoretically have fewer rejection problems. Neither of these human embryonic tissue sources are able to form effective communication with the recipient's existing tissue. Without such connections, the transplanted tissue will not be functional.

No large-animal studies have successfully demonstrated functional recovery from embryonic stem cell transplantation experiments, although many successful experiments have been published utilizing the patient's own adult stem cells.

Cellular transplantation material obtained from developing embryos 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 pa-

tient's own tissues to replicate at the desired sites. If the patient's own tissue could be induced to regenerate at the desired 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 to induce regeneration of a specific kind of tissue in animal and human patients. My hypothesis was that exposing the cells to an environmental structure similar to that present during natural embryogenesis might induce the patient's cells to behave as they did during embryogenesis and thereby induce explosive generation of tissue.

This artificial embryonic scaffolding was made from modified naturally occurring compounds synthetically polymerized to give the desired structure. This product contained no cells—no adult stem cells, no embryonic stem cells, no cloned cells—only structures for the patient's own cells to bind to at the damaged site.

The results I am about to show have been presented at several scientific meetings and have recently been submitted to a peer-review journal.

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, as are seen in patients with diabetes. 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 longstanding diabetes.

After a one-time injection of the artificial embryonic scaffolding, the dog's wounds healed with regenerated tissue. And what we did was, we injected around the periphery of the ulcer, as seen on the left, and through the center. And what you see is, within 6 days we had total closure with newly generated skin, newly generated blood vessels.

The new tissue resulting from exposure to the embryonic-like matrix was determined to be structurally identical to non-wounded areas. And those studies were performed at the request of the Food and Drug Administration.

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 which did not respond to any conventional or to any other experimental therapy.

Shown here is the heel of a patient with 20 years of longstanding diabetes. This man had a ulcer that was refractory to all kinds of therapy for 4 years. Every 2 weeks, he went to the University of North Carolina's Wound Healing Center and had appropriate treatment applied. He was not able to heal this wound because his blood vessels had degenerated around it. As with the dog, what we did was, we injected around the periphery and then through the center of the lesion. This allows the artificial scaffolding we developed to bind to the patient's own tissues.

Now, remember, what we were trying to do was provide an embryonic environment that would induce the same kind of generation that occurs during embryogenesis. There were no cells involved at all.

This is study-day one. Here we are a week later. This is very, very exciting to the patient, obviously. What you see there is the very fine, delicate, gelatinous-almost-like tissue that you see during fetal development. The blood that you see is the result of the surgical debridement procedure where the surgeon poked the tissue and blood spurted out, indicating that new blood vessels had explosively regenerated as they do during embryogenesis.

This is 14 days out. Remember, this wound was here for 4 years. Here, it is closed. And again, you are starting to see now the generation of all the appropriate structures.

A month out, you start to see the epidermis, the outer layer of the skin, growing. This is 2 months later, and this is 3 months later. Three months after this photo was taken, the patient who was not able to walk for 4 years, danced at his daughter's wedding.

Senator BROWNBACK. Here, here.

Dr. USALA. Transplantation strategies, whether derived from foreign donors or cloned cells from the patients themselves, are clearly not the only approach to replace damaged tissues. Other avenues are further along in clinical trials. The results that I showed you were obtained with my first biotech company, which I am no longer with and own less than .1 percent of the company's stock. I have no financial interest in showing this to the Committee. We did this study on six patients, and I understand that the company is now engaged with a large pharmaceutical company to do the next phase of testing.

While other avenues are further along in clinical trials, it should be considered as a first approach for study that does not use human embryonic or cloned cells. Indeed, the patient's existing cells provide the most rational source for fully integrating replacement tissues, as occurred during all of our own embryogenesis.

Thank you.

[The prepared statement of Dr. Usala follows:]

PREPARED STATEMENT OF DR. ANTON-LEWIS USALA, MEDICAL AND ADMINISTRATIVE DIRECTOR, OFFICE OF REGULATORY REVIEW OF CLINICAL TRIALS, EAST CAROLINA UNIVERSITY

Chronic disease states such as Type 1 Diabetes, Parkinson's Disease, and Spinal Cord Injury result from the destruction of specific cells. Replacement of these tissues may provide immense relief, and possibly cure, of the disease.

One approach to replace these tissues is to find acceptable transplantation sources and implant donor cells into a patient. If these cells are derived from a source other than the patient, there will be problems with rejecting the "foreign" transplant material. Cloned patient cells (cells that are induced to replicate with the same DNA template as the patient) do not have many of foreign markers and theoretically would not be rejected. However, cloning by the transfer of somatic nuclei into unfertilized eggs requires a dramatic remodeling of chromosomal architecture. Many proteins are specifically lost from nuclei and others are taken up from the egg cytoplasm. These proteins determine which DNA genes are promoted and expressed, and which DNA genes are repressed.

The specialization of cells for specific function occurs during embryogenesis, fetal development, and continues throughout adult life. The microenvironment that developing cells are exposed to plays a major role in determining which factors of the DNA are expressed, and which factors are not expressed. We all have met identical twins, which have the same DNA template, but have quite different personalities and even different physical appearances. These differences are largely determined by differences in environment that the differentiating cells are exposed.

Since cellular transplant material obtained from developing embryos 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. Embryonic stem cell transplantation has repeatedly been shown to be ineffective in large animal models largely because they are not capable of integrating into mature host structures. Even if the stem cells are obtained from cloned embryos, and subsequently are not rejected on the basis of major immunologic compatibility, the transplanted stem cells are still not capable of forming the complex integrative network that many structures require.

The developing embryo is surrounded by unique proteins and environmental factors. Once the embryo reaches a more mature fetal stage, the cells are surrounded by more mature proteins and growth factors, leading to more highly differentiated cell functions. Throughout this process, the DNA template that codes for the expression of all cell functions remains the same. One hypothesis states that if the correct embryonic environment could be duplicated, a patient's cells may be able to be induced to regenerate in a given site, as they rapidly did earlier in the patient's life during embryogenesis. This would result in totally compatible, integrated, replacement tissue for the disease being treated.

I would like to share with the Committee the preliminary results of a product I developed to induce regeneration of a specific kind of tissue in animal and human patients. My hypothesis was that exposing cells derived from a specific embryonic germ layer (the mesoderm) 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. Mesodermally derived cells give rise to such differentiated structures as blood vessels, deep skin structures, bone and cartilage. The artificial embryonic scaffolding I invented was made from modified long chain, naturally occurring coumpounds that were synthetically polymerized to give the desired structure. This embryonic scaffolding contained no cells, only structures for the patient's cells to bind to. If the hypothesis were correct, after exposing the patient's damaged tissue to this synthetic biopolymer, the patient's tissues should 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 for review in a peer reviewed journal. 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. 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.

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.

Destroying a human embryo to obtain cellular material does in fact destroy a human life, not a potential human life. Shortly after conception, a human being has a DNA template from which ALL other cells are generated. The process by which cells become specialized is called differentiation. A differentiated heart cell has the same DNA template as a differentiated skin cell, and they both have the same DNA template as the undifferentiated cells early in embryogenesis.

The mass of cells that begins this replication and differentiation, either shortly after conception or induction through nuclear transfer, defines the beginning of any mammal's life. This differentiation process continues until death. The continuum of human life thus starts at the beginning of the complex, explosive process of cellular DNA differentiation during embryogenesis and ends at death. One cannot stop the continuum at any one point and say it is not human life because it lacks the ability to do certain functions. When the mass of cells has feelings or reason is subject to debate. When it begins as human life is a biologic fact.

All laws are based on precedent. The difference between a just and an unjust society is the precedent the society accepts to base its jurisprudence upon. In my view, the United States is a uniquely just society because it is the first government in the history of humankind in which the right of the individual supersedes the perceived right of the state, thus defining the individual as society's most valued entity. The first ten amendments to our constitution explicitly prevents government, even if so desired by the majority, from violating these individual rights. As a developing embryo, whether cloned or naturally created, is scientifically a human being, the United States must not set the precedent of allowing individuals to be sacrificed for the illusion of a greater good.

Transplantation strategies, whether derived from foreign donors or cloned cells from the patient themselves, are clearly not the only approach to replace damaged tissues. 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.

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Senator BROWNBACK. Thank you very much. That's exciting to see.

Ms. Gulden, I think you have testified before at the Labor Subcommittee on Appropriations, Appropriations Subcommittee.

Ms. GULDEN. It was the Judiciary Committee.

Senator BROWNBACK. The Judiciary? Good. I remember hearing you testify at another place, and I was not quite sure where. It is good to see you again.

Ms. GULDEN. Thank you.

Senator BROWNBACK. The groups—the patient groups that you work with, have they stated a date that they would like to see the clone—or the somatic cell nuclear transfer, being, however you would want to refer to it—live up until before it would be destroyed? You mentioned you represent a number of different patient groups. Have they identified a date by which they would not want it to live any longer than?

Ms. GULDEN. My understanding is that the five-to-seven-day period is what is practiced. I have not heard anything officially from CAMR, though.

Senator BROWNBACK. They have not taken an official position that, OK, we want to—when we create this—I realize we have a—

differences of terminology, but we want to create a clone or an entity, and we want it to live for a certain period of time to be able to then harvest the stem cells that are there? But is the period of time in the five to 7 days, are they set firm on that, or is there——

Ms. GULDEN. My understanding is five to 7 days is their position.

Senator BROWNBACK. OK. You heard the testimony earlier about—that if this happens, and—but it turns out that you could get differentiated cells by letting the entity—the clone—the somatic cell nuclear transfer body, whatever you want to refer to it as—live for a longer period of time, or you could get the differentiated cells that may be more useful, how do you—how do you react to that sort of statement, that if you do not—if you can say five to 7 days, what is to keep you from going to 14 days or to 21 days or to 35 days, if it turns out that would be a more useful body of cells?

Ms. GULDEN. How do I respond, personally, to that?

Senator BROWNBACK. Yes.

Ms. GULDEN. I think that the sooner you can get them, that is—you know, I am more comfortable with cells coming out sooner rather than later.

Senator BROWNBACK. Would you have any objection if it were later if it proved that it could be valuable usefulness for the cells, if it could be more useful in research?

Ms. GULDEN. At this point, when the cells are useful is when I would like to see them come out. And that, to me—it would be preferable for them to come out sooner rather than later.

Senator BROWNBACK. But you do not have a firm number of saying there is something special about five to 7 days—the groups do not have anything firm about what is special about the five-to-seven-day time period?

Ms. GULDEN. Not that I am aware of.

Senator BROWNBACK. OK. I mean, that—that has a part of the issue. I think you have—as you have heard the other testimony—you were very good at being patient about being here for it—but that we wanted to—people were curious, "Well, what's magical in the five-to-seven-day time period?" But—and I think that is, you know, a point that there is some concern about, that that could slip to a further period of time.

Ms. GULDEN. Dr. Baufman might be able to better explain the five-to-seven-day period, or whatever that time window is.

Senator BROWNBACK. OK.

Dr. Usala, let me refer to your testimony. And this is work that you have done. You keep referring to an "embryonic matrix," but you did not use embryonic stem cells, is that correct—in doing this?

Dr. USALA. That is correct, Senator. Basically, it was some long-chain proteins that I derived from skin taken from pigs and polymerized that with some other long-chain compounds to try to replicate the molecular structure of certain scaffoldings that are present during the time of embryogenesis.

Senator BROWNBACK. And you were able to get, then, that structuring to take place to heal these gaping ulcerated type of wounds.

Dr. USALA. Yes, Senator, that is correct.

Senator BROWNBACK. And the point being that you do not have use embryonic stem cells to get the body to react in a way to build an embryonic-type of growth medium and structure, then.

Dr. USALA. Right. I think the idea of taking something that is less differentiating and putting it into a patient and thereby hoping that it will assume the properties of the tissue that you are trying to replicate has been shown to be naive.

As was mentioned earlier, the—taking of fetal tissue, which—I remember in the late 1980's and early 1990's—I have had type-one diabetes since I was a year old, and I remember all of these things—they wanted to cure type-one diabetes by taking fetal pancreatic cells and implanting them into people, thereby thinking, because they were less differentiated, they would take better.

I was involved with all kinds of transplantation experiments. And what we found was this, that when you take a cell out of its natural environment, whatever it is, and you put it someplace else, things happen. And what I mean by that is, the DNA in the nucleus is very much influenced by the environment. And so if you pluck it out of where it—that cell started to grow up, and put it in a different area, it does not make the connection it needs to be functional.

Knowing that, what I did was, I made—I brought the mountain to Mohammed—what I did was, I brought the structural scaffolding that we all see during embryogenesis, and I put it in the patient's own tissues. The connections are already made. The environment calls for the tissue to become what is needed. And so, thereby, we have demonstrated, and I believe we are the only people that have thus far demonstrated, the ability to induce that kind of regeneration.

There are such scientific hurdles involved with trying to make all of these billions of connections work just by taking something that is not differentiated. It is mind-boggling. It is easier to raise money that way at the NIH, because everybody knows there is a lot of work to be done, so it is easy to get 20-, $30 million thrown at something if it holds great promise but there is not much data, because everybody understands a lot would be required.

What I am suggesting is that there are many, many reasons why we should not be destroying a human life. And where I take exception with Senator Hatch and agree with Dr. Weldon, human life starts at conception. That is a scientific fact.

Now, what I heard Senator Hatch saying was, you know, there may be philosophic and other ethical reasons to suggest that that is not worthy of the protections provided by the law, but human life does start when the differentiation process commences, when the sperm and the egg DNA merge. You cannot stop it at any point after that, because that differentiation and replication continues until you die.

So I think that it is not wise for us to shake the foundation of the republic and, for a greater good, sacrifice individuals. That would be the first time in the history of the United States where the government chooses to sacrifice individuals for the benefit of someone else without that individual's consent.

Senator BROWNBACK. Ms. Gulden, if you wanted to solicit information from any of the people that you work with to clarify your answer earlier—I have got another question for Dr. Usala, but if you would like to get some information from them while I ask this, I would sure be happy to receive that.

Ms. GULDEN. Thanks.

Senator BROWNBACK. Well, thank you for being here.

Dr. Usala, what happens when we focus our research—let us say we put millions of dollars into human cloning because it seems interesting. We might find something here, but then it does not go into places like the research you have shown us here or adult stem cells. There is a finite set of dollars. We all want to cure these diseases. I am sure, in your case, with diabetes, you wanted to see that cured in the most profound ways, as we all want to see these things cured. But what happens in the research community when we take off on areas that may have the—may have a general image to them, but that do not have the real data behind them to be able to produce results?

Dr. USALA. It is like throwing a pebble in the water. What happens is that efforts, like my effort, which was funded almost entirely with private funds—that was funded by a 5-and-a-half-million-dollar venture capital round. Why? Because this was an out-of-the-box kind of idea. It would have no chance at all of being funded by the NIH.

What happens when we say, OK, this is an exciting proposition. Billions of dollars are invested in investigating it. Well, what the standard of the researcher is held to is—is not the production of a therapeutic entity. The standard is publishing papers. And I am absolutely certain many, many papers will be published with the research. But what will also happen is that people will have to—if they take a different route, will have to get the funding totally separately, from private sources, and demonstrate it in human beings before the rest of the scientific community will look at it. And that is, in fact, what happened here.

It is not just that there is not enough money to fund all ideas like this. It seems that what would make the most sense—if what the Congress is interested in is creating effective medical therapy, let us go with those things that are closer to being executed than—rather than a fishing expedition.

So in addition to the money, it has to do with things like publication, it has to do with grant submissions to other non-government sources. It has a profound effect on the conduct of research, in general.

Senator BROWNBACK. It is, to me, to try to go where you can be most productive in getting the yield of the cures that you are looking for on injuries, on ALS, all these particular areas.

My time is up, but, Ms. Gulden, I would hope Senator Wyden—if you have explanation on that—the question I had, I would be happy to receive that.

Ms. GULDEN. Thanks. I hope this will clarify it.

At—between the fifth and seventh day, there appears to be enough cells that cells can be extracted to create the stem cell lines. However, I understand there is other wording in the Senator Hatch bill. It says by 14 days, you either must implant, or the blastocyst will die. So five to 7 days is the period we tend to focus on, because that is when stem cells can be extracted and cell lines can be obtained.

Senator BROWNBACK. OK. So your distinction is based strictly upon the physiology of the actual cell, and it is not on any, "We

think there's an important developmental stage, that human life begins after 7 days," or anything of that nature. It is based upon the physiology of the clone or of the SCNT, as others would refer to it. Is that correct?

Ms. GULDEN. Before the differentiation begins.

Senator BROWNBACK. OK. If—and if you do not want to answer this, you do not have to, but I just—I want to try to get it from the patient advocacy groups—if it is shown that once differentiation takes place, you have more opportunities to get the type of replacement tissues, cells that you are looking at at the 14-day stage, rather than the five-to-seven, is your group supportive of that, or in opposition, or have they not taken any stand?

Ms. GULDEN. I will choose not to answer that.

Senator BROWNBACK. OK. All right. I just—I think it is an important issue for us to get at. And the more we go into this debate, I think we need to get to the sharpness of the point of, you know, what period of time are we talking about here of being able to let the clone grow to? Because I think that is going to be, I think, a very key issue as we get focused in more on—if we are going to have human cloning, we are going to do this research technology, how many days, and what is the ethical line as to why you would draw it, or what is the physiological line that you would draw, and why do you draw it there? And that is why I hope you would see this—and other people have problems with the whole issue, because some of these lines can shift pretty easy, based upon needs or desires and—but not—there is not a clear philosophical reason of why five to 7 days is any different than 14 or 30.

Senator Wyden?

Senator WYDEN. Well, thank you, Mr. Chairman.

And I want you to know, first, Ms. Gulden, I am going to do everything I can, as a United States senator, to not foreclose scientific options for progress and opportunity for people like yourself. I think that is what your government owes you.

I appreciate the fact that you have come today, and you have made it clear you are not a scientist. We are going to have various kinds of complicated questions. We have talked about some of them here today. I think it would be especially sad if options were foreclosed here, in this country, and then similar cures were available overseas. What we would have said to our citizens here is that we did not make the effort. We did not try. And I am going to work with those who do not share my views to set in place the kind of rigorous safeguards, because I think that is important. And you have made it clear you support safeguards. We are going to do everything we can to find the cures, because there are too many people in this country suffering and hurting, and we owe it to them. So I thank you for coming.

And I have just one question for you. What do you make of the—this change from so many of the influential sponsors, that they are now going to remove the ban on the importation of SCNT-derived technologies? To me, that is a clear admission that there is tremendous scientific progress here. What do you think?

Ms. GULDEN. I was not aware that that had been removed.

Senator WYDEN. Well, that is what is being discussed. What has been widely reported in the news media is that—at the request of

the Senate Majority Leader, that would be removed by the sponsors. And perhaps you could get back to us when you have had a chance to reflect on it.

But I think it is a major, a very significant, development. I think it undermines one of the basic propositions that supporters of the outright ban have been making. They have been saying it does not have great scientific promise, there are not great opportunities for breakthroughs, and yet they are willing to say that they will change their position on importation.

So we will look forward—we will get your response in writing. And mostly thanks for coming. You are a powerful voice for making sure we are not foreclosing scientific options. We sure need that right now, and I thank you for it.

I have one question, just for you, if I might, Dr. Usala, with respect to your research. And it is certainly interesting and important. My question would be, how effective would this kind of work be in conditions, various medical problems, such as genetic disorders, like Parkinson's or Alzheimer's?

The reason I ask the question is, it would seem to me that, in one sense, you are, in effect, reintroducing the genetic disorder with regeneration. Is that an issue in your mind? And how would you react to that?

Dr. USALA. There certainly would be some conditions, Senator, where you are absolutely right. Alzheimer's, Parkinson's are not two of them. All diseases probably have some genetic basis for predisposition. But, for instance, in diabetes, remember, before 1992, everybody at the NIH believed that the complications associated with diabetes were genetic and that blood-sugar control made no difference. And this was the cognoscenti of the medical/scientific community. And those that believed that blood-sugar control did make a difference were viewed as extremist and not quite right.

Well, in 1992, after those extremists really pushed the issue, we found out that the extremists were right, and the NIH and the ADA, American Diabetes Association, were wrong, at the cost of hundreds of thousands of lives.

My point here is that, for things like Alzheimer's, there are still tissues. If we took that person's brain tissue and replicated it from the—as it was during embryogenesis, you would still have another 60, 70 years of functional utility before the Alzheimer's again became a problem.

So I do agree that in certain very aggressively lethal genetic problems, like Tay–Sachs Disease, this would not be of any help. But neither would therapeutic cloning or embryonic stem cell implantation.

Senator WYDEN. Mr. Chairman, I think this has been an important hearing. As I said, I guess, 2 hours ago, you and I are going to agree on plenty of issues in the course of this Subcommittee's work, and I think it is fair to say this is one where we do have differences, and we are going to talk about them in a reasonable fashion, without the decibel level breaking the building.

But I will tell you and those who are here, I just hope we can find a way to make sure that we send the message to all of those families and all of those Americans who are suffering today that we are going to stand by them. We are going to pick up on the ex-

cellent ideas of Dr. Kass here, Senator Brownback, who is an authority on this subject, to make sure that every reasonable precaution is in place.

But when we are dealing with heart disease and stroke and diabetes and Parkinson's and spinal cord injuries, let us do what those organizations, the letters of which I have put into the record, are urging, and that is—they are saying, "Let us pursue the route of careful science, rather than putting up roadblocks of resistance."

And Sam, I thank you. I wish you well as you begin your service as Chairman of the Subcommittee. I wish I did not have to give it up, but I am looking forward to working with you.

Senator BROWNBACK. Thank you.

And I want to thank the panel. And I also want to add my statements to what Senator Wyden was saying about our search and push for answers. I think we have got some great opportunities, and we are pushing them. I have supported strongly the doubling of the NIH budget, because I thought we had some great opportunities and still think we have got a number of them out there—very important to do.

I do think, as well, you have to consider the dignity of each and every person. And we could learn a lot by researching—maybe even researching on me, you could learn something. I do not know, I may be too old and broken-down at this point to do that.

But there is a dignity to each and every person, and I hope we never forget that, whether we agree or disagree on topics, that there is a great dignity to each and every person.

I do want to answer, Senator Wyden, your comment about the change of the bill on the international issue. And that was raised a number of times last year, that people said, well, if you find a cure overseas, it comes here, you will get penalized for that. It is not because of any findings that we are finding anything of success in the cloning field. Far be it—actually, the research work is all what Dr. Weldon has said, we are not finding that, but to take away that area of argument, because our desire is not to limit—not to address things overseas; it is to address things in the United States. And so we put that change in the bill to say we are addressing what is going on in the United States, not what is going on in other places. That is where our legislation should focus, we hope.

And there are ongoing international negotiations at the U.N. A number of countries, as Dr. Kass has pointed out, have already banned, totally, all forms of human cloning, because they see the route of where this is going to.

But it was to raise that and deal with that argument that some had raised. It was not an admission that there is promise here, because we still have not seen that in animal models, and certainly not in humans.

Thank you all. Excellent hearing, excellent panel. And we will have further discussions on the topic. The hearing is adjourned.

[Whereupon, at 5 p.m., the hearing was adjourned.]

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