

STEM CELL RESEARCH, PART 3

HEARINGS
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED SIXTH CONGRESS
SECOND SESSION

SPECIAL HEARINGS
APRIL 26, 2000—WASHINGTON, DC
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FEDERAL FUNDING FOR STEM CELL RESEARCH

WEDNESDAY, APRIL 26, 2000

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 11:02 a.m., in room SH-216, Hart Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Harkin, Reid, and Murray.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed.

We are taking up a very important subject today, and that is the issue of Federal funding for stem cell research. This is the fifth hearing which the subcommittee is holding on this very important subject, and we do it as a preliminary to action on the Senate floor on this subject, which will be taken up in the course of the next several weeks.

When the medical possibilities of stem cells was noted in November of 1998, this subcommittee very promptly scheduled a hearing in December of 1998 to take up the issue of the private research which had been done showing that stem cells had enormous potential for many diseases, Parkinson's, Alzheimer's, amyotrophic lateral sclerosis, known as Lou Gehrig's disease, possibly implications for heart disease.

And subsequent hearings were held, one on the subject of the proprietary interest in these patents. A very major question arises as to whether this is something which ought to be in the private domain or ought to be in the public domain. And we have had hearings which have taken up the ethical and moral considerations. And there is a very profound debate which has been undertaken on this very, very important subject.

My analysis has been that the use of discarded embryos would not affect human life, that in in vitro fertilization, there are many embryos taken, and if there is any possibility of human life, I would be the first to oppose any use for medical research if potential human life were to be involved. My analysis and study has demonstrated that the discarded embryos are not going to be used for human life, so it is not a question of taking human life or the risk of taking human life, but the potential for saving life. I believe

that stem cell research has the potential for a veritable fountain of youth.

And there are other views and other views must be taken into account and will be considered as the Congress considers the issue of whether the current ban on use of Federal funding for embryonic research will take place.

The General Counsel for the Department of Health and Human Services has rendered a ruling that Federal funding may be used on the stem cells once extracted from the embryos, but not on the embryos themselves. And there is a substantial body of medical evidence which says that is not sufficient, that the embryos really need to be used.

This issue has a corollary on fetal tissue which had been banned for many years, and after extensive consideration, fetal tissue is now used for medical research. There had been a concern that the use of fetal tissue would encourage abortions, and I think those fears were finally allayed. Senator Thurmond was a key vote on that matter, and I think persuaded many in the Senate when Senator Thurmond voted for the use of fetal tissue for medical purposes in a very close personal matter which his daughter having juvenile diabetes, given his deep respect for human life, as I also have that deep respect and I think we all do, but now fetal tissue is used for medical research because the conclusion was reached that it does not promote or encourage abortions.

We had inserted a provision in the appropriations bill last fall to eliminate the ban on Federal funding, and when it appeared that that would tie up the appropriations bill, we removed that provision with the understanding reached with our distinguished Majority Leader Senator Lott that the Senate would take up the bill as a freestanding bill, which was introduced in January by Senator Harkin and myself on bipartisan support.

We will now proceed with our first panel: Dr. Gerald Fischbach and Dr. Allen Spiegel. If you gentlemen would step forward.

STATEMENT OF GERALD FISCHBACH, M.D., DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Dr. Fischbach was appointed Director of the National Institute of Neurological Disorders and Stroke in 1998. From 1990 until 1998, he served as Director of the Neurobiology Departments at the Harvard Medical School and Massachusetts General Hospital. He has also been Professor of Neurobiology and head of the Department of Anatomy and Neurobiology at Washington University School of Medicine.

Thank you for joining us, Dr. Fischbach, and we look forward to your testimony.

Dr. FISCHBACH. Thank you, Mr. Chairman.

In the next 2 or 3 minutes I would like to give you a brief statement with a definition of stem cells, their general promise, and then their promise in the area of my expertise in brain science.

As you know, stem cells are unique in that they have a capability of self-renewal. They can give rise to many cells of the same type, but they also have the very special property of giving rise to unique

highly specialized cells, such as heart cells, muscle cells, nerve cells, and pancreas cells under the right conditions.

There is a hierarchy of stem cells. Some stem cells are more limited in their capacity to proliferate and to give rise to different types of cells than others. Much like seeds in the woods, some seeds can give rise to a few trees with a limited number of branches and potential avenues of growth, whereas other seeds can populate a whole forest and can give rise to trees with an enormously elaborate set of branches and arbors.

The pluripotent human stem cells, which we will discuss further, are in the latter class according to current scientific information. They have the broadest potential for renewal and the broadest potential for specialization at the same time.

Stem cells have enormous promise in four major areas. The one that really brings us here today, that has ignited patient advocacy communities and inspired scientists, is the ability of stem cells to repair damaged tissue, to replace cells that have become dysfunctional. And while Dr. Spiegel and I are here representing two organs, the pancreas and the brain, I know you realize that virtually every institute at the NIH has a deep interest in stem cell research for replacing various tissues throughout the body. The potential in this regard is exciting and unlimited, and I think it is the reason Science magazine named stem cells as the breakthrough of the year last year in all fields, chemistry, physics, and biology.

Stem cells are also promising as a means for discovering new drugs with modern new assays. They are very important for understanding the mechanism of disease, and very recently it has been found that they have enormous potential for delivering medicines. They seem to track the path of disease cells and deliver medicines right to the source.

There is nowhere, I believe, a more urgent need for the use of stem cells than in these devastating neurodegenerative disorders of the brain. Nerve cells in the brain, by and large, are a non-renewable resource. When they are damaged or lost, they cannot, with very, very rare exception, be replaced. In previous years, there has been hope only for symptomatic, not for therapeutic interventions. And there are cases now where we can pinpoint deficits where stem cells have already had great promise in animal models of human disease, replacing as you have mentioned, dopamine neurons in Parkinson's disease, motor neurons in ALS and spinal muscular atrophy, cholinergic neurons in Alzheimer's disease.

But you have to realize that the brain is probably the most complex structure in the known universe with over 100 billion cells of great diversity. So, it is important to choose stem cells that themselves have the potential for great diversity and that can repopulate the needed environment. The complexity of the brain requires team work, so in other disorders, in repair after stroke, in repair after spinal cord injury, or in general diseases such as multiple sclerosis, the full diversity of the stem cell phenotype is needed.

Now, there are problems and there is a need to do additional research. And I will end with this. These are very important challenges that many of us feel are on the horizon. We must understand how to regulate the proliferation of stem cells. We must learn how to steer them into one branch of that tree versus another, and

we must really learn how to promote their long-term survival once they are implanted. The hope is that with Federal funding of the use of stem cells, we can bring one of the the world's treasures, which I believe is the American scientific community, funded by the NIH, to bear on these problems.

Senator SPECTER. Thank you very much, Dr. Fischbach.

STATEMENT OF ALLEN M. SPIEGEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. We turn now to Dr. Allen Spiegel, appointed Director of the National Institute of Diabetes and Digestive and Kidney Diseases last year. Prior to his appointment as Director, Dr. Spiegel had a number of positions at the Institute, including Director of Intramural Research and Chief of Metabolic Disease Branch. He holds an M.D. from Harvard, a bachelors from Columbia.

Thank you for joining us, Dr. Spiegel, and we look forward to your testimony.

Dr. SPIEGEL. Thank you, Mr. Chairman. I appreciate the opportunity to appear before you today to discuss the promise of research on human pluripotent stem cells.

The research holds great potential for treatment of many of the diseases within the research mission of the National Institute of Diabetes and Digestive and Kidney Diseases, but I'd like to focus my remarks today on the treatment of type 1, or juvenile, diabetes.

In type 1 diabetes, there is a lack of insulin due to destruction by the body's own immune system of the insulin-producing cells in the pancreatic islets. While treatment with insulin is life-saving, it is not a cure. Our research has shown that tight control of the blood sugar with insulin treatment can delay or prevent the complications of diabetes, such as blindness, and kidney failure, but tight control is extremely difficult to achieve. In this regard, nothing I could say would be as eloquent as the testimony you yourself heard last year from the children who came to Washington as part of the Children's Congress on Diabetes. The frequent needle sticks and constant danger of low blood sugar they described are only some of the difficulties they and their parents must endure every day and night of their lives.

This is why scientists are working so diligently to find ways to cure type 1 diabetes. Of the many approaches we are pursuing toward this goal, the most promising, in my view, is transplantation of the insulin-producing islet cells. For many years, this approach had minimal success, but recent advances in immunology research have led to innovative treatments that effectively block islet transplant rejection. While the results in humans are still preliminary, and there is certainly need for wide replication before we can be sure, islet transplantation offers the prospect of a real cure for type 1 diabetes.

PREPARED STATEMENT

The very real problem, though, is that the available supply of pancreases for harvesting islets is completely inadequate for the

hundreds of thousands of patients with type 1 diabetes who would be candidates for such transplants. It is here that research on human pluripotent stem cells with their theoretical ability to provide a limitless source of islet cells is so important. Some have argued that we could achieve the same goal by using adult pancreatic stem cells, and I agree that this line of research must be vigorously pursued. But at this point, we have no certainty that adult pancreatic stem cells can be isolated in a practical way, nor that they can replicate to provide sufficient numbers of islet cells for transplantation. For this reason, it is vital that we simultaneously pursue research on human pluripotent stem cells, which offer the greatest promise of providing an adequate supply of islet cells for treating and ultimately curing type 1 diabetes.

Thank you for your attention.

Senator SPECTER. Thank you very much, Dr. Spiegel.

[The joint statement follows:]

JOINT PREPARED STATEMENT OF ALLEN M. SPIEGEL, M.D. AND GERALD D. FISCHBACH, M.D.

Mr. Chairman and Members of the Subcommittee, we are pleased to appear before you to discuss the promise of human pluripotent stem cell research. Recent published reports on the isolation and successful culturing of the first human pluripotent stem cell lines have generated great excitement among scientists, patients and their families. Research using human pluripotent stem cells holds enormous promise for advances in the prevention, treatment, and diagnosis of a vast array of diseases. Virtually every realm of medicine might be touched by this innovation. Because of this enormous promise, NIH believes that this research must proceed, as long as it is conducted ethically and legally.

WHAT ARE STEM CELLS?

Stem cells are self-renewing and can give rise to the more specialized cells of the human body, such as muscle cells, blood cells and brain cells. They are best described in the context of normal human development. When a sperm fertilizes an egg, the product is a single cell that has the potential to form an entire organism. This fertilized egg is a totipotent stem cell, which has the potential to develop into a complete organism. In the first hours and days after fertilization, this cell begins to divide into identical totipotent stem cells. Then, approximately four days after fertilization, these totipotent stem cells begin to specialize, forming a hollow sphere of cells called a blastocyst. One part of the blastocyst is a cluster of cells called the inner cell mass, which are the stem cells that will go on to form most of the cells and tissues of the human body. These are pluripotent stem cells, which are different than totipotent stem cells. Pluripotent stem cells do not develop into a complete organism.

Recently, human pluripotent stem cells have been isolated from two sources: the inner cell mass of human embryos at the blastocyst stage and from fetal tissue obtained from terminated pregnancies. Because these cells are capable of limitless division and self-renewal, they can be maintained indefinitely in tissue culture, making them a vital resource for research.

WHY ARE HUMAN PLURIPOTENT STEM CELLS IMPORTANT?

There are several reasons why the isolation of human pluripotent stem cells might lead to better treatment, even cures, of many diseases. At the most fundamental level, pluripotent stem cells could help us to understand the complex events that occur during normal human development. By identifying the mechanisms underlying routine cell differentiation we hope to understand how disease-causing aberrations occur. Another goal of this research would be the identification of the factors involved in the cellular decision-making process that results in cell specialization—why do some cells become heart cells, for example, while other cells become liver cells? We know that turning genes on and off is central to this process, but we do not know much about these “decision-making” genes or what turns them on or off. Some of our most serious medical conditions, such as cancer and birth defects, are due to abnormal cell differentiation and cell division. A better understanding of

normal cell processes will allow us to further delineate the fundamental errors that cause these often deadly illnesses.

Human pluripotent stem cell research could also dramatically change the way we develop drugs and test them for safety. While a limited number of cultivated cell lines are currently available and provide invaluable tools for drug development and testing, pluripotent stem cells would allow expansion of this testing to more varied cell types. For example, drugs could be tested first on particular cell lines to determine toxicity, before they are tested in either animals or humans. Although this would not replace testing in animals and in human beings, it would streamline the process of drug development, and reduce potential for harm in humans and animals. Only the drugs that are both safe and appear to have a beneficial effect in cell line testing would graduate to further testing in laboratory animals and human subjects.

Perhaps the most far-reaching potential application of human pluripotent stem cells is the generation of cells and tissue that could be used for "cell transplantation therapies," which are aimed at diseases and disorders resulting from the destruction or dysfunction of specific cells and tissue. Although donated organs and tissues can sometimes be used to replace diseased or destroyed tissue, the number of people suffering from such disorders far outstrips the number of organs and tissues available for transplantation. Pluripotent stem cells, stimulated to develop into specialized cells and tissue, offer real hope for the possibility of a renewable source of replacement cells and tissue to treat a myriad of diseases, conditions, and disabilities for which replacement tissue is in short supply. Examples of these include neurological disorders, burns, heart disease, osteoarthritis and rheumatoid arthritis.

HUMAN PLURIPOTENT STEM CELLS AND DIABETES RESEARCH

One of the best examples of the promise of this line of research is in the treatment of Type 1 diabetes. Research on islet cell transplantation and stem-cell biology offers compelling opportunities for the development of new, innovative approaches for treating and ultimately curing this disease.

Type 1 diabetes, often referred to as Juvenile Diabetes, is characterized by the inability of the body to produce insulin, a hormone necessary for glucose metabolism. This form of diabetes occurs when the body's immune system attacks and destroys its own insulin-producing beta cells in the islets of the pancreas. As a result of inadequate insulin production, glucose does not enter cells as readily as when insulin levels are normal. The standard treatment is to try to control the glucose level with insulin injections. Insulin treatment can sustain the patient's life, but not necessarily prevent the devastating complications of type I diabetes, which include kidney failure, blindness, amputation, heart attack and stroke. Clinical trials have shown that these complications can be prevented or significantly delayed by maintaining blood glucose levels as close to normal as possible. However, precise blood glucose control is difficult to achieve and requires multiple daily injections of insulin or use of an insulin pump. These regimens are extremely challenging to follow, especially for children and teenagers. In addition, one risk of such precise blood glucose control is the development of dangerously low blood sugars which could cause loss of consciousness, seizures or other complications.

To address these problems, researchers are investigating alternative approaches to restoring insulin-producing capacity, including attempts to develop an artificial pancreas, whole pancreas transplantation, and islet cell transplantation. Formidable bioengineering problems attend development of an artificial pancreas, and while researchers are working diligently to overcome them, a time frame for success cannot be predicted. Whole pancreas transplantation, while successful in some patients, is an extremely difficult surgical procedure and it requires lifelong treatment with immunosuppressive drugs that can have toxic side effects. This surgery is typically performed only in adults, often in conjunction with a needed kidney transplant for which immunosuppressive drugs would already be required. But, the success rate for the survival of the transplanted pancreas is much lower than the survival rate for the transplanted kidney.

Islet cell transplantation is a much simpler procedure than whole pancreatic transplantation and has several potential advantages. Until very recently, serious technical problems have been a major impediment to rapid progress in islet transplantation research. These key challenges have been: (1) to keep the body's immune defense system from rejecting the transplanted islets; and (2) to ensure that there is a sufficient supply of islet cells for transplantation. To date, only about five percent of people with diabetes who have received transplanted islets along with immunosuppressive drugs have been able to stay off insulin longer than one year. Stem cell research offers the potential to overcome these obstacles.

The renewed promise of islet cell transplantation derives from two complementary research opportunities. The first is the development of new methods for adjusting the immune system to keep the body from rejecting transplanted islet cells. The second is the prospect that stem cell research could ensure the needed supply of islet cells for transplantation. Human pluripotent stem cells offer the greatest promise of providing a limitless source of islet cells for treating and curing type 1 diabetes. Together, these opportunities offer unprecedented hope for curing type 1 diabetes, especially for children and young adults whose disease has not yet progressed to the point of debilitating complications.

HUMAN PLURIPOTENT STEM CELL RESEARCH AND THE NERVOUS SYSTEM

As significant as the promise of stem cells is for the treatment of diabetes, the potential of stem cells for treating diseases of the nervous system is equally impressive. It is startling to consider the range of neurological disorders for which scientists are actively investigating stem cell therapies in animal models. A partial list would include classic neurodegenerative diseases such as Parkinson's disease, Alzheimer's disease and amyotrophic lateral sclerosis (ALS); acute insults of stroke, brain trauma and spinal cord injury; multiple sclerosis and other demyelinating disorders; and inherited disorders such as Tay-Sachs disease and Duchenne muscular dystrophy. It might be possible to use stem cells to treat epilepsy and brain tumors. We have only begun to understand the extraordinary range of possibilities that stem cells present for treatment of these maladies.

The most obvious and exciting use of stem cells in neurological disorders is to replace lost nerve cells. Many diseases destroy particular types of nerve cells, and mature nerve cells cannot produce new cells to replace those that are lost. Animal experiments have demonstrated that the potential exists for coaxing stem cells to specialize and replace the dopamine cells that are lost in the brain in Parkinson's disease. A similar approach might apply to several other neurological disorders. Stem cells, given appropriate control signals, might specialize to replace the lost acetylcholine producing nerve cells in Alzheimer's disease, to restore lost motor neurons in ALS, or to produce inhibitory cells to help restrain electrical activity in epilepsy.

Replacing lost nerve cells is only the beginning of the list of possible therapeutic applications for stem cells. For some disorders, such as multiple sclerosis, stem cells might replace supporting cells—such as the glial cells, which provide the insulation necessary to allow some nerves to conduct electrical impulses rapidly. Stem cell strategies might be useful for correcting inherited defects. For example, in disorders that devastate children's brains we might rely on the ability of stem cells to migrate widely in the brain and supply the vital missing enzyme that leads to early and tragic death from Tay-Sachs disease. In addition, stem cells might regenerate the many different kinds of complex brain tissue that are damaged as a result of brain trauma or stroke. Transplanted stem cells might also supply natural growth and survival chemicals to pave the way for regeneration of remaining healthy neural tissue following spinal cord injury. Recent findings suggest that stem cells might be harnessed to seek out and destroy brain tumor cells that evade surgery or radiotherapy. The list of possible applications of stem cells continues to grow as we learn more about these cells.

FUTURE CHALLENGES

There is much to be done before these discoveries can be incorporated into clinical practice. First, we must do the basic research to understand the process by which human cells become specialized, so that we can direct pluripotent stem cells to become the type(s) of tissue needed for transplantation. For example, applying basic knowledge obtained from research in developmental and stem cell biology will enable the production of progenitor stem cells and the rational design of cellular therapies for human diseases such as diabetes. It is essential to underscore that studies of stem cells and the genes that regulate their development could be important for the development of ways to intervene in type 1 diabetes, and various neurological conditions, even beyond their use in transplantation.

Second, before these cells can be used for transplantation, the well-known problem of immune rejection must be overcome. Because human pluripotent stem cells derived from embryos or fetal tissue would be genetically different from the recipient, future research would need to focus on modifying human pluripotent stem cells to minimize tissue incompatibility or to create tissue banks with the most common tissue-type profiles. In addition, just delivering cells to the appropriate sites within the human body is an extremely difficult task. All of these factors argue for intensified

efforts to understand the basic biology of pluripotent stem cells and, with due caution, to apply what is learned towards the treatment of disease.

WHAT ARE THE LIMITATIONS OF ADULT STEM CELLS?

Recent findings have shown that even the adult human brain harbors neural stem cells, and that these adult stem cells can respond to a wide range of external and internal influences, such as learning, stress, exercise, seizures, and trauma. In addition, if pancreatic stem cells are ever isolated from adult tissue, it might be possible to direct these cells to differentiate into islet cells. The identification of adult pancreatic stem cells would open up entirely new prospects, beyond transplantation strategies, for encouraging the body's own stem cells to help repair damage.

It is important to note that scientists who are leading the way in studying adult stem cells present compelling arguments why we must pursue research on both pluripotent and adult stem cells. While some stem cells are present in adults, there may not be an adult stem cell for every type of cell in the body, and they may be present in only minute numbers. In addition, they may be very difficult to isolate; for example, in the case of adult neural stem cells, they may be confined to certain regions of the brain that are not easily accessible. More importantly, pluripotent and adult stem cells are not qualitatively alike. Pluripotent stem cells have truly amazing abilities to self-renew and to form many different cell types, even complex tissues, but in contrast the full potential of adult stem cells is uncertain, and, in fact, there is evidence to suggest they may be more limited. Unlike pluripotent stem cells, the adult stem cells may be able to divide only a limited number of times, which would limit their usefulness in the production of adequate numbers of well characterized cells for reliable therapies. Another issue is the question of how robust transplanted adult cells may be or how vulnerable to disease processes. In light of these limitations, it is important that we pursue research on both pluripotent and adult stem cells simultaneously.

NIH GUIDELINES

Given the enormous promise of human pluripotent stem cells to the development of new therapies for the most devastating diseases, it is important that both privately and federally funded researchers have the opportunity to pursue this promise. To this end, on December 2, 1999, NIH published draft Guidelines in the Federal Register. NIH is currently in the process of analyzing public comments and will publish final Guidelines in the Federal Register. NIH will not fund human pluripotent stem cell research until final Guidelines have been published and an oversight process is in place.

CONCLUSION

Mr. Chairman, we appreciate the opportunity to discuss this promising and extraordinary science and are pleased to respond to any questions you may have.

Senator SPECTER. Dr. Fischbach, could you describe in lay terms exactly what a stem cell is and how it works to cure or prospectively cure, say, Parkinson's disease?

Dr. FISCHBACH. A stem cell is a cell that has the capability of giving rise to many other types of cells. It is like the stem at the root of a tree. It also can renew itself. It can reproduce many times, but it also can, under appropriate cues, give rise to one or another specialized cell.

Senator SPECTER. And illustratively, how would that cell reproduce a cell which is deficient, causing someone to suffer from Parkinson's?

Dr. FISCHBACH. The environment and cues, many of which are known, can steer that cell into a pathway of differentiation, as it is called, to produce a nerve cell that is deficient in Parkinson's disease.

Senator SPECTER. So that it produces a nerve cell to replace a deficient nerve cell in a person's body.

Dr. FISCHBACH. Yes.

Senator SPECTER. And it is the deficiency of that nerve cell, for example, which causes Parkinson's.

Dr. FISCHBACH. That is exactly right.

Senator SPECTER. I have asked for a list of the ailments where there is the potential for cure by stem cells. I would like you to tell me if this is complete. Diabetes, Alzheimer's, heart disease, muscular dystrophy, Parkinson's, spinal cord, amyotrophic lateral sclerosis, stroke, multiple sclerosis, and Tay-Sachs. Is there potential for curing all of those ailments with stem cells?

Dr. FISCHBACH. I think there is great potential for curing or certainly reducing the burden of those diseases to an enormous degree.

Senator SPECTER. Taking Parkinson's, again for illustrative purposes, we have had testimony that we may be within 5 to 10 years, 5 to 7 years of a cure of Parkinson's. What is the expectation of accelerating, speeding up that process through the use of stem cells?

Dr. FISCHBACH. I think that estimate, which I have also heard and been very involved with, is very dependent on the use of stem cells. That is certainly one of the main efforts that will be undertaken to make the Parkinson's strategic research plan successful.

Senator SPECTER. Dr. Fischbach—and, Dr. Spiegel, you may want to comment on this as well—there have been suggestions that there are alternative sources for stem cells besides embryos: umbilical cords, a variety of other sources. Are there other ways to get an adequate number of stem cells to do the medical research which you have described?

Dr. FISCHBACH. I think this is a very important question. I think we both would like to comment.

My strong feeling is there are other sources. The key question is are they adequate? That is a matter for future research. Stem cells have been discovered in many tissues. Specifically, certain types of stem cells have been discovered in the brain, but we do not know as much about them in terms of how renewable they are and what the limits, and range of their capabilities are. And as I said, we need to maximize both of those.

My current reading of the literature is by neither one of those criteria are they as adequate as embryonic stem cells.

SUPPLY OF STEM CELLS

Senator SPECTER. Dr. Spiegel, you had made the comment about diabetes. What is your professional judgment as to whether there would be an adequate supply of stem cells to work on all of these terrible ailments if we do not utilize discarded embryos?

Dr. SPIEGEL. As I indicated in my comments, I think this would be tying one hand behind our back and tying the hands of our most superb scientists who are eager to pursue research in this area.

I indicated that I absolutely agree that we do need to pursue vigorously the adult stem cell area. We convened scientists and experts, from all over the country just this past couple of weeks at the NIH to review stem cell research. They were essentially unanimous in their feeling that we vigorously need to pursue the human pluripotent stem cell in addition to the adult stem cell question. This is particularly true in areas such as the pancreas where, un-

like the blood system and unlike the intestinal system, for example, there is as yet no definitive evidence for adult pancreatic stem cells.

Senator SPECTER. How many scientists were convened at the meeting which you referred to?

Dr. SPIEGEL. On the order of 200, including some of the really most superb scientists in the area of developmental biology and stem cells.

Senator SPECTER. Well, my red light just went on, so I am going to turn to our very distinguished ranking member, Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman. I apologize for being a little late. I will just make a statement. I know other people have been here before me, and I will defer to them for their questions. Then I will come back and ask my questions after them.

As you know, Chairman Specter and I have a very close bipartisan partnership when it comes to medical research. We both strongly believe that medical research holds great hope for improving the health and well-being of millions of our fellow Americans. I want to compliment and congratulate our chairman, Senator Specter, for his very bold leadership on this issue of biomedical research. It is a welcome breath of fresh air amid some of the confusion and I think some of the misinformation that has been bandied about on different aspects of biomedical research, but especially the one that we are here today to talk about and that is stem cell research. So, I just want to thank you, Mr. Chairman, for your leadership on this issue.

I am late because I was just at another hearing on defense. You were there briefly and I knew you had to leave before I did. We were talking about our defense structure, and I was struck by the fact that here we are putting enormous amounts of money in to protecting our country, keeping our country strong. It occurred to me, as I was listening to the amount of money that we are now asking for more missile defense and smart bombs and things like that, that it came back to me a little known fact, and that is in the last 5 years, we have spent more money on military research and development than we have spent on all biomedical research since the turn of the century. That shocks a lot of people when I tell them that, but it is true. You can add it up. I mean everything. I mean smallpox, diphtheria, polio, cancer, everything that we have spent all this money on since the turn of the century, we have spent more than that on military R&D in the last 5 years. So, we have smart bombs and we have smart missiles and we have a strong defense, and I am thankful for that.

We need the smart bombs and the smart missiles to knock out Parkinson's disease and ALS and spinal cord injuries and juvenile diabetes, all of the ailments that I believe can be overcome if we just really focus on research. So, when people tell us under your leadership that we are putting too much money in NIH, I always roll out that fact of what we have done in the military and how little we are doing in medical research.

In this area of stem cell research, it holds so much promise. Of course, there are different areas of getting stem cells: adult stem cells, embryonic, fetal. To say we are only going to use one source is, as you said, Dr. Spiegel, to tie one hand behind our backs. We need to unleash an army, unleash an army of researchers all over this country to use this new resource and to bring us forward in developing stem cell research to the point where I believe it is going to take us. No one can guarantee it. No one can guarantee what it is going to lead to, but to blindly stop it now or to tie one hand behind our back I think is basically to doom millions of Americans and people around the world to perhaps lives that they might not otherwise be leading.

So, I am grateful that you are here. I just wanted to make that statement to say that we need to push the boundaries.

Again, we need the Federal guidelines according to the Bioethics Commission and their findings and the statement they came out with. As you probably have pointed out in your testimony, private research is going on in this area. But to the extent that it is done privately and done chaotically, it is going to push back the time when we have the kind of discoveries that would come if we did it in a regulated, ethical manner. If we did it that way and we were able to guide and direct this research, I believe the fulfillment of the promise would come much more rapidly than if we just leave it in a chaotic system out there with no supervision and no ethical controls.

Mr. Chairman, thank you for affording me this time.

Senator SPECTER. Well, thank you very much, Senator Harkin. Thank you for your good words and for our bipartisan partnership.

Our practice is to take Senators in order except for the ranking member because of the structure of the Senate. We turn now to Senator Reid.

OPENING STATEMENT OF SENATOR HARRY REID

Senator REID. Mr. Chairman, I appreciate very much the bipartisan tone that this subcommittee has set. It is easy to talk in a bipartisan tone in a subcommittee hearing, but you and Senator Harkin have done that on the Senate floor. An example was the budget battle that we won on the Senate floor and lost in conference, but I admire and respect the work that you did on the budget.

I had, Dr. Fischbach, Dr. Spiegel, the good fortune this morning to spend some time with Dr. Ruth Kirschstein, the acting Director of NIH. We talked about a number of things, but one of the things that we spoke about is her experience. She talked about her work in the early 1950's when they knew they were getting close to finding a cure—I do not know if “cure” is the right word, but a way to prevent polio. And growing up in that era, I can remember that was the thing that we were most afraid of. It was not the nuclear holocaust. We were afraid of getting polio, all the young boys and girls. And she said that they knew that they had in their sight a way to cure polio.

We have talked this morning about diabetes, Alzheimer's, Parkinson's, and a number of other things. Do either of you gentlemen think that we have in sight a cure for some of these diseases that

we are so afraid of today: Parkinson's, Alzheimer's? Half the money we spend in nursing homes in America today is spent on those two diseases.

Dr. FISCHBACH. I think there is enormous hope for real advances and in some of the cases, real cures in the sense of stopping the progression of a disease. The analogy with polio is an interesting one and quite stimulating to think about. That was due to the infection by a specific organism and a vaccine worked a miracle.

I think in the disorders I am most familiar with, the complexity of the brain is a hurdle to overcome.

Senator REID. And you made that very clear in your testimony.

Dr. FISCHBACH. But I am as optimistic now as I have been throughout my scientific career in the last 30 years that we will be able to stop and in some cases reverse disorders of the brain that are associated with loss of nerve cells.

Senator REID. Dr. Spiegel, do you agree with Dr. Fischbach?

Dr. SPIEGEL. I would like to make two points in response to your question.

First, I want to indicate, outside of the context of the immediate subject, that we are not focused only on cures. Those are incredibly important, but you mentioned the polio vaccine. Prevention is critical, and we are very heavily focused on prevention of many diseases, including type 1 diabetes.

TRANSPLANTATION

In terms of cures, the situation for some of the diseases—I would say type 1 diabetes and liver failure—the situation is particularly interesting with respect to transplantation. Transplantation is a potential cure, as I indicated, for both of these diseases, and with immunology advances, we have the possibility of not just substituting one disease, complications of treatment with immunosuppressive drugs, for another, but rather of allowing these individuals to lead a relatively normal life.

The problem, though, is that despite the best efforts of increasing organ donation, there simply is an inadequate supply to provide these cures. And this is where stem cell research is so important. I do not want to over promise, and I think we always have to be very cautious. I think Senator Harkin made the point we cannot guarantee it. But certainly, if we do not do the research, it will not happen. That is guaranteed.

Senator HARKIN. That is guaranteed.

Senator REID. Let me say that in biomedical research I certainly do not want anyone's hands tied behind them. We have scientists all over the United States and the direction that they take and the grants that they write that are okayed by you folks at NIH and the work that you do at NIH—I want no hands tied behind anyone's back. I can speak, as someone who has a pro-life voting record here in the Senate, that as far as I am concerned, there are no holds barred on what you should be able to do using embryos, any other place that you feel that you can get stem cells. I am all behind you and I think that the work that you have done has been exemplary and I look forward to joining hands with the members of this subcommittee, the members of the full committee, and the Senate in

giving you all the resources that you need to help people that really need help.

Dr. SPIEGEL. I am certainly grateful for your support and for that of the chairman and Senator Harkin. It has been incredibly important throughout. We appreciate the support for NIH in general and on this issue. I want to just articulate that.

Senator REID. Mr. Chairman, I have other obligations. I wanted to come and make this brief statement. Again, it is a great panel. I am sorry I cannot be here for the rest of it.

Senator SPECTER. Well, thank you very much, Senator Reid, and thank you for your comments about the funding. I think it is worth just a sentence or two to note that in the past 3 years, this subcommittee has taken the lead on increasing NIH funding by more than \$5 billion. It was at \$13 billion, and in the last 3 years, we have added some \$5 billion. And we have done that over the votes which we have not gotten extra funding for, but we have established priorities. One of my frequent statements is that the National Institutes of Health are the crown jewels of the Federal Government. Some say the only jewels of the Federal Government.

But there is nothing more important than health. Health is number one. We have a very large group here today, as we have had with juvenile diabetes and as we have had with cancer and as we will have later in a couple of weeks with amyotrophic lateral sclerosis. The public is very concerned about medical research and about curing Parkinson's or Alzheimer's, these dreaded diseases, or heart disease. And this subcommittee intends to do what it can to get that done.

Senator Murray.

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Well, Mr. Chairman, thank you very much for having this hearing. I want to just personally thank you, Mr. Chairman, for all the time and effort you have spent on this particular issue. I think the work you have done has really built a balanced and a fair hearing record on stem cell research and I think has moved us in a very positive direction.

And I want to thank Senator Harkin as well for his work on this and his excellent statement as well.

You know, my father had multiple sclerosis. He was diagnosed when I was 15. He lived most of my life in a wheelchair, and I know the personal hope that he had many times and the disappointments he had throughout his lifetime.

This research, obviously, will not help him. He passed away several years ago, but I know of thousands and thousands and thousands of families who are counting on us to do the right thing so that there is hope in their future.

So, I really want to thank you, Mr. Chairman, Senator Harkin, for your work on this, and hope that we can continue to push the limits on this and find some resolution not only for MS, for Parkinson's, Alzheimer's, for so many other exciting opportunities that are out there.

I have listened to the people who oppose this, and I think part of what we are hearing is that they have little understanding of some of the bioethical requirements that NIH has regarding stem

cell research. If you could just take a minute and outline for us what ethical standards you do adhere to in this research, I would appreciate it.

Dr. FISCHBACH. Well, we can both take a shot at that. I think the guidelines being proposed by the NIH address these really awesome ethical issues in terms of ensuring informed consent on the part of those who donate embryos, ensuring the utmost care in the scientific use and complete dedication to the full informed use of the data. They are complex and they involve the use of the tissue and the circumstances under which it can be used. It involves oversight to make sure that these guidelines are followed. It involves review by scientists, lay people on council, and NIH officials. So, I think they are a rather complete examination of the legal, the ethical, and the social issues, as well as the scientific issues involved.

Senator MURRAY. Dr. Spiegel?

Dr. SPIEGEL. The only point I would add is very much in line with what the chairman had to say, and that is the guidelines try to ensure to totally dissociate the issue of the availability of embryos from the issue of the use of the stem cells. Informed consent, as we have heard, no monetary remuneration, nothing that would encourage this, in other words, to totally dissociate the two issues and to allow real public oversight and scrutiny of the way that these stem cells would be used. I think that is what is vitally important.

Senator MURRAY. Thank you.

We all understand that without Federal standards and guidelines the potential for abuse of this research is significant. I think the recent front-page article in the Washington Post made that point very clear.

From your opinion, if there is no Federal involvement in there, what would the ramifications be?

Dr. FISCHBACH. My own opinion is that the Federal involvement is critical for the ethical conduct of this type of science. Science conducted behind closed doors is behind closed doors, and we cannot regulate that at all or bring the most disinterested parties to the table to think about the ramifications.

Dr. SPIEGEL. Certainly the ethical issues are paramount, but the other point we have alluded to several times. There is a lot of work going on in the private sector, and at some level, that is fine. But only with Federal funding, and in addition, the oversight, are we going to really see all the talented scientists who want to work in this area contribute and give us their capabilities.

Senator MURRAY. Would there also be ramifications for who would have access to the research and the results of that research if the Federal Government is not involved?

Dr. FISCHBACH. At the present time, we do not have any reason to believe there would be limited access. But this is a very dynamic, rapidly moving field, and there is always the potential for restriction of access. But we do not—perhaps Dr. Spiegel would like to add—see any evidence at the present time for restriction of access.

Dr. SPIEGEL. I will just leave it at that.

Senator MURRAY. All right. Thank you very much, Mr. Chairman.

Senator SPECTER. Thank you, Senator Murray.

Before moving on to the next panel, just a comment about the time table. It was on January 15 of last year that the Health and Human Services General Counsel determined that the use of Federal funds to support stem cell research did not violate the appropriations ban. It was not until April 8 that a meeting was held with public and private groups to discuss the guidelines. On December 2, there were draft guidelines published with the comment period for 60 days, which would have run out in early February. That was extended to February 22.

I know there are a great many comments, but there needs to be a sense of urgency to getting this done because every day is a day lost which could be saving lives. This subcommittee has placed a very high priority on this subject, having five hearings, more than we have had on any other subject, because of the importance of focusing public attention and getting it moving. So, we would urge you to apply a sense of urgency here and get it done.

Dr. FISCHBACH. I think we all absolutely agree with that.

Senator SPECTER. We will not hold you any longer, so you can go back to your offices to get this done.

Thank you very much.

We will now turn to our second panel: Senator Sam Brownback, Dr. Frank Young, and Ms. Mary Jane Owen.

In our previous hearings, we have heard from witnesses who have been opposed to eliminating the Federal ban. In our last hearing, we heard from Congressman Jay Dickey who opposes Federal funding on embryos in stem cell research. We consider it very important to have balance in the presentation of the views so that all of the information can be available to the Senate when we debate this matter and render our judgments and views can be available to the American people.

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

Senator SPECTER. Our lead witness here is Senator Sam Brownback, elected to the Senate in 1996. It says to take the place of Senator Dole. I do not know that anybody can take the place of Senator Dole.

Senator BROWNBACK. That is not possible.

Senator SPECTER. Senator Brownback and I agree on many, many matters. We disagree on this one.

We share common roots. I was born and raised in Kansas and sometimes like to think of myself as Kansas' third Senator.

Senator BROWNBACK. We do too.

Senator SPECTER. I would have to put myself fourth behind Senator Dole whose presence is still on the scene.

Senator Brownback serves on the Commerce, Science, and Transportation Committee, as well as the Health, Education, Labor, and Pensions Committee. He chairs the Subcommittee on the Middle East for the Foreign Relations Committee where he has been very active.

He grew up in Parker, Kansas, has a law degree from the University of Kansas and his bachelor's from Kansas State.

Welcome, Senator Brownback, and we look forward to your testimony.

Senator BROWNBACK. Thank you, Senator Specter, Senator Harkin, Senator Murray. Thank you for allowing me the opportunity to speak in front of you this morning to testify. I do not know that I would consider myself the lead witness of this panel. You have a former FDA Commissioner and I think you will hear from Ms. Owen a very clear statement as well.

Senator SPECTER. In the Senate, Senator Brownback, you are the lead witness.

Senator BROWNBACK. Well, you are kind.

I appreciate this opportunity. I have great respect for your thoughts. I have a great respect for your heart on these matters and on all matters, but on this one, we do disagree. I will be highlighting why I believe this issue should be handled another way, that we should be funding aggressively research in the area of adult stem cell research.

I have supported this panel's efforts to double NIH funding over a 5-year time period. I think that is critically important, very important, that we fund the science.

I also think it is very important that we have a critical ethical view as to what we are doing. At the center of this debate, at the very center of this debate, is the real question: Is the young human person or property? And that is at the very center of what this debate is about, and I want to articulate that further. But that is the center of what this question is about.

We are here today to discuss some of the issues that have been raised regarding Federal funding for human embryonic stem cell research. My position on this is that Federal funding of human embryonic stem cell research is illegal, is immoral, and it is unnecessary. And I want to go into those three issues.

As this subcommittee is well aware, Congress outlawed Federal funding for harmful human embryo research in 1996 and has maintained that prohibition ever since. The ban is broad based and specific. Funds cannot be used for—and I quote now from the act—“research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death.” The intent of Congress is clear. If a research project requires the destruction of human embryos, no Federal funds should be used for this project.

NIH recently published its proposed guidelines to circumvent this language. Marcy Wilder, who I might add was a former legal director for the National Abortion Rights Action League and now Associate General Counsel at the Department of Health and Human Services, wrote a legal opinion that sought to justify the research being proposed by the NIH.

Yet, despite this fig leaf of the HHS legal opinion, the fact remains that this research is illegal. It is illegal for this reason. The deliberate killing of a human embryo is an essential component of the contemplated research, and without the destruction of the embryo, the proposed research would be impossible.

Now, despite the legal gyrations of HHS, this is a point that is not lost on the National Bioethics Advisory Commission. Although their conclusions are wrong in my estimation, NBAC observes in their recommendations to the President the inconsistencies of the HHS legal opinion and the NIH recommendations. Accordingly,

NBAC recommends an approach that is at once both more honest and more heinous.

Which brings us to a discussion of the morality of this legislation. The NBAC position is given legislative form in the Senate bill that we are discussing today, S. 2015, currently referred to the Health, Education, Labor, and Pensions Committee on which I sit. Among other and perhaps more serious policy changes, it would constitute a lifting of the ban on human embryo research. In brief, the Stem Cell Research Act of 2000 seeks to allow Federal funding for researchers to kill living human embryos. Under this bill, Federal researchers would be allowed to obtain their own supply of living human embryos which they would then be allowed to kill for research purposes.

Now, the very act of harvesting cells from live human embryos results in the death of the embryo. Therefore, if enacted, this bill would result in the deliberate destruction of human embryos.

This bill will even violate current Federal policy on fetal tissue in my estimation, which allows harvesting of tissue only after an abortion was performed for other reasons and the unborn child is already dead. Under this bill, the Federal Government will use tax dollars to incentivize the killing of live embryos for the immediate and direct purpose of using their parts for research.

Taxpayer funding of this research is problematic for a variety of reasons. First among those concerns is that if Congress were to approve this legislation, it would officially declare for the first time in our Nation's history that Government may exploit and destroy human life for its own or somebody else's purposes.

Now, this research is also problematic because it would use Federal tax dollars to allow the Government to procure and therefore own a vast supply of living human embryos. Now, this notion of ownership, particularly by the Federal Government, of other human beings I believe is deeply disturbing.

The bill even allows Federal funding for destructive research using embryos created by cloning so long as that does not result in—quote from the legislation—“the reproductive cloning of a human being.” On the one hand, this is an attempt, it seems to me, to authorize the critical issue of human cloning when what is really needed is the continuation of the full public debate on this point. On the other hand, this approach recognizes that for the purposes of possible clinical applications, particularly to avoid possible tissue rejection, human cloning is the logical next step, or so-called therapeutic cloning. This means that live embryos created by researchers can be experimented on and destroyed but cannot be allowed to survive to live birth. That is prohibited in the legislation, which seems to create a new class of human beings who under the law will simply not be allowed to live.

I think history has already taught us some important lessons on separating human beings into different classes. The Dred Scott case issue was on that point where Dred Scott held that African Americans at that time “had no rights which the white man was bound to respect.”

Now, I am not suggesting at all that that is the intent of the chairman or of the ranking member of this committee, but if you look into what the effect of what would happen with this legisla-

tion, I think we get terribly close to those same issues that we have seen throughout our history, and it is deeply troubling to me.

My final point is that the human embryonic stem cell research is unnecessary, and this is a key point because I want to see people healed, which is what the chairman is after, which is what the ranking member is after. We want to see these diseases no more hit our people or anybody else across the planet. That is our heart and that is our objective, and on that we all agree. That is why I am saying this is not necessary. We can go on the areas of legitimate research into adult stem cells which do not create the moral and ethical difficulties that we do in human embryo stem cell research.

Dr. Young will testify more about what is taking place in this area in the research now.

In the past, Congress has increased funding for NIH. New advances in adult stem cell research, being reported almost weekly, show more promise than destructive embryo research. And I want to give just a few of these.

Just this past February, writing in the journal *Neurons*, scientists at Children's Hospital in Boston announced that they had successfully generated new brain cells in birds using adult neural stem cells.

Writing in the March 20 issue of *Nature Medicine*, University of Florida scientists reported that they reversed insulin-dependent diabetes in mice by using adult pancreatic stem cells. Their quote, "The next step is to take this into humans, they say." They have extracted and cultivated viable adult brain stem cells from eight living human patients undergoing surgery for other reasons.

Writing in the March 17 issue of *Science*, University of Toronto researchers reported they found retinal stem cells in the eyes of adult mice, cows, and humans, and have shown that they can be used to produce new neurons presenting the prospects of repairing or regenerating damaged retinas and restored sight.

In April, Dr. Karen Obote and colleagues at Children's Hospital in Boston reported at a meeting of the American Association of Neurological Surgeons in San Francisco that they can use adult neural stem cells to target brain tumors in mice. The cells could be used to reduce or kill the tumors by delivering new genes or carrying cancer drugs to where they are needed.

Clearly we must continue to fight and help cure diseases and to eliminate suffering. I have got a chart over here on some of these areas that are just now coming out in the adult stem cell area.

The other issue that they—we do not have the ethical/moral problems. We do not have the problems of the immunity system rejecting cells, if we use our own adult stem cells.

Mr. Chairman, ranking member of this committee, I have great respect for your heart and your desire in here, and I think on that we completely agree. And I have no question about your motives in doing this. I just think we are crossing an enormous issue here of looking at this human life as a piece of property rather than as a person.

PREPARED STATEMENT

And we do not need to go there. We can address these issues with adult stem cells. We can address these issues with increased funding in NIH and increased funding in these key areas that are showing so much promise right now to address these terrible diseases. That is the way we can go together. That is where our hearts can be pure and we can do the right thing and feel good about it rather than accepting the deliberate killing of one human innocent life in order to help another, which has never been right throughout human history.

I thank you, Mr. Chairman, for your patience and your willingness to hear me out on this point.

[The statement follows:]

PREPARED STATEMENT OF SENATOR SAM BROWNBACK

Thank you Mr. Chairman and members of the Subcommittee for the opportunity to testify on this very important issue.

We are here today to discuss some of the issues that have been raised regarding federal funding of human embryonic stem cell research. My position is that federally funded human embryonic stem cell research is illegal, immoral and unnecessary.

As this subcommittee is well aware, Congress outlawed federal funding for harmful embryo research in 1996 and has maintained that prohibition ever since. The ban is broad-based and specific; funds cannot be used for “research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death.” The intent of Congress is clear if a research project requires the destruction of human embryos no federal funds should be used for that project.

The language of the ban is clear—as are the lessons from history. The Nuremberg Code (from the trials of Nazi war criminals) states, “No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur.” Also, the World Medical Association asserts in the Declaration of Helsinki that, “In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.” Further, “concern for the interests of the subject must always prevail over the interest of science and society.” As well, it is hardly necessary to note that it has already been proven biologically that an embryo constitutes human life (MERCK MANUAL and NBAC recommendation to the President, “Ethical Issues in Human Stem Cell Research”).

Pope John Paul II, quite independent of government law, and particularly of his own ban on embryo research states, in his encyclical, *Evangelium Vitae*, “[The] evaluation of the morality of abortion is to be applied also to the recent forms of intervention on human embryos which, although carried out for purposes legitimate in themselves, inevitably involve the killing of those embryos. This is the case with experimentation on embryos, which is becoming increasingly widespread in the field of biomedical research and is legally permitted in some countries. Although “one must uphold as licit procedures carried out on the human embryo which respect the life and integrity of the embryo and do not involve disproportionate risks for it, but rather are directed to its healing, the improvement of its condition of health, or its individual survival”, it must nonetheless be stated that the use of human embryos or fetuses as an object of experimentation constitutes a crime against their dignity as human beings who have a right to the same respect owed to a child once born, just as to every person.

“This moral condemnation also regards procedures that exploit living human embryos and fetuses—sometimes specifically “produced” for this purpose by in vitro fertilization—either to be used as “biological material” or as providers of organs or tissue for transplants in the treatment of certain diseases. The killing of innocent human creatures, even if carried out to help others, constitutes an absolutely unacceptable act.”

THE NATIONAL INSTITUTES OF HEALTH AND THE HHS

NIH recently published its proposed guidelines to circumvent the congressionally imposed ban on destructive human embryo research.

Marcy Wilder, former Legal Director of the National Abortion Rights Action League, and now Associate General Counsel at the Department of Health and

Human Services wrote a legal opinion that sought to justify the research being proposed by the NIH. Yet despite the fig leaf of the HHS legal opinion, the fact remains that this research is illegal. It is illegal for this reason: the deliberate killing of a human embryo is an essential component of the contemplated research; and without the destruction of the embryo the proposed research would be impossible.

Despite the legal sophistry of HHS, this is a point that is not lost on the National Bioethics Advisory Commission. Although their conclusions are wrong, NBAC observes in their recommendation to the President the inconsistency of the HHS legal opinion and the NIH recommendations. Accordingly, NBAC recommends an approach that is at once both more honest—and more heinous.

WHICH BRINGS US TO A DISCUSSION OF THE MORALITY OF THIS RESEARCH

The NBAC position is given legislative form in Senate Bill 2015. S. 2015, currently referred to the Health Education Labor and Pensions Committee, on which I sit would, among other and perhaps more serious policy changes, constitute a lifting of the ban on human embryo research.

In brief, the “Stem Cell Research Act of 2000” seeks to allow federal funding for researchers to kill living human embryos.

Under this bill federal researchers would be allowed to obtain their own supply of living human embryos, which they would then be allowed to kill for research purposes.

The very act of harvesting stem cells—or perhaps more accurately constructing so-called embryonic stem cells—from live human embryos results in the death of the embryo. Therefore, if enacted, this bill would result in the deliberate destruction of human embryos.

This bill even violates current federal policy on fetal tissue, which allows harvesting of tissue only after an abortion was performed for other reasons and the unborn child is already dead. Under this bill, the federal government will use tax dollars to kill live embryos for the immediate and direct purpose of using their parts for research.

Taxpayer funding of this research is problematic for a variety of reasons. First among those concerns is that, if Congress were to approve S. 2015, it would officially declare for the first time in our nation’s history that government may exploit and destroy human life for its own or somebody else’s purposes.

This research is also problematic because it would use federal tax dollars to allow the government to procure, and therefore “own,” a vast supply of living human embryos. The notion of “ownership,” particularly by the Federal government, of other human beings is deeply disturbing.

The bill even allows federal funding for destructive research using embryos created by cloning, so long as this does not result in “the reproductive cloning of a human being.” On the one hand, this is an attempt to authorize the critical issue of human cloning by stealth; when what is really needed is the continuation of the full public debate. On the other hand, this approach recognizes that for the purposes of possible clinical applications, particularly to avoid possible tissue rejection, human cloning is the logical next step—so-called, “therapeutic cloning.” This means that live embryos created by researchers can be experimented on and destroyed, but allowing them to survive to live birth is prohibited. The bill defines a new class of human beings who, under the law, will simply not be allowed to live.

History has already taught us the lessons of separating human beings into different classes. The Dred Scott case held that African-Americans, “had no rights which the white man was bound to respect.” Today, 143 years later, it is precisely this same argument which is now being used to legitimate the destruction of human embryos. It is the contention of S. 2015, as well as the NIH, that human embryos do not have rights which people, already born, are bound to respect.

HUMAN EMBRYONIC STEM CELL RESEARCH IS ALSO UNNECESSARY

There are legitimate areas of research which are showing more promise than embryonic stem cell research and which do not create moral and ethical difficulties. Dr. Frank Young, former FDA commissioner, under Ronald Reagan has detailed some of the alternatives in his testimony which you will hear later.

In the past, Congress has increased funding for NIH. New advances in adult stem cell research, being reported almost weekly, show more promise than destructive embryo research.

Just this past February, writing in the journal *Neuron*, scientists at Children’s Hospital in Boston announced that they successfully generated new brain cells in birds using adult neural stem cells (MSNBC, Feb. 23).

Also, writing in the March 2000 issue of *Nature Medicine*, University of Florida scientists reported that they reversed insulin-dependent diabetes in mice by using adult pancreatic stem cells. "The next step is take this into humans," they say. They add that they have extracted and cultured viable brain stem cells from the hippocampus of eight living human patients undergoing surgery for other reasons (Reuters, February 28).

Writing in the March 17 issue of *Science*, University of Toronto researchers reported that they found retinal stem cells in the eyes of adult mice, cows and humans and have shown that they can be used to produce new neurons, presenting the prospect of repairing or regenerating damaged retinas and restoring sight (UniSci, March 17).

In April, Dr. Karen Aboody and colleagues at Children's Hospital in Boston report at a meeting of the American Association of Neurological Surgeons in San Francisco that they can use adult neural stem cells to target brain tumors in mice. The cells could be used to reduce or kill the tumors, by delivering new genes or carrying cancer drugs to where they are needed (Reuters, April 10).

Clearly we must continue to fight to help cure disease and to alleviate suffering. However, it is never acceptable to deliberately kill one innocent human being in order to help another. When did it become acceptable to use an evil means to pursue a good end, even a great one? Doesn't the so-called good end actually become bad by using bad means? If we manage the cure of some diseases and the betterment of some aspects of bodily health by means that involve the killing of the most defenseless and innocent of human beings, we will rightfully be judged harshly by history as having sought some benefits at the expense of our humanity and moral being. The twentieth century has already taught these lessons—are we to ignore them at the beginning of this century? Or to put it another way, as George Santayana once said, "Those who cannot remember the past are condemned to repeat it."

Thank you, Mr. Chairman.

Senator SPECTER. Well, thank you very much, Senator Brownback for your testimony. We appreciate your sincerity and your position, and we will have some questions on the morality and the alternatives to human stem cells. But first we are going to go to our other two panelists.

**STATEMENT OF FRANK YOUNG, M.D., Ph.D., FORMER COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF AGRICULTURE**

Senator SPECTER. I would like to call now on Dr. Frank Young, Commissioner of the Food and Drug Administration from 1984 to 1989. Previously served as Deputy Assistant Secretary for Health in the Bush administration and as Director of the Department of Health and Human Services of Emergency Preparedness. He was Dean of the University of Rochester Medical School, a microbiologist by training. He now serves also as pastor of adult ministries at the Fourth Presbyterian Church in Bethesda, MD.

It is a 1-year anniversary, Dr. Young, since you testified on April 26 last year. So, welcome back.

Dr. YOUNG. Thank you very much, Mr. Chairman and the distinguished Senator Harkin. I thank you both from the bottom of my heart for your years of steadfast support of the National Institutes of Health and biomedical sciences. I have had a chance to work with both of you in the past and I know of your genuine commitment. I only urge you on in the support of this.

As a pastor, it would be remiss of me not to remind all of us that we are totally biodegradable. I have conducted more memorial services than I would like to admit now. So, as we look at curing disease, we have to recognize that we each at one day will ourselves die. And it is with that perspective of the role of research that I would like to put my comments before you today.

I also want to thank you, Mr. Chairman, for the excellent way in which you have held these hearings. You have brought forth witnesses of all persuasions, a rare event in Washingtonville. And I thank you for what you have done in that way.

Two quotes might frame this, and I have brought for the press table the copy of the Science issue, which I am sure you have, if not, I can provide you with more of these.

One is cited in there by Rabelais in 1532 who stated, "Science without conscience is but death of the soul." So, we have to look at where and how we develop our advances.

And more recently Robertson stated in a California Law Review—and I quote—"Science is not an unmitigated blessing. It is expensive and its discoveries, like the Tree of Knowledge in Eden, expands man's capacity for evil as well as good. More knowledge is not a good in itself, nor is it necessarily productive of net good. Society as the provider of resources, the bearer of costs, the reaper of the benefits has an overriding interest in the consequences of science and hence the direction and routes that research takes," which you are doing today.

I will just summarize my statement.

Senator SPECTER. That is fine, Dr. Young.

Dr. YOUNG. There are these issues that I think are critical.

First, we are dealing with utilitarian ethics. We are focusing on the decision of whether or not to use the promise of potential good for the end of a life that we know is essentially here. And that decision, as the Senator said, is not one to be taken lightly. So, as we focus our energy, it is at what price is humanness in the 21st century.

My worry, as both a physician and a pastor, is the degree of violence that we see on human beings. We just saw it the other day at the National Zoo. We see it in Bosnia. We have seen it in Kosovo. We have seen it in many places. And I believe the sacredness of human life is at the very heart of what we will be in the 21st century.

I would suggest that as we do research, we take research in a cautious fashion and first of all do no harm. As the Senator summarized, we are blessed with the capacity to have stem cells in most every organ in the body, and it was also stated in the former panel. These enable us to regenerate our skin, to be able to have liver regeneration at times. These are very important parts that are just being discovered now.

When I last testified before you, Mr. Chairman, we had very little knowledge of adult stem cells. One of the most interesting ones was one in mice recently where they were able to take from bone marrow, the adult bone marrow, and isolate stem cells in as few as 50 stem cells added to the animal with liver disease was able to produce a change in symptomatology.

The stem cells from an adult have these advantages. One, it does not carry the moral baggage. Two, they are readily isolated particularly from bone marrow. Three, they can be isolated and preserved from cord blood, and in fact, one company now is advocating at a small fee the preservation of cord blood stem cells for use of the individual later on. Therefore, it is not a need to destroy embryos that are "spare" at this time.

Four, I would like to say that we have been lax in the Federal Government in regulating in vitro fertilization clinics. Some of the margins that we see now are related to this very expensive therapy unregulated that does generate these "excess" individuals. And if we are not careful, they can easily regenerate and develop more of "spare" embryos.

Next, it is critical to realize that the immunological capacity and also the relative ease of differentiating the adult stem cell vis-a-vis the pluripotent stem cell from embryos may provide an advantage. As the first panel said, these are promises. Remember President Nixon led a war on cancer in 1968. Unfortunately, we are still a ways from there.

Research is critical but research crossing a line of destroying human life I believe borders on not only the unnecessary but the immoral at this time.

I thank you, sir, for the privilege of testifying again.

Senator SPECTER. Thank you very much, Dr. Young, for your testimony. Thank you.

STATEMENT OF MARY JANE OWEN, M.S.W., EXECUTIVE DIRECTOR, NATIONAL CATHOLIC OFFICE FOR PERSONS WITH DISABILITIES

Senator SPECTER. We now turn to Ms. Mary Jane Owen, Executive Director for the National Catholic Office for Persons with Disabilities since 1991. In 1986, Ms. Owen established the Disability Focus, Incorporated which is an organization promoting a disability perspective on all social policy and advocating for the appointment of qualified people with disabilities at all levels of Government and business. She received her master's degree in social work from the University of California at Berkeley.

We welcome you here, Ms. Owen, and if we may be of any assistance to you on the hearing or anything else, let us know. We look forward to your testimony.

Ms. OWEN. Thank you. That is very kind of you to offer your assistance.

I am so gratified to be here to be able to participate in the testimony that you are hearing about this very critical issue.

If I overstay my time in terms of talking, please forgive me. It is not out of disrespect for the lights. As a blind, partially hearing person, it is very hard to stop me when I get going. So, I simply in advance say please give me warning if I have extended—

Senator SPECTER. Ms. Owen, we will give you a little slack here.

Ms. OWEN. OK.

I am very concerned about this topic. I think that it is completely unnecessary and immoral for us to use live embryos, to use living human beings for research which is unnecessary because as my two compatriots here on this panel have stated so clearly, we have alternatives.

I hope that you will review my written testimony which has been submitted to you. I think that so much of what I was planning to say, in terms of the moral concerns, as well as the alternatives, have already been very, very adequately covered by them. But I do think that as a disabled person, as a person who has been a national leader in this disability rights movement since 1972, that I

do want to share some of my concerns as it relates to disability and cure.

The title that I gave my testimony involves the word “frenzied.” I think that we are involved in a frenzied pursuit based on fear. As a matter of fact, I think one of the members of the committee even referred to the fact that we fear our own vulnerability.

You know, it was over 20 years ago that I first developed a definition that has been accepted rather widely, and that is that disabilities are the normal, expected, anticipated outcome of the risks and stresses of the living process.

Now, I think that many of us do not accept that reality. We are fragile creatures. I do not think that it is an error in our Creator’s planning. I think that our vulnerability is one of the factors that causes us to be more civilized.

I see fear in my society almost every day. I give some examples in my written testimony where people approach me and say, I would rather be dead than live like you. I am blind. I am partially hearing. I am a wheelchair user because of neurological and spinal injuries. But I live a very successful life because of the advances that we have made in treatment and in rehabilitation.

Sometimes as an outpatient at the National Rehabilitation Hospital, I am amazed at the lack of those services that are available to young people currently entering that facility. When I was there most recently, I was there for 6 months. That does not happen anymore. Young people today are being turned out of that facility in a matter of weeks. We need to fund the kind of things that allow people with disabilities to truly fulfill their potential.

Yes, I think we are terrified of disabilities. We are terrified of disease.

It was suggested that possibly we were looking for a cure. I think that realistically what we can expect is a postponement of our mortality, and Dr. Young referred to that. We do not cure our vulnerability because it exists, and I would submit that it is a positive, not a negative.

When I travel—and I often travel alone. And it is obvious to everyone, including you, Mr. Chairman, that I might need assistance. It is amazing to me how, as I travel alone, as I need help, as I need assistance, that people thank me when they have been given the excuse to be civilized, to be interactive, to be a part of a larger community.

I would further submit that this fear, this frenzy to escape our destiny, which truly is what Dr. Young was referring to—we are biodegradable. I would submit that our fear, our frenzied fear, our dread, our abhorrence of our shared vulnerability is what drives this pursuit of some way to escape.

You know, as a child, I mentioned in my written testimony that there was a Navajo rug that hung on the family home. There is always a flaw in those beautiful Navajo rugs. Any of you from New Mexico know this. And I remember as a child recovering from meningitis, running my finger over the break in the pattern and thinking this is profound. This is profound.

We are not manufactured like Ken and Barbie. We are not uniform. You know, Ken and Barbie, if they come down the production line and there is a flaw, they are pulled out. They are no longer

a part of the Mattel family. They are cast aside into the bin for discards. Their essence is regenerated and becomes a part of another Ken or Barbie. We, in contrast, are created unique, separate from all else. We have gifts, we have weaknesses. My weaknesses, your weaknesses, my strengths, your strengths, each one of you, I would suggest that those intertwined weavings create the strongest social fabric.

So, I would say I would beg you to stop and think. Is the fear of disability so great in this Nation that we must choose an immoral and unnecessary strategy to avoid recognition that—yes, we do need to cure, we do need to treat, we do need to find ways to prolong life. And I am fully in support of stem cell research, and I would hope that NIH would continue to be funded to the extent that it can pursue adult stem cell research. Adult stem cell research.

You have heard and I read some of the same articles that Senator Brownback referred to. They are so inspiring. Do I want to see again? Do I want to hear as well as I used to? Do I want to dance again? Yes, it would be okay. But please know that I do not want those things at the cost of any living person. And I consider live embryos to be people.

I want to just say one more thing in terms of my daughter. My daughter was born with a 1 percent chance of survival. I had heard as a young woman during the height of the push for abortion that children the size of my daughter were simply collections of cells. I watched her. I watched her tenacity. I watched her desire to live. I watched every breath as she was breathing it. If she had not had a pro-life doctor there who spent 24 hours promoting her life, she would not have survived. She struggled to stay alive. Every time I hear people talk about the ease of utilization of live embryos, I am reminded of the beauty of that tiny, tiny little body of my daughter. She is a wonderful, brilliant, young woman today. I am so thankful that there was no one in the corridor outside the delivery room who might have grabbed her.

Senator SPECTER. Ms. Owen, your red light has been on for quite a while now. If you could—

Ms. OWEN. I am sorry.

Senator SPECTER. I say your red light has been on for a while now.

Ms. OWEN. Thank you for letting me go on. I appreciate your indulgence.

Senator SPECTER. I know you have not observed, you cannot see it, but we did want to hear you out. If you could wrap up.

Ms. OWEN. I am finished.

PREPARED STATEMENT

I just want to say that immoral? Yes. Unnecessary? Yes. The results from adult stem cell research is very exciting and I hope that each one of you are keeping up with that research possibility.

Senator SPECTER. Thank you very much, Ms. Owen.

[The statement follows:]

PREPARED STATEMENT OF MARY JANE OWEN

INTRODUCTION

First, I wish to thank all who have welcomed me to appear before this important Committee to offer testimony on an issue with profound social, medical, and most of all, moral implications.

I am Mary Jane Owen, the Executive Director of the National Catholic Office for Persons with Disabilities, a national organization charged with creating welcome and justice, within the church and the total fabric of society, for over 12 million Catholics with disabilities. This mission requires extensive travel, speaking and writing, which I have been able to do despite—or possibly better—because of being a blind, partially hearing woman with neurological and spinal impairments which require use of a wheelchair.

Over a half century of my working life, I have been a psychiatric social worker, a professor of social research, a federal administrator, a free-lance consultant and a businesswoman. More importantly, I have been a participant observer in the difficult decades of change and progress as our society has created new options and opportunities for people with disabilities. Remarkable changes have taken place, including passage of the Americans with Disabilities Act, an effort in which I worked, along with thousands of other disabled people in our search for fuller participation within our society.

I am here to urge you: Do not, in the name of progress for disabled people, certify or justify the destructive harvesting of human embryos for stem cell research, a practice both immoral and unnecessary.

While disabled people are interested in cures, as well as better tools for living, greater inclusion in society and other possibilities which will improve our quality of life, we are not so desperate for cures that moral considerations disappear.

Do not use our struggles and aspirations to justify an immoral policy that will encourage the destruction of unborn babies. Instead, direct researchers to use the many alternative sources of stem cells so that this promising area of research may be developed in an ethically defensible manner!

MORAL CONSIDERATIONS

Congress determined once, and I believe rightly, that harvesting fetuses is wrong. There are many moral reasons for this. In addition to the opposition to abortion itself, shared by many Americans, there is also the conviction that human embryos and fetuses should not be harvested lest they come to be seen as products for sale.

This is not an insignificant issue. The medical and biotechnology revolution will be even more powerful in its implications than our internet/information technology revolution. Medical and biological technology can change our very identity as human beings. I do not propose that we stop this revolution, but I am confident we must carefully consider where we want to go and where we are being carried by frenzied attempts to deny our shared vulnerability.

Technology, commerce and science are all pushing us inexorably in the direction of regarding human beings as products. We need to consider if we continue down this slippery slope, are we ready to justify the creation of human beings for spare parts? We are forced to ask this question today, for the possibilities lie just ahead. Researchers are already harvesting fetuses, and their so-called utility has already become part of the moral calculus of abortion. Now the demand for live embryos for stem cell harvesting threatens to become part of the moral calculus of fertility treatments.

Yes, medical progress is desirable. Yes, new research vistas require new ethical guidelines—But I pray they will NOT involve a repudiation of our past moral stance and move toward an exclusively utilitarian set of “ethical” rules. We must carefully calculate what is essential to human decency and then defend that essence, even hedging it about with an extra margin of caution. We Americans disagree about many things, but most of us consider the idea of harvesting fellow human beings for the advantage of the few as abhorrent. Let us respect that moral intuition and the traditional values upon which it rests.

There are medical experts who will assure us we need not sacrifice scientific progress because of our abhorrence of a utilitarian approach toward human life.

THE ALTERNATIVE SOURCES OF STEM CELLS

It is clear that researchers should have access to stem cells. The issue is: why embryonic stem cells? Some would claim that refusing to subsidize this particular kind of stem cell research would unduly hamper medical progress. However, there are many other sources of these vital human tissues which give clear indication of

their potential for positive results. Some would even avoid the possibilities of rejection which are inherent in the use of tissue not recognized by the host body.

Exciting possibilities lie ahead in making use of self-contributed stem cells, as well as those harvested as a result of necessary surgical interventions, tissue contributed by consenting adults and the by-products of natural births.

THE PUSH TO BETRAY THE UNBORN

Congress has already attempted to prevent federal funding for harmful human embryo research, but now the issue has arisen again, and some say it is urgent to allow and encourage the use of embryonic cells in research. What has changed since that earlier decision? Yes, research possibilities have opened up but every day we are learning more about alternative sources of stem cells.

And so we are forced to ask ourselves why a civilized society would seek to overcome its moral compunctions about harvesting the unborn. Is it that our fear of disease, disability and mortality is so overwhelming that we forget or deny what we know is morally correct? I am suggesting the frenzied rush to harvest embryonic humans is based upon an undue fear of human fragility and disabilities. We fear anticipated pain. Yet we know that management of pain has made tremendous strides in the past few years.

I witness society's fear and anxiety about disability every day. I have often been amazed by strangers who approach me to confide that they would rather be dead than become blind or use a wheelchair. Aside from the bluntness of these remarks, what surprises me is that many people can not imagine that I have a happy life. And yet I am as happy, as successful and productive as anyone I know. It seems obvious to me that their fears about their own future disabilities keep them from seeing the reality of my life—and the possibilities for all people with assorted disabilities.

In my lifetime I have also observed our medical system negate the idealism of the Hippocratic Oath and move from viewing its services as having ties to charity. Within a for-profit enterprise, the view that some human lives are potential "product" may be tempting but it is still immoral. The sacrifice of some human lives for the benefit of others must be defined as illegal, as it has been in the past.

My view can be summarized thus: Many of my fellow citizens suffer unduly from fears and frenzied anxiety about assorted disabilities and fragilities.

A NEW UNDERSTANDING OF DISABILITY AND VULNERABILITY

Twenty years ago I proposed a new and positive definition of disabilities which has been used by advocates in the intervening years:

Disabilities are the normal, expected and anticipated outcome of the risks, stresses and strains of the living process itself.

The eventual outcome of the shared fragility of our bodies is the development of physiological glitches at some point in the normal life cycle. Disabilities are not something which happens only to the unlucky few but is an event which takes place for us all. We may face this eventuality before birth, in early life, during the height of our productive years or at the end of life. When we view our shared vulnerability with these conceptual lenses, we understand that the principles of universal design should be considered as we modify our environments, programs and institutions.

Broadly available medical services, rehabilitation techniques and technology and the evolving expectations of millions of American citizens with disabilities can revolutionize the future status of those millions of Americans who are destined to experience physical, cognitive and sensory limitations. Public recognition and support of these alternatives can relieve the rampant anxiety evident in the frenzied pursuit of "cures" at any moral cost.

Unfortunately, the picture of life with disabilities often seen in the popular media and skillfully utilized by those segments of our population seeking to deny the essential dignity and value of all human life, are generating the current pressure to authorize destructive harvesting of stem cells from embryos as essential in our struggle to prolong our productive lives.

We are not manufactured like Ken and Barbie, expected to fit a model of physical perfection; required to be uniform in all those characteristics by which we might be judged as having value. We are not fabricated of high impact plastic. When a single Ken or Barbie appears on the production line with even a tiny flaw, the results are thrown into the recycle bin. That member of the Mattel family will be broken down into its component parts to be used again in the ongoing effort to reach uniform perfection.

In contrast to that process, each of us was uniquely and individually created. For those of us who are Christian, we believe that this variety in abilities and strengths,

disabilities and weaknesses, in some mysterious way which we can not fathom, reveal some essential part of our Heavenly Father. Other faith and cultural groups confirm the normality of assorted "imperfections." The beautiful Navaho rug that hung on the wall of my childhood home was woven with the traditional "flaw" which marked it as reflective of the traditional belief that only the "Creator" was perfect. As I traced that defect in perfection, it comforted me as I dealt with the minor disabilities caused by an early bout of meningitis.

Not only are we created to be unique, we are created of extremely fragile material. We may be born without disabilities, but we must anticipate that at some point in our lives we will be forced to recognize our shared vulnerability. That recognition can inspire us to acknowledge our need for each other and for the Creator. It may also move us to cherish those of our community who are in need of assistance, medical services or rehabilitation.

Many of us unfortunately believe that disabilities are a cosmic accident which we must correct. I agree that we must work to do what we can to reduce or prevent disabilities, using morally defensible means. Much progress has already been made in prevention, treating or even curing a variety of disabling conditions. However, I would affirm we would never completely eliminate the vulnerability of the human organism nor would it be such a great blessing if we could. My personal experience convinces me that it is by God's wisdom that the gift of life comes in fragile earthen vessels. Many of the virtues we feel are the best that humanity has to offer, such as love, faith, hope, mercy, and courage, are associated directly or indirectly with our vulnerability.

I suggest that we, as a nation, need to use these alternative lenses through which to view human vulnerability and disabilities as we re-compute our outmoded "scientific" formulae for assessing other people's quality of life. We need you, members of the United States Senate, to call for a nation-wide calming of the frenzied research efforts based upon destroying future citizens, rather than endorsing this national anxiety. The potential quality of any human life can not be judged by outside authority.

THE POSITIVE ASPECTS OF HUMAN VULNERABILITY

I propose that the catalytic effect of our mutual need for each other is a social positive which must not be lost for it fosters a sense of the need for mutual aid and interaction within our communities.

We no longer need to respond in the same way our ancient ancestors did to the dangers rampant in their primitive world. Fearful avoidance, the patterns of behavior called forth by fear that the weak and vulnerable would fall prey to the woolly mammoth, is no longer appropriate. Superior brawn, eyesight, hearing and speed are not the only human characteristics essential today. Many of us sit at our computers which meet the needs of those of our brothers and sisters with the palsied movements of Parkinson disease; the paralyzed arms of the quadriplegic, or which speak to the blind or accommodate the confused efforts of the poor speller. Today these "imperfect" characteristics no longer need throw us into a panic or deep depression. Our quality of life can remain quite satisfactory in spite of those impairments which would have severely limited the lives of our grandparents.

In my travels, I have observed that the intertwining threads of the interaction between people are enhanced when we acknowledge our need for assistance or help. Apparently, at this point in our history, we seek "excuses" to be interactive and to discard our sense of complete autonomy. This serves to refresh our sense of being an essential part of a vital community. This interaction is a potent antidote to the rampant alienation which threatens so many of our neighborhoods today.

ON A PERSONAL LEVEL

I carry the genes for the blindness which knocked me from my ivory tower. And I may have passed that pattern of visual impairment to my daughter. Growing up I was surrounded by elderly blind women, all of whom were active in their communities, well educated for their time and place and recognized for their abilities more than their limitations. I was unprepared for the loss of my sight at the height of my rapid climb up the academic ladder.

The two women closest to me both died with Alzheimer's disease. I may be programmed for a similar experience. Awareness of that possibility makes each day of intellectual exploration more precious and pushes me to greater achievement.

The women who built the base upon which I exist would never have wished for a single life of an unborn baby to be sacrificed so that their physical or cognitive challenges might have been eliminated or postponed. They were strong feminists in

the model of Susan B. Anthony. They saw abortion as anti-woman and recognized that overcoming challenges as a characteristic to be admired, not avoided.

When I visited with my aunt, Naomi Harward, during the period when her Alzheimer's disease was being diagnosed, one morning I found her in tears. She had been widely recognized as a political force, having headed up a campaign to recall Governor Meecham. She was the oldest woman to appear on the cover of MS Magazine.

She said, "I don't want to have Alzheimer's." She had watched her sister, my mother, another widely recognized and strong feminist, live with that condition for long years. We embraced as I reminded her that none of us know what the future holds. I told her that at each step in her life she had showed me the way to live gracefully and successfully, no matter the challenges faced. That was a powerful moment in my life. She died quietly and peacefully during the few moments when her beloved grandson and his wife stepped out of her room. We felt she had chosen that moment to slip away and join those parts of herself which had already gone before.

She was so strongly opposed to abortion; the idea of harvesting stem cells from defenseless unborn children would have aroused loud and political protest, I am sure.

When my daughter was born, she had less than 1 percent chance of survival based upon her prematurity. I'd been told that babies at her stage of development were merely blobs of cells, not unique and individually crafted tiny people. I shall never forget the power and beauty of her tiny body; the fragility of life and her stubborn hold on it. I could see the intensity of her desire to live as each breath was aided; each beat of her heart monitored. That image continues to inspire me and that tiny essence of human life comes to mind every time I hear reference to the harvesting of stem cells from unborn children as an essential medical practice.

My daughter graduated cum laude from Harvard twenty years later and continues to be a joy and support. Thank God no one was lurking in those sterile halls, awaiting the emergence of a frail and fresh "product" to be marketed for research or "therapeutic" purposes.

I have neurological impairments and have sustained spinal injuries, and while I enjoy dancing in my wheelchair, it might be pleasant to do so in what is considered a normal way. But be very clear in this: I am deeply opposed to any gain in my sight, mobility, or even my hearing if it was purchased at the cost of a single human life.

As I've already noted, I may face Alzheimer's disease at some point in my future. But that eventuality is less frightening than a world in which, as a matter of medical intervention, one life can be casually eliminated in order to offer a few additional months of "normality" to another.

I've talked with and cried with hundreds of my colleagues within the disability movement. We seek better funding for rehabilitation, not a quick fix. I challenge you, members of the United States Senate and all my fellow citizens, to create environments, fund current rehabilitation programs and alter perceptions of human vulnerability which frighten those who fear what their future might hold. We can escape from the ancient demons which haunt nightmares.

The worse thing in life is not disability, or pain, or even death. The worse thing I can imagine is to create a society which sees itself as justified in treating other people as objects to be used or discarded, as best fits the desires of the moment. I would not wish to live in such a world. And the moral choices we make today will surely shape our future. Even a "small thing" like the fate of an unborn child can have great implications as we create that future for ourselves and our children.

Senator SPECTER. Senator Brownback, when we deal with the morality issue, I totally agree with you that that is the principal concern, that we proceed in an ethical and in a moral way. I would join you totally in your objection, abhorrence, disdain for interfering with human life. But the embryos which are to be used here for extracting stem cells are discarded. They are not to be used. They have been prepared for in vitro fertilization, and if they are not used for the research, they will not be used at all. So, how do you deal with that fact that no human life is to be taken?

Senator BROWNBACK. Well, I think the issue you raise here, what you are talking about is strangely familiar from our past where we say these are going to be discarded and die anyway, so therefore, why

not get some benefit out of them. That sounds strangely like some of the things that happened in World War II.

Senator SPECTER. Well, how so? These have been discarded. It is not that they are going to be discarded. How would that run afoul or be analogous to what happened in World War II?

Senator BROWNBACK. Well, you are taking live human embryos in this case and they will be extracted—their stem cells from them. You had the Nazis in World War II saying, of these people, they are going to be killed. Why do we not experiment on them and find out what happens with these experiments? They are going to die anyway.

Senator SPECTER. But they were living people unlike the embryos.

Senator BROWNBACK. These are living embryos. These are living embryos. And they are being treated in this case as property.

Senator SPECTER. But the people whom the Nazis experimented with in the abhorrent way in the holocaust were living.

Senator BROWNBACK. These are living embryos. You are taking living embryos.

Senator SPECTER. Let me ask you, Senator Brownback, do you oppose in vitro fertilization?

Senator BROWNBACK. I have not thought through that one, and I am not prepared here today to talk about that particular issue. The issue in front of us is you have a live embryo.

Senator SPECTER. I raise the in vitro fertilization issue—and you are correct. It is not before us. We are exploring the matter today, but we are going to have an opportunity to discuss it on the Senate floor at greater length.

But I raise the in vitro fertilization issue because there are some who do object to that, and it is a consequence of in vitro fertilization that these embryos are created. There might be an argument that every one of these embryos is entitled to life. But the process of in vitro fertilization is to have a large group and then to use some but not to use others. So, this is something we will be getting into.

But I understand your point of view.

Let me shift for just a moment to the question of—

Senator BROWNBACK. If I could on that very point.

Senator SPECTER. Go ahead, sir.

Senator BROWNBACK. Because you are seeing the courts now across the country starting to discuss this issue of are these embryos then person or property. And that is at the core of what we are talking about here. We will hopefully have some of the legal opinions of what are developing on this, but does that not sound dangerously close to things that we have skirted around in the past and dealt with in this body a number of years ago?

And my point on all this is we do not have to go this way. Let us go the way that I will join you—and I do not know if you can ask for a level of funding on adult stem cell research that I would not support because I think it is so promising for its potential and ethical. But let us not go into this one that we have so many of these questions that mankind has been around for a long time.

Senator SPECTER. Well, I am going to come to that in a moment.

Ms. OWEN. Could I respond to your question?

Senator SPECTER. Not yet, Ms. Owen. You can but not quite yet. When you talk about a person—you cannot, Ms. Owen, because I want to develop this thought with Senator Brownback which we are discussing, but I will come back to you.

When you talk about a person and we have these concerns about when life begins and you have conception and then abortion—and I am personally very much opposed to abortion, although I think it has to be a decision for the woman.

But when you talk about conception and whether there is a person, that conceived entity is on its way to life. But that is not the situation—just to pursue this for another step, Senator Brownback—with the discarded embryo. A discarded embryo is not on its way to life. I do not like the concept of property as opposed to person. As we consider the issue of a person where there is conception, that entity is on its way to life. But I do have that distinction which I would be interested in your comment about with respect to the discarded embryo.

Senator BROWNBACK. If it is a live embryo and it is destroyed for this purpose, it is killed. And you have that destruction that is taking place. And then in this case we are even saying that destruction we will then do this with the parts out of it. I cannot see that that is something that this great Nation really wants to move along when we have another option that is so promising in front of us. We just do not have to go this way.

Senator SPECTER. Well, let us take up that option for just a moment with you, Dr. Young. I note, in one of the commentaries from your magazine that you made available to us, the following statement with respect to adult stem cells. I had a concern from other materials which I have studied that the stem cells from adult tissue, matured cells are already differentiated into a narrow type, range of stem cells. Those cells cannot support the kind of research on a broad basis.

Quoting from the publication which you have made available to us on page 1419, “Adult stem cells have a drawback, however, in that some seem to lose their ability to divide and differentiate after a time in culture. This short life-span might make them unsuitable for some medical applications.” Do you disagree with that limitation on adult stem cells?

Dr. YOUNG. I think the jury is out in general. This is a very well-balanced set of articles, and there are other articles there which state that one of the liabilities of the embryonic stem cells is that they differentiate in a more uncontrolled fashion, whereas it is better to use adult embryonic cells which would be able to differentiate more unidirectionally. I think that further research has to be undertaken.

But in the interim, I do believe that it is critical to focus on the animal work with embryonic stem cells which can yield a great deal of information and the work on human adult stem cells, and then pause for a while.

If I could add one answer to the question that you asked the Senator, I think it could be very enlightening. There was a case a short time ago where one of the in vitro fertilization clinics—it was about a year and a half ago—found that they had an embryo, “a spare embryo,” that was left from a woman’s in vitro fertilization about

6 to 8 years ago. It was reported in the Los Angeles Times that that woman then desired to have that embryo implanted and gave birth to a twin, if you would, 6 to 8 years down the line. It goes in accordance with what the Senator was saying.

My remark that I really think the Senate needs to address is that of the regulation of in vitro fertilization. I have supported in vitro fertilization, have counseled couples in our church, and have worked with them on this area. But there does not need to be "the development of excess embryos." And there does not need to be the concept of spare or embryos that are about to be destroyed. I think that is one the Senate might like to look into.

Senator SPECTER. Before turning to Senator Harkin, Ms. Owen, you had a comment you wanted to make. Ms. Owen?

Ms. OWEN. Yes. I would like to respond to your question about the viability.

Senator SPECTER. Fine. We would be pleased to hear you.

Ms. OWEN. You see, I think that one of the things that possibly needs to be considered is that fact that we are in a society where we are beginning to talk about the sale of body parts. I think that when we begin to say it is all right to have excessive numbers of embryos created, we are saying go ahead, private industry, go ahead, NIH, go ahead and create excess embryos not just for in vitro fertilization, but with the idea—maybe it is behind closed doors—but with the idea we can make a profit by selling these embryos. So, I do not think it is just simply a few embryos that we are talking about today. We are talking about the potential of creating hundreds of embryos for research purposes.

Senator SPECTER. Thank you, Ms. Owen.

Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman. I too want to thank especially my colleague, Senator Brownback, with whom I have a great working relationship and friendship. I know how deeply you feel about this issue, and I respect that. I respect it greatly. I respect all of you who have perhaps come at this from a different viewpoint perhaps than I come at it from.

But I believe that by working together in a rational, reasonable way, I think that we can find pathways out of this. I just want to make sure that we are all talking about the same thing and that we are all knowing that the words we use—we kind of agree upon what they mean. I think a lot of times maybe both sides of an issue talk to themselves a lot and they do not talk to each other enough to try to figure out some pathways that we can move ahead.

To that extent, I just again wanted to reiterate what our chairman said, that we are looking at the—without getting into whether adult stem cells will do the job or not. No one knows. OK, we do not know. We do not know. But we do know and scientists do have a belief that at least in the pluripotent stage of embryonic stem cells that they do hold great promise. Again, there are no guarantees out there. The only guarantee is that if we do not do it, possible cures, interventions and preventions for a whole host of illnesses will be put off for longer periods of time. That guarantee we do have.

Second, with regard to the issue of embryos—again, Sam, we get in this whole debate about the Nazi Germany and that kind of

thing. But I think we do have to keep some perspective on this. I put something on this piece of paper, and I will bet no one out there can tell me what is on that piece of paper because you cannot see it. But I took my pencil and I put a dot on it. That is how big we are talking about. That is how big the human embryo is that we are talking about. In fact, in most cases you cannot even see it with the naked eye.

Now, again I am not a theologian, but to equate that with the individual person that the Nazis were experimenting upon I think is to stretch the meaning of humanness and what a human being is.

Now, with regard to that little dot that is on the piece of paper, there are, as the chairman said, leftover—and this is where it gets to you, Dr. Young. There are leftover embryos of this size, frozen, about 100,000, Sam. We estimate about 100,000 of these are frozen in liquid nitrogen right now that are left over. I have been told by scientists that we probably do not need any more than that. I mean, we do not need to go out and get more stem cells and that. We have 100,000 embryonic stem cells right now left over from in vitro fertilization. Regardless of what you may think about in vitro fertilization, they are there. They are frozen. The question is, what is going to happen to them?

Dr. Young, you pointed you—and I read that article about the woman that can back 6 years later. Well, again, that is fine.

Now, the guidelines that we set up—I am going to just jump ahead here a little bit. The guidelines that were proposed said this. And this gets to you, Ms. Owen, about the sale. You were talking about selling human parts and stuff. The guidelines stated three things. We could only use embryonic stem cells from excess in vitro embryos, ones that are there right now. OK? Second, there must be no financial compensation. No one can sell these. No one can pay for them. And third, they can only be used with the informed consent of the donors, the two parents, whoever that is. So, if there is someone who donated that in vitro fertilization and they are deceased now, they cannot give that informed consent. Only those who can give their informed consent could use it. Those are the guidelines.

So, we have no need to create more than the 100,000 that we have now, regardless of what you may think about whether we should go on with in vitro fertilization or not. Those are already frozen. They are there. The question for us I think, Sam, and others is they are there. Are we going to keep them in liquid nitrogen forever and ever and ever? I doubt it.

Senator BROWNBACK. Well, if I could answer that.

Senator HARKIN. Yes.

Senator BROWNBACK. Because you are seeing now court cases of people coming back that these have been frozen and kept. The couple is divorced.

Senator HARKIN. Right.

Senator BROWNBACK. One wants to implant the frozen embryo, the other does not.

Senator HARKIN. Yes.

Senator BROWNBACK. And the court is then wrestling with the issue, who gets to decide, and are they person or property. The

court is wrestling with this now. Should we in legislation say—because as I read this, it would appear to me we are saying these are property.

Senator HARKIN. We are saying that only with the informed consent of the two donors, Sam.

Senator BROWNBACk. Well, but I am saying what the court is wrestling right now.

Senator HARKIN. But you have two donors that are wrestling with each other.

Senator BROWNBACk. You do but the central question, the central legal question is, is it person or property? The court, in a line of decisions that I think is probably going to start developing here, is wrestling with the same sort of thing they did 100 years ago in this country.

And there is a Boston case where they are saying, well, it is not really a person, it is not really property, it is an entity with the potential for life is one lower court ruling. Now, does that sound like saying somebody is three-fifths of a person and not a whole as we have in our prior history as a country? I think in this legislation, we are saying these are property to be decided upon by these two people what happens to this.

I do not think we are there at deciding that issue at this point, and I do not think it is wise for us to, particularly since we have got an option that we do not have to do this.

Senator HARKIN. The option I think, Sam, as others have pointed out, and as Science magazine, as scientist, after scientist, after scientist will tell you there may be some benefit to adult stem cells, but as far as they can determine now, their life is very short. They are not eternal like the pluripotent stem cells of embryos.

Senator BROWNBACk. Pluripotent are not eternal. I do not think you would say that those would be eternal masses either.

Senator HARKIN. No. They can regenerate. They can regenerate.

Dr. YOUNG. They can also differentiate very rapidly.

Senator HARKIN. But they can also regenerate too.

So, you can use adult stem cells. I am not saying we should not use them. I am saying why close off all these doors that researchers could use.

Again, Sam, keep in mind there are private entities out there right now conducting this kind of stem cell research. It is being done chaotically. It is being done without guidelines. Who knows what is happening out there?

I think we have taken the responsible, reasonable approach. We set up a Bioethics Commission. We said only from excess in vitro embryos, no financial compensation, informed consent of the donors. To me, you know, you are talking about these as being spare and products for sale. They are not for sale. These are not spare. They are there.

It seems to me the height of morality to say that in order to help someone's life to prevent Alzheimer's or ALS or to regenerate neurons, to help people with juvenile diabetes, it seems to me the moral thing to do would be to use what we have there in these in vitro cells that are left over, the 100,000, to permit the kind of ethical guideline structure that we set up so that scientists can use those to help make lives better. To me that seems to me—again,

I know we differ on this but I hope you give me as much benefit as I give you approaching this from a moral standpoint.

Senator BROWNBACk. And I have stated that repeatedly. I do. I do not think our hearts are any different of what we want to get done.

Senator HARKIN. But I think our position is just as moral and as morally defensible as your position.

Senator BROWNBACk. Well, I would question whether we want to destroy one human life for another. And there is private work going on. There are also 10 States that have banned the destructive embryo research even privately funded. 10 States have already done that. So, this would have a Federal stepping in on top of what States are doing as well.

We do not have to go this route. I listed the research that is taking place in the very areas that you are talking about solving and the promising work. Would it be not only moral but also wise to invest more in that area and focus our efforts there that we can get there faster?

Plus, we have not talked about the immunosuppressant problem that you are going to have if we develop these off of bodies that are not the same as the body that you want to put this new entity in. You do not have that issue that you have to wrestle with. If you develop pancreatic cells out of an embryo, you can have, and in likelihood will have, immunosuppressant problems with the body rejecting that. Whereas, if you pull it out of your own adult stem cells, you do not have that issue.

I think we have got a wise and moral route that we can all go together on.

Senator HARKIN. With adult stem cells, you have one door to open. Maybe it will work. But using other embryonic stem cells, you open up a whole host of other doors that may lead you to the right path for the prevention and the cure of many of our common ailments. That is all I am saying.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Harkin.

Thank you very much, Senator Brownback, Ms. Owen, Dr. Young. Dr. Young, you remind us that we are biodegradable. Maybe now we can be bio-regeneratable.

Dr. YOUNG. I think for a short time that is possible.

Senator SPECTER. One of the heroes of my youth was Ponce de Leon who searched for the fountain of youth, and if we have it here, let us look at it.

Stay tuned, ladies and gentlemen. This debate is not over. We will be on the Senate floor where we have unlimited time to speak, and on this issue, we will probably be using it.

Thank you very much, Senator Brownback.

Ms. OWEN. Thank you.

Dr. YOUNG. Thank you very much.

**STATEMENT OF CHRISTOPHER REEVE, ACTOR/DIRECTOR; CHAIRMAN,
CHRISTOPHER REEVE PARALYSIS FOUNDATION**

Senator SPECTER. We now turn to our third panel. We have Mr. Christopher Reeve, Ms. Jennifer Estess, and Dr. Lawrence Goldstein.

We thank you very much, Mr. Reeve, specially for your personal crusade on stem cells. We noted with America generally and the world the traumatic experience you had with your accident on horseback and the severing of your spinal column, but you have come back to lead this crusade in a very inspirational way. The current issue of Time magazine has your comments and pays special tribute to what you have done. I know that this is a matter of—well, it is of life concern to you. It is that important. Possible regeneration of your spinal column to enable you to fly again. So, we thank you for all of your extraordinary work here, and we thank you for being available to testify. We now turn the floor to you.

Mr. REEVE. Well, thank you very much, Mr. Chairman. I appreciate the opportunity to be here to testify.

I would start by saying that in vitro fertility clinics have been around since the 1950's, and as far as I am aware, even though the Pope, of course, stated a position against it and it is a sin for a Catholic to use in vitro fertilization, there has not been an enormous outcry or protest. In other words, these clinics have existed in relative peace for nearly 40 years, and I do not understand why all of a sudden there is a huge issue about it, now that discarded embryos will be used for research instead of just being thrown into the garbage.

A critical factor in the quality of life for present and future generations will be what we do with human embryonic stem cells. These cells have the potential to cure disease and conditions ranging from Parkinson's and MS to diabetes, heart disease, to Alzheimer's, Lou Gehrig's, even spinal cord injuries like my own. They have been called the body's self-repair kit.

Their extraordinary potential is a recent discovery. And much basic research needs to be done before they can be sent to the front lines in the battle against diseases. But no obstacle should stand in the way of responsible investigation of their possibilities. To that end, the work should be turned over to the Federal Government through the National Institutes of Health. That will avoid abuses by for-profit corporations, avoid secrecy and destructive competition between laboratories, and ensure the widest possible dissemination of scientific breakthroughs. Human trials should be conducted either on the NIH campus or in carefully monitored clinical facilities.

Now, fortunately, stem cells are readily available and easily harvested. In fertility clinics, women are given a choice of what to do with unused fertilized embryos: they can be discarded, donated to research, or frozen for future use. Under NIH supervision, scientists should be allowed to take cells only from women who freely consent to their use for research. One very important factor is that this process would not be open-ended. Within 1 to 2 years, a sufficient number could be gathered and made available to investigators. So, for those reasons, the ban on federally funded human embryonic stem cell research should be lifted as quickly as possible.

Again, why has the use of discarded embryos for research suddenly become such an issue? Is it more ethical for a woman to donate unused embryos that will never become human beings or to let them be tossed away as so much garbage when they could help save thousands of lives?

Now, treatment with stem cells has already begun. They have been taken from umbilical cords and become healthy red blood cells used to cure sickle-cell anemia. Stem cell therapy is also being used against certain types of cancer. But those are cells that have significantly differentiated; that is, they are no longer pluripotent or capable of transforming into other cell types. For the true biological miracles that researchers have only begun to foresee, medical science must turn to undifferentiated stem cells. We need to clear the path for them as quickly as possible.

Now, controversy over the treatment of certain diseases is nothing new in this country. Witness the overwhelming opposition to Government funding of AIDS research in the early 1980's. For years, the Government tossed this issue around as a political football until a massive grassroots effort forced legislators to respond. And today NIH is authorized to spend approximately \$1.8 billion annually on new protocols, and the virus is largely under control in the United States.

Now, at this point I wish to submit a letter of support from four theologians representing the Protestant, Catholic, Jewish, and Islamic faiths. They say:

Our opinions about embryonic stem cell research reflect several different religious perspectives: Jewish, Catholic, Protestant and Islam. While they do not represent a single voice from these religious communities, they do offer a collective belief that is based on similar views about certain moral and ethical questions.

According to our religious beliefs, all human life must be protected. However, they also indicate that there is a significant difference between an embryo suspended in liquid nitrogen that will never be implanted inside a womb and an unborn child who is already in the womb.

Our religious beliefs also stress the importance of compassion. Thus, we support embryonic stem cell research because it would use these frozen or otherwise discarded embryos to help ease the suffering of those with catastrophic diseases such as diabetes, Parkinson's, cancer, Alzheimer's, heart disease, osteoporosis and arthritis.

As theologians, we put a great deal of importance upon the need for ethical standards in biomedicine. Currently, stem cell research is being conducted solely in the private sector, where it is not subject to the important guidelines developed by the NIH, parameters that reflect critical input from ethicists and theologians. However, the guidelines would only come into effect with Federal funding, which is another reason we support moving forward with the research under NIH. In addition, Federal funding would not only speed the discovery of cures, but ensure infrastructure is in place that will guarantee ethical conduct and maximize the benefit to society.

Our religious beliefs tells us that embryonic stem cell research is worthy of Federal support for millions across the country who are suffering from diseases. We hope you will join us and support stem cell research through the NIH.

We look forward to your support for this research, as the lives of millions are counting on you.

And this is signed by Rabbi Elliot Dorff, Ph.D., who is Professor of Philosophy at the University of Judaism. It is signed by Nancy J. Duff, Ph.D., Associate Professor of Theological Ethics at Princeton Theological Seminary. It is signed by a name I cannot pronounce: Abdulaziz Sachedina. I cannot say this. Anyway, Islamic Ph.D., Department of Religious Studies at the University of Virginia. And in my opinion, most importantly, by Margaret Farley, Ph.D., who is Professor of Christian Ethics at the Yale University Divinity School, and she is a Catholic.

PREPARED STATEMENT

Finally, I wish to enter into the record a list of over 100 disease groups, clinicians, foundations, universities and medical schools, all of whom are supportive of me and my advocacy for stem cell research. You will see that in attachment 2.

But while we prolong the stem cell debate, millions continue to suffer. It is time to harness the power of Government and go forward. Thank you.

[The statement follows:]

PREPARED STATEMENT OF CHRISTOPHER REEVE

We must pursue research on embryonic stem cells.

With the life expectancy of average Americans heading as high as 85 to 90 years, it is our responsibility to do everything possible to protect the quality of life of the present and future generations. A critical factor will be what we do with human embryonic stem cells. These cells have the potential to cure diseases and conditions ranging from Parkinson's and multiple sclerosis to diabetes and heart disease, Alzheimer's, Lou Gehrig's disease, even spinal-cord injuries like my own. They have been called the body's self-repair kit.

Their extraordinary potential is a recent discovery. And much basic research needs to be done before they can be sent to the front lines in the battle against disease. But no obstacle should stand in the way of responsible investigation of their possibilities. To that end, the work should be funded and supervised by the Federal Government through the National Institutes of Health (NIH). That will avoid abuses by for-profit corporations, avoid secrecy and destructive competition between laboratories and ensure the widest possible dissemination of scientific breakthroughs. Human trials should be conducted either on the NIH campus or in carefully monitored clinical facilities.

Fortunately, stem cells are readily available and easily harvested. In fertility clinics, women are given a choice of what to do with unused fertilized embryos: they can be discarded, donated to research or frozen for future use. Under NIH supervision, scientists should be allowed to take cells only from women who freely consent to their use for research. This process would not be open ended; within one to two years a sufficient number could be gathered and made available to investigators. For those reasons, the ban on federally funded human embryonic stem cell research should be lifted as quickly as possible.

But why has the use of discarded embryos for research suddenly become such an issue? Is it more ethical for a woman to donate unused embryos that will never become human beings, or to let them be tossed away as so much garbage when they could help save thousands of lives?

Treatment with stem cells has already begun. They have been taken from umbilical cords and become healthy red cells used to cure sickle-cell anemia. Stem cell therapy is also being used against certain types of cancer. But those are cells that have significantly differentiated; that is, they are no longer pluripotent, or capable of transforming into other cell types. For the true biological miracles that researchers have only begun to foresee, medical science must turn to undifferentiated stem cells. We need to clear the path for them as rapidly as possible.

Controversy over the treatment of certain diseases is nothing new in this country: witness the overwhelming opposition to government funding of AIDS research in the early 1980's. For years the issue was a political football until a massive grass-roots effort forced legislators to respond. Today, the NIH is authorized to spend approximately \$1.8 billion annually on new protocols, and the virus is largely under control in the United States.

In conclusion, I wish to submit a letter of support from four theologians representing the Protestant, Catholic, Jewish and Islamic faiths (see Attachment 1).

And finally, I wish to enter into the record a list of over 90 disease groups, clinicians, foundations, universities and medical schools, all of whom have endorsed my testimony (see Attachment 2).

While we prolong the stem cell debate, millions continue to suffer. It is time to harness the power of government and go forward.

Attachments.

ATTACHMENT 1

October 12, 1999.

Hon. J. DENNIS HASTERT,
House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE HASTERT: Our opinions about embryonic stem cell research reflect several different religious perspectives: Jewish, Catholic, Protestant and Islam. While they do not represent a single voice from these religious communities, they do offer a collective belief that is based on similar views about certain moral and ethical questions.

According to our religious beliefs, all human life must be protected. However, they also indicate that there is a significant difference between an embryo suspended in liquid nitrogen that will never be implanted inside a womb, and an unborn child who is already in the womb.

Our religious beliefs also stress the importance of compassion. Thus, we support embryonic stem cell research because it would use these frozen or otherwise discarded embryos to help ease the suffering of those with catastrophic diseases such as diabetes, Parkinson's, cancer, Alzheimer's, heart disease, osteoporosis and arthritis.

As theologians, we put a great deal of importance upon the need for ethical standards in biomedicine. Currently, stem cell research is being conducted solely in the private sector, where it is not subject to the important guidelines developed by the National Institutes of Health (NIH)—parameters that reflect critical input from ethicists and theologians. However, the guidelines would only come into effect with federal funding, which is another reason we support moving forward with the research under NIH. In addition, federal funding would not only speed the discovery of cures, but ensure infrastructure is in place that will guarantee ethical conduct and maximize benefit to society.

Our religious beliefs tell us that federal funding of embryonic stem cell research is worthy of federal support for millions across the country who are suffering from diseases. We hope you will join us and support stem cell research through the NIH.

We look forward to your support for this research, as the lives of millions are counting on you.

Sincerely,

RABBI ELLIOT DORFF, PH.D.,
Professor of Philosophy, University
of Judaism

MARGARET FARLEY, PH.D.,
Professor of Christian Ethics, Yale
University Divinity School

NANCY J. DUFF, PH.D.,
Associate Professor of Theological
Ethics, Princeton Theological Sem-
inary

ABDULAZIZ SACHEDINA, PH.D.,
Department of Religious Studies,
University of Virginia

ATTACHMENT 2

EDITOR'S NOTE: This is a list of over 100 disease groups, clinicians, foundations, universities and medical schools, all of whom are supportive of Christopher Reeve and his advocacy for stem cell research. This group of supporters was gathered with the assistance of the American Society for Cell Biology. For more information, please contact Tim Leshan at 301-530-7153 or at TLeshan@ascb.org.

AIDS Action
Alliance for Aging Research
Alpha One Foundation
ALS Association
American Association for Dental
Research
American Association for the
Advancement of Science
American Association for the Study of
Liver Diseases

American Association of Anatomists
American Association of Immunologists
American Autoimmune Related Diseases
Association
American College of Obstetricians and
Gynecologists
American Dental Education Association
American Foundation for AIDS Research
American Gastroenterological
Association

American Medical Association
 American Parkinson Disease Association
 American Pediatric Society
 American Physiological Society
 American Society for Biochemistry and
 Molecular Biology
 American Society for Cell Biology
 American Society for Clinical Nutrition
 American Society for Microbiology
 American Society for Pharmacology and
 Experimental Therapeutics
 American Society for Reproductive
 Medicine
 American Society of Hematology
 American Society of Human Genetics
 American Society of Pediatric
 Hernatology/Oncology
 Americans for Medical Progress
 Association for Research in Vision and
 Ophthalmology
 Association of American Medical
 Colleges
 Association of American Universities
 Association of Independent Research
 Institutes
 Association of Medical School Pediatric
 Department Chairs
 Association of Professors of Medicine
 Association of Subspecialty Professors
 Bay Area Bioscience Center
 Biophysical Society
 Boston University Medical Center
 Canavan Research Fund
 Cancer Treatment Research Foundation
 Candlelighters Childhood Cancer
 Foundation
 Cedars-Sinai Medical Center
 Christopher Reeve Paralysis Foundation
 Coalition of Advocates for Research on
 the Eye (CARE)
 College of American Pathologists
 Cooley's Anemia Foundation
 Coriell Institute for Medical Research
 Council of Graduate Schools
 Endocrine Society
 Federation of American Societies for
 Experimental Biology
 Foundation Fighting Blindness
 FRAXA Research Foundation
 Friends of the National Institute of
 Dental and Craniofacial Research
 Genetics Society of America
 Hadassah
 Harvard University
 International Foundation for Anticancer
 Drug Discovery
 International Longevity Center—USA,
 Ltd.
 International Myeloma Foundation
 Interstitial Cystitis Association
 Jeffrey Modell Foundation
 Johns Hopkins University
 Joint Steering Committee for Public
 Policy
 Juvenile Diabetes Foundation
 International
 Kidney Cancer Association
 Lankenau Medical Research Center
 Lombardi Cancer Center
 Medical College of Wisconsin
 Medical University of South Carolina
 Memorial Sloan-Kettering Cancer Center
 Mount Sinai School of Medicine
 Myasthenia Gravis Foundation of
 America
 National Alliance for Eye and Vision
 Research
 National Alopecia Areata Foundation
 National Association for Biomedical
 Research
 National Association of State
 Universities and Land-Grant Colleges
 National Childhood Cancer Foundation
 National Coalition for Cancer Research
 National Health Council
 National Psoriasis Foundation
 Oncology Nursing Society
 Paralyzed Veterans of America
 Parkinson's Action Network
 Parkinson's Disease Foundation
 Patients' Coalition for Urgent Research
 (CURE)
 Prevent Blindness America
 Project A.L.S.
 The Protein Society
 PXE International
 Radiation Research Society
 Research!America
 Research Society on Alcoholism
 Research to Prevent Blindness
 RESOLVE, National Infertility
 Association
 Sjogren's Syndrome Foundation
 Society for Pediatric Research
 Society for Women's Health Research
 The Genome Action Coalition (TGAC)
 Treatment Action Group (TAG)
 University of California, San Diego
 School of Medicine
 University of Minnesota
 University of Rochester Medical Center
 University of Washington
 University of Wisconsin-Madison
 UPMC Health System
 Washington University School of
 Medicine
 Weill Medical College of Cornell Univer-
 sity

Senator SPECTER. Thank you very much, Mr. Reeve, for that very impressive testimony. We see your enthusiasm and your determination, notwithstanding your own personal situation, and we will work with you to try to get the research necessary to revitalize the spinal column.

We will make a part of the record, Mr. Reeve, the long list of groups, clinicians, foundations, universities, and medical schools which support stem cell research, which you have provided to us, together with the letter which you made available, and the record will be able to handle all those names we cannot pronounce.

Mr. REEVE. Thank you.

STATEMENT OF JENNIFER ESTESS, ACTOR/PRODUCER

Senator SPECTER. We turn now to Ms. Jennifer Estess, who helped form the off-Broadway theater company, Naked Angels. She is the Executive Producer of a CBS original movie based on her life, scheduled to air early next year. She received her bachelor's degree in fine arts from the New York University and is now President of the Amyotrophic Lateral Sclerosis Foundation which she organized in 1998 after being diagnosed with ALS in 1997 at the age of 35.

We thank you very much for joining us, Ms. Estess, and look forward to your testimony.

Ms. ESTESS. Thank you.

Good morning, Chairman Specter, Senator Harkin, and members of the committee. I also want to thank Christopher Reeve for inviting me here today to speak with him. It is an honor. And I want to thank you for inviting me to speak today.

I am Jennifer Estess. I have ALS, also known as Lou Gehrig's disease, which is always fatal.

As a little girl growing up in America, I had great plans. I dreamed of falling in love, getting married, and raising a family. I dreamed of making a difference.

As a teenager, I learned from my sisters that hard work, commitment, and family would make my dreams a reality.

As a woman of 35, my American dream was starting to come true. I was a producer living in New York City. I was working 12-hour days and loving it. I was a healthy and strong young woman looking for Mr. Right and ready to take the next step.

Then one day I started to feel tired and run down. I thought it was the flu. But weeks passed and the feeling did not go away. A city block seemed like a mile. Stairs were like mountains. And suddenly I was having trouble holding my 3-year-old nephew in my arms.

It was like a scene out of a bad movie when the neurologist turned to me and said, you have ALS. In 2 to 5 years, you will lose the ability to walk, to talk, to swallow, to breathe. You will die. There is no medicine I can give you.

That first year ALS took my legs, the second my hands, my arms. Now I sit before you unable to breathe freely, but my mind is fine and it is alert. And I am still dreaming.

The day of my diagnosis, I asked the neurologist why, if we could transplant hearts and lungs, could we not also replace damaged motor neurons, the cells destroyed in ALS? The neurologist shook his head. He told me, the cell transplants were science fiction.

Three years later I am here to say that we may have discovered a way to replace the cells that carry messages from the brain to the muscles.

Project ALS, which I built with my sisters and my friends, has assembled and funded a Dream Team of scientists. In the last 9 months, these scientists have produced stunning evidence that neural stem cell replacement can replace damaged motor neurons. These new cells may one day allow me to do the things I miss so much like brushing my hair, laughing out loud, and holding a cup of coffee.

The evidence now shows that neural stem cell replacement is our best hope for treatment and cures, not only for ALS, but for Alzheimer's, Parkinson's, stroke, multiple sclerosis, and spinal cord injury affecting over 10 million Americans today. I am sure each of you will be touched by one of these devastating diseases.

I believe it is upon us as brothers, sisters, fathers, mothers, Americans to join us in this growing family that will solve these problems. I also believe that stem cell research will be the answer for millions of people, babies, children, and adults, who will be blind-sided as I was. And I am here because I do not want anyone else to have to go through this.

Make no mistake. ALS is a national disaster. We must land at the heart of this disaster. I hope that Congress, the National Institutes of Health, and the Food and Drug Administration will join Project ALS and me in pursuing the safest, shortest distance between stem cells and the patients who desperately need them.

Each day I speak from inside my body which has now become a prison. I am still here and dreaming of an America that will protect the right to life, liberty, and the pursuit of happiness for all.

Thank you so much.

Senator SPECTER. Ms. Estess, we are very grateful to you for appearing here today. We understand the difficulties that you have described. Your voice is loud and clear and we hear the message. When you appear and Mr. Reeve appears and we have your circumstances in mind and know that you are representative of many, many people in America and in the world whose lives may be saved by stem cell research, it provides the kind of public understanding that I think is going to be necessary to change the law and activate this kind of National Institutes of Health funding which is the source of the real hope to deal with ALS, to deal with spinal cords, and to deal with heart disease, and to deal with Parkinson's.

When you look at Senator Harkin and me and say that we will have the same problems, we could tell you some stories of our own. So, we thank you.

Ms. ESTESS. Thank you.

STATEMENT OF LAWRENCE B. GOLDSTEIN, Ph.D., PROFESSOR, DIVISION OF CELLULAR AND MOLECULAR MEDICINE, UNIVERSITY OF CALIFORNIA, SAN DIEGO SCHOOL OF MEDICINE; INVESTIGATOR, HOWARD HUGHES MEDICAL INSTITUTE

Senator SPECTER. Dr. Goldstein, we now turn to you, Professor of Pharmacology at the Division of Cellular and Molecular Medicine, investigator of the Howard Hughes Medical Institute at the University of California, Ph.D. from the University of Washington. You testified before the subcommittee at one of our early hearings in January of last year. We thank you for joining us and we appreciate your focus on the issue as to adult stem cells versus embryonic stem cells.

Dr. GOLDSTEIN. And related topics, yes.

Mr. Chairman, members of the subcommittee, I am Lawrence Goldstein. I am here today as a representative of the American Society for Cell Biology. The society represents 10,000 basic biomedical researchers most of whom work in our Nation's leading research universities and institutes.

I am a professor now in the Department of Cellular and Molecular Medicine at the University of California, San Diego School of Medicine and an investigator in the Howard Hughes Medical Institute. Before moving to San Diego, I was a professor in the Department of Cellular and Developmental Biology at Harvard University for 10 years. My research focuses on the roles of protein motors in neuronal function and neurodegenerative disease.

It is a pleasure to be here again today and it is a particular honor to be here with Ms. Estess and Mr. Reeve who have been such articulate advocates for biomedical research. My oral remarks will be a shorter version of my written remarks, so they will not be identical.

Senator SPECTER. Your full written statement will be in the record, Dr. Goldstein.

Dr. GOLDSTEIN. Thank you, Senator.

I want to thank you, Senator Specter and Senator Harkin, for your leadership in ensuring that the NIH is funded sufficiently to pursue the most promising basic and clinical research opportunities. One such opportunity is human embryonic stem cell research. S. 2015, the Stem Cell Research Act of 2000, which you have introduced, would allow federally funded scientists to not only use, but also to derive human embryonic stem cell lines from embryos that are in excess of clinical need and that would be donated with appropriate informed consent from in vitro fertilization clinics. These cell lines would be used for research purposes with the goal of developing new therapeutic strategies to treat devastating human disease.

The American Society for Cell Biology stands firmly in support of this bill. We believe that permitting peer-reviewed, Federal funds to be used for this research is our best assurance that the research will be of the highest quality and benefit and performed with proper ethical oversight and public input.

There are five supporting points I want to make.

First, as you have heard, human embryonic stem cells have enormous potential research and therapeutic value because they appear to be capable of generating many, if not all, of the cell types that make up a human organism. Research work over the past 20 years using mouse embryonic stem cells has demonstrated that these cells by themselves cannot form an adult organism, but they can differentiate into any adult cell type. Most important, mouse embryonic stem cells have been used in a variety of "proof of therapeutic principle" experiments in several animal models of human disease. For example, these cells appear to be able to produce neural progenitors that can repair spinal cord damage and reconstitute various types of brain cells and neurons. If reproducible with human embryonic stem cells, we may be able to treat Parkinson's disease, Alzheimer's disease, and other diseases such as ALS. We may be able to produce bone marrow cells to treat cancer and other

diseases and pancreatic cells to alleviate diabetes. In fact, we may be on the verge of a new era of medicine, one in which cell therapy could help restore normal function to a variety of affected tissues.

Second, some have argued that so-called adult stem cells derived from adult tissues are of equivalent promise, less ethically compromised, and should therefore be pursued exclusively. But it is far too early to know if adult stem cells have the same potential as embryonic stem cells, whether they can be harvested in sufficient quantities to treat disease, and whether they can grow indefinitely as can embryonic stem cells. In fact, it is likely to take years to find out if adult stem cells will be useful for treating many diseases that may be treatable sooner with embryonic stem cells.

Senator SPECTER. When you say years to find out, Dr. Goldstein, could you give us your judgment on approximately how long? Because we are really looking at an alternative here and the duration is a relevant factor in so many people not being treatable in the interim.

Dr. GOLDSTEIN. There are many different claims about how long it will take to do these things. Adult stem cells could give us something in a year. It could be 10 years. Embryonic stem cells have shown, I think, greater promise in some of the animal models, and we could be looking at something in 2 to 3 years.

But we cannot work with one hand tied behind our back, as was so eloquently pointed out by Senator Harkin and by others. And, of course, if we delay with diseases that prove to be treatable with adult stem cells, we risk unnecessary delays for patients such as Ms. Estess who may die or endure needless suffering while the promise is being tested. Thus, it is critical that we not prohibit or hinder research in any of these areas.

The third point I want to make is that the Stem Cell Research Act ensures that important avenues of medical research will not be restricted to the private sector. Precluding federally funded scientists from using human embryonic stem cells would effectively bar the majority of the Nation's most qualified researchers from pursuing scientific opportunities most likely to lead to rapid advances.

In fact, past experience has proven that broad access to breakthrough discoveries increases the likelihood of novel and innovative extensions. The molecular biology revolution, as I am sure you know, which is responsible for enormous social, economic, and medical advances is the product of innovations and discoveries made by thousands of highly qualified and creative federally funded scientists who developed new techniques and applications.

Fourth, an important feature of S. 2015 is that it will allow federally funded investigators to derive human embryonic stem cell lines with appropriate ethical safeguards. This is important because we know that a variety of poorly understood factors cause embryonic stem cells to lose their capacity to differentiate into all possible cell types. This loss of capacity may be caused by growth conditions, derivation conditions, or other variables of handling or storage. Enabling individual publicly funded investigators to derive cell lines using a variety of conditions is the best way to learn what conditions are critical to generate therapeutically useful cells.

Fifth and finally, there are serious ethical implications to not proceeding. Thus, we have heard many well-meaning ethical concerns about the sacrifice of embryos to prepare stem cells. However, the embryos in question will be legally destroyed in any case, and I have to ask, is it ethical to literally throw away one of our best opportunities to help our friends, our parents, and our children, many of whom will suffer and die if we do not find suitable therapies?

PREPARED STATEMENT

In closing, we have before us an unprecedented scientific opportunity to engage in a noble effort to develop new forms of medicine. That opportunity offers hope to the many millions of our citizens who rely on the shared stewardship of our scientists and our political leaders to enable science's achievements to relieve all people of the burden of serious disease.

I want to thank you for your courage in providing leadership on this most important, indeed, life or death issue and for inviting my testimony today.

[The statement follows:]

PREPARED STATEMENT LAWRENCE S. B. GOLDSTEIN

Mr. Chairman and members of the Subcommittee: I am Lawrence Goldstein. I am here today as a representative of the American Society for Cell Biology. The Society represents 10,000 basic biomedical researchers throughout the United States and the world, most of whom work in our Nation's leading research universities and institutes. It is my pleasure to appear before you again and it is a particular honor to be here with Mr. Reeve who has been such an articulate and effective spokesperson on behalf of biomedical research.

I am a Professor in the Department of Cellular and Molecular Medicine at the University of California, San Diego School of Medicine. I am also an Investigator of the Howard Hughes Medical Institute. Before moving to San Diego I was a Professor in the Department of Cellular and Developmental Biology at Harvard University for 10 years. My research focuses on the molecular and genetic analysis of protein motors and their roles in neuronal function and neurodegenerative disease.

I want to thank you, Senator Specter and Senator Harkin, for ensuring through your leadership of this important subcommittee that the NIH is funded sufficiently to pursue the most promising basic and clinical research opportunities. One such opportunity is embryonic stem cell research. S.2015, "The Stem Cell Research Act of 2000" which you have introduced, would allow federally-funded scientists to not only use, but also to derive embryonic stem cell lines for research purposes with the goal of developing new therapeutic strategies to treat devastating human disease. The American Society for Cell Biology stands firmly in support of this bill.

Just over a year ago, a milestone in biomedical research was achieved when human embryonic stem cell lines were obtained by growing cells from the inner cell mass of early stage human embryos. This discovery catalyzed a serious debate on Capitol Hill about whether federal funds should be used to support further research in this area. At issue is whether the merits of public funding and the dreadful burden of disease balance concerns about the origin of these special cells. Because of its great potential to treat disease and alleviate human suffering, the American Society for Cell Biology along with many other scientific organizations and societies have expressed strong support for Federal funding of this important research.

The American Society for Cell Biology supports The Stem Cell Research Act Of 2000 for four major reasons:

First, research work over the past 20 years using mouse embryonic stem cells has demonstrated the promise of embryonic stem, or ES, cells for basic research and potential disease therapy. These cells by themselves cannot form a mouse, but they can differentiate into any of the cell types that comprise a mouse. Mouse ES cells have been used to elucidate many important aspects of normal mouse embryology and development, but, most important, mouse ES cells are currently being used in a variety of "proof of therapeutic principle" experiments in several animal models of human disease. For example, these cells appear to be able to produce neural pro-

genitors that can repair spinal cord damage and reconstitute brain cells that produce the chemicals that control cognition, motion and sensory perception. If reproducible with human ES cells we may be able to treat Parkinson's disease and Alzheimer's disease. We may be able to produce bone marrow cells to treat cancer and other hematopoietic diseases, and pancreatic cells to alleviate diabetes. In fact, we may be on the cusp of a new era of medicine, one in which cell therapy could restore normal function to a variety of affected tissues.

It is important to note that some have argued that so-called "adult stem cells", derived from adult tissues are of equivalent promise, less ethically compromised, and should therefore be pursued exclusively. But, notwithstanding important advances in the field of adult stem cell research, it is far too early to know if adult stem cells have the same potential as embryonic stem cells, whether they can be harvested in sufficient quantities to treat or cure disease, and whether they can grow indefinitely as can ES cells. For example, for juvenile diabetes, there is little reliable evidence at present that adult stem cells could be used for treatment, and thus embryonic stem cells are the best near-term candidates for therapy. Furthermore, embryonic, fetal and adult stem cells are very different from each other. It is not at all clear that they will prove to be interchangeable or equally receptive to manipulations that would make them useful for therapy. Thus, it is likely to take years to find out if adult stem cells will be useful for treating many diseases that may be treatable sooner with embryonic stem cells. For diseases that prove not to be treatable with adult stem cells, we risk unnecessary delays for patients who may die or endure needless suffering while the promise of adult stem cells is being tested. It is critical that we not prohibit or hinder research in any of these areas.

Second, there is great medical need and urgency for stem cell research. To understand the need for rapid research progress with human pluripotent stem cells, one need look no further than many common, and often fatal, diseases such as cancer, heart disease and kidney disease. These diseases are treatable in whole or in part by tissue or organ transplants, but there are persistent and deadly problems of rejection and a woefully inadequate supply of suitable donor organs and tissues. In addition, the grim arithmetic of most organ transplants requires those who are seriously ill to wait for the tragic accidental death of another person so that they may live. Worse, for juvenile diabetes and many other diseases, there is not even a suitable transplantation therapy or other cure. Unless we use federal funds for all aspects of human pluripotent stem cell research new treatments for these conditions may be delayed by years, and many who might otherwise have been saved will surely die or endure needless suffering.

Third, The Stem Cell Research Act of 2000 ensures that important avenues of medical research will not be restricted to the private sector. We agree with the National Bioethics Advisory Commission that, "relying on cell lines that might be derived exclusively by a subset of privately funded researchers who are interested in this area could severely limit scientific and clinical progress." The effect of precluding federally-funded biomedical from such work will effectively bar the majority of the Nation's most prominent and most-qualified researchers from engaging in this critical research. Excluding these publicly funded investigators will close off scientific opportunities to those most qualified to make rapid and dramatic advances towards using stem cells for the treatment of disease.

We also know that a variety of poorly understood factors cause embryonic stem cells to lose their capacity to differentiate into all possible cell types. This loss of capacity may be caused by growth conditions, derivation conditions, or other variables of handling. Enabling individual publicly-funded investigators to derive cell lines using a variety of conditions in their own laboratories is the best route to finding out what conditions are critical to generate useful cells for therapeutic purposes. In the future, it is likely that cells prepared in one's own laboratory will have been derived, stored, and maintained in ways that maximize their potency for particular uses, whereas cells obtained from commercial sources are likely to be of unknown genetic background and history and therefore less useful for some important studies.

Federal funding is also the best way to guarantee that stem cell therapies are developed with the greatest consideration of the public good. Left to the private sector alone, stem-cell derived treatments may only be pursued for diseases that commercial companies project to yield the largest profit if treated. Thus, market forces could create a situation where deadly, but less widespread, diseases are ignored.

In fact, past experience has proven that allowing greater and more diverse access to breakthrough discoveries increases the likelihood of novel and innovative extensions. The Molecular Biology Revolution, which is responsible for enormous social, economic, and medical advances is the product of innovations and discoveries made by thousands of highly qualified and creative individual scientists who developed

new techniques and applications. Our world would be very different today had this vital technology been restricted to just a few investigators.

Fourth and finally, the American Society for Cell Biology supports The Stem Cell Research Act of 2000 because it guarantees that this important biomedical research will proceed with the highest possible ethical standards, and with sensitivity to the public concern about the origins of these cells. The National Biomedical Ethics Advisory Commission held numerous hearings and debates on this issue and solicited input from the public, scientific experts, and religious leaders from different faiths. After careful deliberation, the National Biomedical Ethics Advisory Commission concluded that it would be ethically permissible to prepare stem cell lines from embryos that had been obtained in the course of in vitro fertilization procedures, but were deemed by the donors and the physician to be in excess of the clinical need for the intended procedure: that is, those destined to be ethically and legally discarded.

The National Biomedical Ethics Advisory Commission also recommended specific regulatory and oversight procedures to ensure that the creation and use of human stem cells would meet the highest ethical standards. In fact, the draft guidelines developed by the NIH to govern use of embryonic stem cells specify similar criteria to those suggested by the National Biomedical Ethics Advisory Commission. Analogous procedures are wisely specified in the Stem Cell Act of 2000. These guidelines include complete separation between those who conduct research and those who donate stem cells, thus preventing any potential effort to develop embryos for the purpose of research. For federally funded research, this bill would also prohibit the use of embryos that are purchased or sold, and will continue to ensure that human embryos are not created for research purposes.

It is important to keep in mind that banning federal funding for human pluripotent stem cell research will not eliminate it. Such research will proceed in private industry and in other countries. This fact prompts serious concern that such work could be conducted in secret, without benefit of ethical regulation or public debate. Thus, prohibiting Federal funding will de facto prohibit public involvement and input into the future of this important field. Permitting peer-reviewed federal funds to be used for this research, combined with public oversight, is our best assurance that research will be of the highest quality and performed with proper ethical oversight and public input. Federal funding of this research will require the scientific community and the government to work together to establish an appropriate set of rules for this research. These rules will ensure the advancement of critical medical research and maintain respect for public sensibilities.

There are also serious ethical implications to not proceeding. Thus, while I am acutely and personally aware of the well meaning ethical concerns that have been expressed about the sacrifice of embryos to prepare stem cells, I am also cognizant that the embryos in question will be legally and ethically destroyed in any case. We must then ask: Is it ethical to literally throw away the opportunity to allow all people to benefit from the demise of these embryos? How can we justify not pursuing every reasonable means of finding cures for our friends, our parents, and our children, who will suffer and die if we do not find suitable therapies?

In thinking about the answers to these questions, I am reminded of the many parallels between our debate today about the potential use of human embryonic stem cells to treat disease and past debates about organ transplants and the proper treatment of donor families. The famous heart transplant surgeon Dr. Christian Barnard, stated it best in response to questions he received about the ethics of heart transplantation. He said: "Would it not be immoral to bury a heart when we have the ability to save a life?" We submit that the answer is the same for human embryonic stem cells. Ethics, scientific opportunity, and medical need can surely be balanced.

In closing, we have before us an unprecedented scientific opportunity to engage in a noble effort to develop new forms of medicine. That opportunity offers hope to the many millions of our citizens who rely on the shared stewardship of our scientists and our political leaders to enable science's achievements to relieve all people of the burden of serious disease.

Thank you for your courage in providing leadership on this most important—indeed, life-or-death—issue, and for inviting my testimony today.

Senator SPECTER. Thank you very much, Dr. Goldstein.

It is now 1 o'clock and we have a news conference scheduled at 1:00 so that there may be broader coverage to what Mr. Christopher Reeve and Ms. Jennifer Estess have to say to America and the world. Your testimony has been eloquent, and I do not think that any questions would lead to embellishing it.

I have never done this before, but I am going to invite people—I understand this is being carried live on C-SPAN I—to write to me and/or your own Senators as to whether you think there ought to be Federal funding used for stem cell research. You can write to me, Arlen Specter, United States Senate, in Washington, D.C., and I will get it. Or if you choose to write to your own Senator or Senators, send me a copy. I think it would be interesting to see what the response is.

This is a very controversial issue and there are many people who feel very strongly about the factors which have been testified to here today. Like the issue of fetal tissue, it has become embroiled in another debate. We have heard three witnesses testify in opposition to your views, Mr. Reeve, Ms. Estess, and Dr. Goldstein, in opposition to my views. I think the balance of authority is that the embryos are discarded and will not be used, as Dr. Goldstein puts it, an ethical question in discarding them and in not using them.

But this matter is going to be on the Senate floor and Senators pay attention to constituents. So, let us hear from you because we will post the tally on the website.

Dr. Goldstein, do you want the last word?

Dr. GOLDSTEIN. I would, if that is OK with you, Senator.

Senator SPECTER. I am not guaranteeing you will have the very last word, but go ahead.

Dr. GOLDSTEIN. I would not presume.

I just want us to pose the scenario that Senator Brownback and others have suggested where we stop embryonic stem cell work and work exclusively on adult stem cells for 5 years, say. So, what happens if in 5 years we find out that adult stem cells are not going to do the job? What do we tell Mr. Reeve and Ms. Estess at that time? Sorry, we have to start over? There may not be another opportunity. I cannot accept that conclusion.

Senator SPECTER. Well, you raise a good point. You know that stem cells from embryos will work, and that is what we have to make happen.

Ladies and gentlemen, we thank you for coming today. It is a very large group here in the hearing room. Would you keep your seats please? Keep your seats until Mr. Reeve and Ms. Estess have a chance to move out of the room. Then we will be assembling in the outer corridor for the news conference.

Thank you all very much, Mr. Christopher Reeve, Ms. Jennifer Estess, Dr. Lawrence Goldstein.

CONCLUSION OF HEARING

Thank you all very much for being here. That concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 1:04 p.m., Wednesday, April 26, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

STEM CELL RESEARCH

THURSDAY, SEPTEMBER 7, 2000

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:35 a.m. in room SD-124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Gorton, and Harkin.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. We will be proceeding with this appropriations Subcommittee on Labor, Health and Human Services and Education, and I am delighted to see our witnesses arriving. Traffic in Washington today is unusually bad, I am advised.

Do not pause in the audience, Dr. Fischbach and Dr. Spiegel. Move right up into the chairs which were occupied yesterday by executives from Firestone and Ford, where the Appropriations Transportation Subcommittee, which I am a member of, had a hearing, and I want you to know that our question for you today will be much more difficult and tough than they were for the officials from Ford and Firestone.

We have convened this session of the subcommittee to further our inquiry into stem cells. This is the sixth hearing which the subcommittee will have held on this very important subject going back to December of 1998, within a few weeks after the stem cell opportunities were disclosed. It was apparent at that time that stem cells had enormous potential as a veritable fountain of youth to replace cells in the human body which were diseased, and to solve many serious problems, many serious diseases.

With some of the results now showing enormous progress on Parkinson's and progress on Alzheimer's and on spinal cord and on a wide range of medical problems, this subcommittee felt a special responsibility to undertake this issue because it was in an appropriations bill in the mid-nineties where there was a prohibition against using Federal funds for stem cell research.

There has been an interpretation by the General Counsel for the Department of Health and Human Services that Federal funds may be made on stem cell research once stem cells have been extracted from embryos, but Federal funds may not be used to extract these stem cells from embryos, and that still leaves a very wide area of restriction on Federal research.

Let me note the arrival of my distinguished colleague from Iowa, Senator Harkin. It is nice to see you. We have an ongoing partnership which has survived the political process, as he says from time to time. When Democrats control the Senate he chairs this subcommittee. When Republicans now control, I chair, and we both learned a long time ago that if you want to get something in Washington you have to be willing to cross party lines.

We have maintained our approach on a nonpartisan, bipartisan basis, and I think the results show, such as our funding for the National Institutes of Health, where we have increased the funding very, very materially.

The three times of stem cells which are possible for extraction are embryonic stem cells, fetal tissue stem cells, and adult stem cells. Without going into the details, it is apparent scientifically, and we will hear from the experts on this today, that adult stem cells do not have the potential which is present with the embryonic stem cells.

The issue has been raised as to the propriety of using embryos, and we have had in our hearings the leading opponents from both the House and the Senate who have testified, and we propose to present the full picture, and in addition to the hearing today we are going to be having a hearing next week, because we expect this issue to come to the Senate floor for a vote.

The subcommittee report had included last year a change in this prohibition on Federal funding for stem cell research, and we removed it at full committee last year because it had the potential for tying up our appropriations bill and our Majority Leader, Senator Lott, agreed to bring the issue to the floor as a freestanding bill, which now will be taken up sometime this month, so we have had the full range of hearings.

In my opinion the issue on stem cells is very much like the issue on fetal tissue, where there was a lot of controversy, pro-choice versus pro-life, and then it was finally established to the satisfaction of, I think, almost everyone that use of fetal tissue would not encourage abortions, but it would only be discarded fetal tissue.

The matter with stem cells I think is highly analogous. These are embryos which are not going to be used. They have been created for in vitro fertilization, but they are to be discarded, so the issue boils down to whether they will be discarded and have no use, or whether they can be used to save lives, and I think that is a balance which comes out in favor of savings lives.

But there is serious debate on this subject, and this subcommittee will pursue it as far as we can to set the stage at having a very meaningful floor debate, and I think the Senate vote will be very, very important not only on this subject but on the future of medical research as we have this opportunity for a veritable fountain of youth.

Simultaneously with my red light going on—I have a little trouble understanding, frankly, why there are lights on for the chairman, but there were, so I will abide by them.

Now I would yield to my distinguished colleague, the Ranking Member, Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Senator Specter. It is good to be back with you here in this subcommittee and back in the Senate after our brief break period. I want to thank you for your determined and continued leadership on a broad variety of health-related issues, especially, as you mentioned, leadership on the continued funding for the National Institutes of Health.

I am pleased and honored to be a partner with you in those efforts. As Senator Specter said, we have a close bipartisan relationship in regards to medical research. We both believe in the strong potential that medical research holds for improving the lives of our fellow Americans and again I want to thank Senator Specter for his leadership on those issues, but more specifically on this issue that confronts us today.

I am pleased that we have the opportunity to hear from our panelists on the issue of the final NIH guidelines for the conduct of embryonic stem cell research. These guidelines are a critical step forward in the pursuit of medical breakthroughs, and I believe they will help lead to new therapies and treatments that could save or improve the lives of countless Americans.

I look forward to discussing both the scientific and the ethical impact of this research with our panelists today. Quite frankly, we are in a war, a war against cancer, spinal cord injury, and Parkinson's and diabetes and Alzheimer's and a host of other diseases and disorders which rob so many people and their loved ones of health.

These enemies are in many ways more fierce than those encountered in any military operation in our Nation's history. The death toll from just one of these, cancer, over the past 10 years exceeds the casualties for all of the military wars in our history. In fact, there have been nearly five times as many American casualties in the war against cancer in the past 10 years than all of the military wars fought since the American Revolution.

In World War II we left no stone unturned to gain victory. In the Persian Gulf War we developed the smart bombs that could go down Main Street and take a left on Elm and go into the window of Apartment Number 25. We developed these smart bombs. Well, we should have the same attitude when it comes to our wars against disease.

We should leave no stone unturned, and that is why the NIH guidelines and the ability to move forward with this research are so important. I believe we are at the crossroads of what could be a smart bomb against many diseases, and the key to victory, and we should pursue it.

Now, we will hear, I know, testimony as to whether we should use embryonic stem cells or just use adult-derived stem cells. Well, again my feeling on this is that all avenues should be pursued. I have often said that basic research is like having a number of doors that are closed. If you have 10 doors closed and you open one, chances are, your odds are, what about 10 to 1 that you are going to find something, but you open all 10 doors your odds are pretty good that you are going to make the breakthrough, and so rather than just going down one pathway I think we need to go down a number of different pathways.

I believe the NIH guidelines are an important step forward so that scientists have a procedural and ethical framework to pursue this research in an ethical and sound manner.

Again, I just would close by saying that stem cell research holds a lot of hope, a lot of potential for millions of people around the world who are sick and in pain, and I think it is wrong for us to prevent or delay our world-class scientists from building on the progress that has been made. If we are going to win this war, we have to pursue every path.

Thank you very much, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin, and thank you for your cooperation and your leadership on this subcommittee on these very important issues.

STATEMENT OF GERALD D. FISCHBACH, M.D., DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. The focus of today's hearing is to be on the National Institutes of Health guidelines which were published very recently, August 25, for research involving human embryonic stem cells, and our first witness is the distinguished Director of the National Institute of Neurological Disorders and Stroke, a position which Dr. Gerald Fischbach has held since 1998.

Prior to that time, he served as chairman of the Neurobiology Department at the Harvard Medical School and the Massachusetts General Hospital, past president of the Society for Neuroscience, a member of the National Academy of Science, a very, very distinguished research scientist, representative of the caliber of the National Institutes of Health.

Dr. Fischbach, welcome. You can skip the traffic problems and go right to the guidelines.

Dr. FISCHBACH. Thank you, Mr. Chairman and Senator Harkin. I am pleased to be here today, and actually relieved to be here on time, but pleased to be here to discuss the use the medical promise of human pluripotent stem cells and the new NIH guidelines released a couple of weeks ago, which are designed to ensure that such cells are used in an ethical and legal manner.

Stem cells indeed are revolutionary tools, perhaps the most exciting development in biomedical science in my career, at least dealing with the nervous system. They are exciting for many reasons but they do, as very few other therapies do, offer the possibility of reversing the course of disease, of actually curing disease in addition to controlling symptoms.

This for the first time offers the possibility of reversing disease processes and replacing damaged parts in the body, and the promise is due to two properties of stem cells. One, they can proliferate, and they can multiply and produce a large supply of these tools and cells. Second, they can be, under proper coaxing, forced to differentiate. That is, to develop into mature cells that actually can function as missing parts in various organs.

Now, there are many, many uses of stem cells. One of them certainly will be in the area of novel tools for drug discovery. There is some evidence that they will be the vehicle that will enable breakthroughs in gene therapy, and they certainly will teach us a

great deal about the fundamental biology of development and the pathogenesis of disease.

But perhaps the most striking aspect of stem cell biology which has attracted most attention is the ability to transplant them into the body, and this is what has caused such great excitement, and if I can for a moment speak about the nervous system of the brain, with which I have been particularly involved, this is a vital, vital property of these cells and the nervous system.

With rare exception our nerve cells are nonrenewable resources. When a nerve cell dies in our brains it is simply not replaced, or not replaced easily. With rare exceptions cells do not divide in the brain, so when they degenerate they are lost. Therefore, the ability to replace cells is extremely important and major advances have been made, as you said, Senator Specter, in Parkinson's disease and a number of other disorders.

In Parkinson's disease, we know exactly where the lesion starts. We know the type of nerve cell that degenerates initially, and it has been possible, using tissue, fetal tissue, to replace these degenerating cells and to reverse the symptoms of Parkinson's disease in animal models and in first studies in human trials. This offers great promise, and challenges us to do more research on stem cells and to replace the fetal tissue implants with a much more controllable and useful source.

But it does not stop there. Stem cells have been used recently in treatment of sequelae of stroke, ALS, spinal cord injury, tumors of the nervous system, and strangely enough, because it is widely disseminated, even in multiple sclerosis.

Now, there is a hierarchy of stem cells. I think the consensus of scientific opinion is that cells proliferate and differentiate when isolated from the adult nervous system, but there is a common view that cells proliferate more plentifully, and they have a wider range of choices, if taken from the fetal or embryonic tissue, so we would like to discuss that hierarchy.

Now, much remains to be learned. Although I have emphasized the promise, much research needs to be done about how we can control the proliferation of these cells and how we can urge them to differentiate in one half or another, and how we can prevent overproduction of cells.

Now, we recognize that there are difficult ethical issues involved in formulating policies in dealing with human embryonic stem cells, which in my view are the most promising at the present moment of all the stem cells isolated to date, and therefore the NIH has formulated guidelines. They have proceeded slowly and in public.

This committee has had several public hearings. The NIH developed a working group from the Advisory Council to the Director which included scientists, ethicists, patients, patient advocates, lawyers, and laymen, and that resulted in the guidelines which we are prepared to discuss, and I want to thank you for the opportunity to present this statement, and I would be prepared to answer questions that may arise.

Senator SPECTER. Thank you very much, Dr. Fischbach. Before calling on Dr. Spiegel, I would like to yield to our distinguished col-

league, Senator Slade Gorton, for an opening statement if he has one.

Senator GORTON. Please go ahead.

STATEMENT OF ALLEN M. SPIEGEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. All right, then. We turn to Dr. Allen M. Spiegel, appointed Director of the National Institute of Diabetes and Digestive Kidney Diseases last year, and prior to that appointment Dr. Spiegel held significant positions in the Institute, including Director of Intramural Research, and Chief of Metabolic Disease, an M.D. from Harvard and a B.A. from Columbia. Thank you for joining us, Dr. Spiegel, and we look forward to your testimony.

Dr. SPIEGEL. Thank you very much, Mr. Chairman, and Senators Harkin and Gorton. I appreciate the opportunity to appear before you today with Dr. Fischbach on behalf of my colleagues at the National Institutes of Health to discuss the promise of research on human pluripotent stem cells, research that will be funded under the recently released NIH guidelines.

The guidelines prescribe procedures to enhance both the scientific and ethical oversight of this important area of research. As described in our written statement, the guidelines specify the documentation and assurances that must accompany requests for NIH funding for research utilizing human pluripotent stem cells. These include cells that were derived in the private sector from human embryos that were created for fertility treatment, were frozen, and are in excess of clinical need. They also set out specific conditions for the use of pluripotent stem cells derived from fetal tissue.

These guidelines will encourage openness, help make certain that researchers can make use of these critical research tools, and help assure public access to the practical medical benefits of research using these tools.

You have heard from Dr. Fischbach of the potential applications of research on human pluripotent stem cells to developing treatments for neurological disorders. In fact, this research holds great potential for leading to new cell therapies for many other types of disease, such as those involving the heart and the liver.

Perhaps one of the best examples of the promise of this line of research is in the treatment of Type 1 diabetes, or juvenile onset diabetes. This form of diabetes is characterized by the inability to produce insulin, the hormone necessary for sugar metabolism. Type 1 diabetes occurs when the body's immune system attacks and destroys its own insulin-producing islet cells in the pancreas. The standard treatment is to try to control the sugar level with insulin injections. This is exceedingly difficult even in adults, and much more difficult in children with the disease. Transplantation of insulin-producing islet cells, in theory, offers a much better approach to controlling sugar levels.

In a recent published study, seven patients receiving islet transplants became completely independent of the need for insulin injections. NIH is currently funding a multi-center trial of the protocol used in this study to determine if the same high rate of success can be achieved in a larger number of patients. A successful outcome

to this trial, as exciting as it would be for patients with Type 1 diabetes, and for their families, will only serve to underscore the limitation in the supply of islets available for transplantation compared with the need.

While many approaches to address the islet supply problem, including research on adult stem cells, should be and are being vigorously pursued, human pluripotent stem cells offer the greatest promise of providing a limitless source of islet cells for transplantation in patients with Type 1 diabetes.

PREPARED STATEMENT

The release of the NIH guidelines now allows us to fund this research that could lead to a cure for Type 1 diabetes and for other serious diseases for which there is no satisfactory current treatment.

Thank you, Mr. Chairman. Dr. Fischbach and I would be pleased to respond to questions you and the other members may have.

[The joint statement follows:]

PREPARED JOINT STATEMENT OF GERALD D. FISCHBACH AND ALLEN M. SPIEGEL

Mr. Chairman, Senator Harkin, and Members of the Subcommittee, I am Dr. Gerald Fischbach, Director of the National Institute of Neurological Disorders and Stroke. I am accompanied by Dr. Allen Spiegel, Director of the National Institute of Diabetes and Digestive and Kidney Diseases. We are before you again to discuss one of the most exciting areas of biomedical research: the enormous potential of human pluripotent stem cells to treat and cure debilitating and deadly diseases.

Only two years ago, researchers discovered and isolated these primordial cells—whose existence in humans had been theorized but never proven—the precursors of most of the other cells in the body. Their unique properties of self-renewal and the ability to differentiate into the full spectrum of other cell types make them ideal candidates for repairing and replacing tissues and organs ravaged by disease. New more effective treatments, and maybe even cures, might be developed for juvenile-onset diabetes, Parkinson's Disease, spinal cord injury, ALS or Lou Gehrig's disease, Alzheimer's Disease and many other brain disorders. There is similar potential for the treatment of cancer and heart disease. Virtually every realm of medicine and human health might benefit from this innovation. Stem cell research could alleviate a great deal of human suffering.

Chairman Specter, you and Senator Harkin, in particular, have encouraged the National Institutes of Health (NIH) to invest our resources in stem cell research in order to pursue its enormous opportunities. Patients who are suffering from the most deadly and disabling diseases have also asked that NIH fund this promising arena of research. We believe that federal funding would encourage openness, stimulate more discoveries and translate the promise of this research into practical use more quickly, efficiently, and effectively—and with procedural safeguards.

Recognizing that the ethical issues related to this research required careful consideration, NIH and the Department of Health and Human Services were committed to developing Guidelines to help ensure that pluripotent stem cell research funded by NIH would be conducted in a legal and ethical manner. In drafting the Guidelines, the NIH sought the advice of scientists, patients and patient advocates, ethicists, clinicians, lawyers, the National Bioethics Advisory Commission, and members of Congress. Draft Guidelines were published in the Federal Register last December. The NIH reviewed and considered all comments in preparing the final Guidelines.

We are pleased to inform you that, on August 25, NIH published final Guidelines for research using human pluripotent stem cells. NIH is prepared to begin receiving applications immediately. As soon as the oversight process is in place, NIH will be in a position to fund such research. We expect broad interest from researchers seeking funding for pluripotent stem cell research, and we are hoping to begin funding this research as soon as possible. For procedural reasons, the soonest that awards could likely be made is early next year.

WHAT ARE STEM CELLS?

Human pluripotent stem cells are a unique scientific and medical resource. They can develop into most of the specialized cells and tissues of the body, such as muscle cells, nerve cells, liver cells, and blood cells, and they are self-renewing, making them readily available for research, and potentially, for treatment purposes. Scientists derived these unique cells from human embryos and from fetal tissue.

WHY ARE HUMAN PLURIPOTENT STEM CELLS IMPORTANT?

There are three reasons why the isolation of human pluripotent stem cells is so important to science and the future of public health.

First, pluripotent stem cells could help us to understand the complex events that occur during human development.

Second, human pluripotent stem cell research could also dramatically change the way we develop drugs and test them for safety and efficacy. Rather than evaluating safety and efficacy of a candidate drug in an animal model of a human disease, these drugs could be tested against a human cell line that had been developed to mimic the disease processes. This would not replace whole animal and human testing, but it would streamline the road to discovery, and ensure that only the safest drugs are tested in humans.

Third, and perhaps the most far-reaching potential application of human pluripotent stem cells, the generation of cells and tissue could be used for "cell transplantation therapies." Such therapies are aimed at diseases and disorders resulting from the destruction or dysfunction of specific cells and tissue. Although donated organs and tissues can sometimes be used to replace diseased or destroyed tissue, the number of people suffering from such disorders far outstrips the number of organs and tissues available for transplantation. Pluripotent stem cells, stimulated to develop into specialized cells and tissue, offer real hope for the possibility of a renewable source of replacement cells and tissue to treat a myriad of diseases, conditions, and disabilities for which replacement tissue is in short supply. Examples of these include neurological disorders (including spinal cord injuries and ALS), diabetes, burns, heart disease, and arthritis.

REQUIREMENTS OF THE GUIDELINES

The Guidelines prescribe procedures to ensure that NIH-funded research in this important arena is conducted in an ethical and legal manner. They specify the documentation and assurances that must accompany requests for NIH funding for research utilizing human pluripotent stem cells. These Guidelines will encourage openness, help make certain that researchers can make use of these critical research tools, and help assure public access to the practical medical benefits of research using these cells. The Guidelines accomplish these goals in the following ways.

First, the Guidelines help ensure that embryos will not be created for the purpose of deriving human pluripotent stem cells to be used in NIH-supported research. Investigators seeking NIH funds are required to provide documentation that the human pluripotent stem cells were derived from frozen embryos that were created for the purpose of fertility treatment and that were in excess of clinical need. They require a clear separation between the fertility treatment and the decision to donate embryos for this research. In addition, the donation of the human embryos must be made without any restriction regarding the individual who may be the ultimate recipient of the cells for transplantation. Similarly, researchers wishing to use human fetal tissue to derive stem cells must demonstrate that they are in compliance with all applicable laws and regulations. The Federal statute applicable to NIH-funded fetal tissue transplantation research also includes provisions creating a separation between the decision to terminate a pregnancy and the decision to donate fetal tissue for research.

Second, the Guidelines ensure that individual choosing to donate embryos cannot receive any inducements, monetary or otherwise. The Guidelines detail specific elements that must be included in the informed consent to help ensure that potential donors receive sufficient information to allow them to decide whether or not to donate human embryos for this type of research. The Guidelines require review and approval by an Institutional Review Board (IRB) to ensure that consent was informed, voluntary, and meaningful.

Third, the Guidelines require accountability on the part of the researcher. Detailed documentation must be submitted to NIH to demonstrate compliance. For example, the grantee institution must sign an assurance that the research to be conducted is in compliance with the Guidelines, and that the institution will maintain

documentation to support the assurance. The researcher/grantee institution must submit a sample informed consent document, with patient identifier information removed, a description of the informed consent process, and documentation of IRB review.

Fourth, the Guidelines specify types of research that the NIH will not fund. For example, NIH will not fund any research that seeks to derive pluripotent stem cells from human embryos, research utilizing pluripotent stem cells that were derived from human embryos created for research purposes, or any research that seeks to derive or utilize stem cells from embryos that were created using somatic cell nuclear transfer (cloning technology).

Fifth, the NIH has designed an oversight process that will provide an extra level of protection, above and beyond standard peer review of grant applications, to ensure that researchers have complied with the Guidelines. A newly-created NIH working group called the Human Pluripotent Stem Cell Review Group (HPSCRG) will review documentation submitted by researchers demonstrating that they are in compliance with the Guidelines. Members of the HPSCRG will subsequently make recommendations to its parent committee, the Center for Scientific Review Advisory Committee. NIH will not fund research or allow existing funds to be used for research using human pluripotent stem cells derived from human embryos or human fetal tissue until the required compliance documentation receives HPSCRG review and approval of the NIH Center for Scientific Review Advisory Committee. Continued compliance with the Guidelines will be a term and condition of the NIH award.

HUMAN PLURIPOTENT STEM CELLS AND DIABETES RESEARCH

One of the best examples of the promise of this line of research is in the treatment of Type 1 diabetes. Research on islet cell transplantation and stem-cell biology offers compelling opportunities for the development of new, innovative approaches for treating and ultimately curing this disease.

Type 1 diabetes, often referred to as juvenile diabetes, is characterized by the inability of the body to produce insulin, a hormone necessary for glucose metabolism. This form of diabetes occurs when the body's immune system attacks and destroys its own insulin-producing islet cells in the pancreas. As a result of inadequate insulin production, glucose does not enter cells as readily as when insulin levels are normal. The standard treatment is to try to control the glucose level with insulin injections.

Transplantation of insulin-producing islet cells is an alternative approach to controlling glucose levels. In a recent study, seven patients receiving islet transplants became completely independent of the need for insulin injections. NIH is currently funding a multi-center trial of the protocol used in this study to determine if the same success can be achieved in a larger number of patients. A successful outcome to this trial, as exciting as it would be for patients with Type 1 diabetes, will only serve to underscore the limitation in the supply of islets available for transplantation compared to demand. While many approaches to address the islet supply problem, including work on cell bioengineering and adult stem cells are being vigorously pursued, human pluripotent stem cells offer the greatest promise of providing a limitless source of islet cells for treating and curing Type 1 diabetes.

HUMAN PLURIPOTENT STEM CELL RESEARCH AND THE NERVOUS SYSTEM

As significant as the promise of stem cells is for the treatment of diabetes, the potential of stem cells for treating diseases of the nervous system is equally impressive. The most obvious and exciting use of stem cells in neurological disorders is to replace nerve cells lost to disease or injury. Many diseases destroy particular types of nerve cells, and mature nerve cells cannot produce new cells to replace those that are lost. Animal experiments have demonstrated that the potential exists for coaxing stem cells to specialize and replace the dopamine cells that are lost in the brain through Parkinson's disease. A similar approach might also apply to several other neurological disorders. Human pluripotent stem cells, given appropriate control signals, might specialize to replace the lost acetylcholine producing nerve cells in Alzheimer's disease, to restore lost motor neurons in ALS, or to produce inhibitory cells to help restrain electrical activity in epilepsy.

Replacing lost nerve cells is only the beginning of the list of possible therapeutic applications for stem cells. For some disorders, such as multiple sclerosis, stem cells might replace supporting cells, such as the glial cells, which provide the insulation necessary to allow some nerves to conduct electrical impulses rapidly. In addition to their potential in replacement therapy, stem cells can provide nutritive factors that might prevent the loss of nerve cells in the first place. Stem cell strategies might be useful for correcting inherited defects. For example, in disorders that dev-

astate children's brains, we might rely on the ability of stem cells to migrate widely in the brain and supply the vital missing enzyme that leads to early and tragic death from Tay-Sach's disease. In addition, stem cells might regenerate the many different kinds of complex brain tissue that are damaged as a result of brain trauma or stroke. Transplanted stem cells might also supply natural growth and survival chemicals to pave the way for regeneration of remaining healthy neural tissue following spinal cord injury. Recent findings suggest that stem cells might be harnessed to seek out and destroy brain tumor cells that evade surgery or radiotherapy. The list of possible applications of stem cells continues to grow as we learn more about these cells.

CONCLUSION

Mr. Chairman, we appreciate the opportunity to discuss this promising and extraordinary science and are pleased to respond to any questions you may have.

Senator SPECTER. Thank you very much, Dr. Spiegel. As you men have testified, I have made notes of the kinds of diseases which could be cured by stem cells and I have noted the following, and I would like to ask you if I am correct and if there are others, and the follow-up question is going to be, how many Americans, in ball park figures, are affected by these diseases?

Parkinson's, amyotrophic lateral sclerosis, strokes, spinal cord, tumor, multiple sclerosis, heart, liver, diabetes? Is that the total? How about the impact on cancer, if any?

Dr. FISCHBACH. Cancer should be included in that list. There is evidence for stem cells homing to tumors to deliver toxins to tumor cells.

Senator SPECTER. Could you give a ball park figure as to how many Americans suffer from these ailments?

Dr SPIEGEL. I will address that with an example. For liver disease, we need to understand that liver transplantation is a cure for liver failure caused by hepatitis viruses, by autoimmune diseases, by many other conditions.

Thousands of Americans die every year awaiting liver transplants. Therefore, an alternative to the insufficient supply of cadaveric livers is vital, and thousands of American lives could be saved if cell therapy for liver disease could be developed as an alternative to liver transplantation.

Senator SPECTER. We may have a short answer. Senator Harkin has anticipated this issue and has listed these categories, and I would be interested in your response to put it into the record beyond the hearsay document which Senator Harkin has handed me: cardiovascular disease, number of persons affected, 58 million; autoimmune, 30 million; diabetes, 16 million; osteoporosis, 10 million; cancer, 8.2 million; Alzheimer's, 4 million; Parkinson's, 1.5 million; severe burns, .3 million, spinal cord injuries, .25 million; birth defects, 150,000 per year, total of 28,400,000.

Does that sound about right to you, Dr. Fischbach?

Dr. FISCHBACH. Yes, it does, and if you are listing the number of people affected by those disorders, that does sound right, certainly.

Senator SPECTER. That is about half of America.

Senator HARKIN. Well, heart disease gets about half the people in America.

Senator SPECTER. Well, that is quite an impressive list. Thank you, Senator Harkin.

With respect to the opportunities for adults themselves, I know you have already testified that the adults themselves are not as well-directed, and we are going to have another panel in opposition to your views, but could you elaborate, Dr. Fischbach, on why adult stem cells do not eliminate the need for stem cells from embryos, as you earlier generalized?

Dr. FISCHBACH. That is actually the perfect way to state it, and I think we can both respond to that. I believe that stem cells have been discovered in adult tissues, actually quite surprisingly in the brain, and that they do have the capacity to proliferate, and to differentiate. Indeed, they may even switch identities, and cells from other organs, from the blood, have some promise of forming nerve cells in tissue culture, but I think these are early reports and the conversion to a neuronal phenotype is not complete, and the overwhelming evidence is that they do not generate sufficient numbers of nerve cells to be useful in the brain.

So I think the way you phrased it is exactly right. It would not be responsible of us to use these cells in place of embryonic stem cells, which at the present time most of the advances I described are using embryonic stem cells, and that is where the lead effort is right now, and the most promise.

Senator SPECTER. Well, could you specify which of these enumerated diseases have promise with the embryonic stem cells and which do not with the adult stem cells?

Dr. FISCHBACH. It is hard to say do not, because the research is such that there can be, and we are hoping for further breakthroughs in the use of stem cells from adult tissues, but the embryonic stem cells have already been used in the treatment of Parkinson's disease, stroke and some aspects of spinal cord injury, and adult stem cells have not.

Senator SPECTER. My red light has just gone on. I will yield to Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman. Just a couple of follow-ups. I expect many scientists have been anxious to get started on this research, and waiting for these guidelines for sometime now. Do you have any idea how many researchers have already told NIH that they want to apply for funding?

Dr. FISCHBACH. I do not think we have those numbers in yet. I have seen one report that one of the developers of embryonic stem cells has had 150 requests the day after the stem cells were published, but I do not have the numbers for NIH receipt.

Senator HARKIN. A number of privately funded researchers are already working on stem cells. What will the impact on the field be once NIH starts funding this research, since it is already being done in the private sector? Tell us what, once we move ahead with these guidelines, assuming we do, what will be the impact on the field?

Dr. SPIEGEL. I can comment in part relating to the previous question. Our institute now funds several dozen investigators who have expressed interest in working on these human pluripotent stem cells, particularly with reference to the pancreatic islets and the liver cells.

We support a very large portfolio of research currently on adult stem cells. We are very vigorously supporting research in that area.

These same researchers, recognizing the incredible potential of the human embryonic stem cells and pluripotent stem cells from fetal tissue, are eager to be able to do this. I think the impact will be enormous, because—although some private sector investigators are working in that field—we need to harness the entire brain power the NIH is capable of mobilizing.

Dr. FISCHBACH. I think it will make the research more open, more public, more published, and more diverse, and better.

Senator HARKIN. And since there are guidelines now for the private sector, I was told one day it was sort of like the Wild West, there is no real guidelines, and while the guidelines promulgated by NIH are not forced on the private sector, these are not mandatory on private researchers, is it your understanding that once NIH publishes guidelines like this it sort of—because NIH is so big and the funding comes to NIH that the private researchers then would follow and sort of come under the umbrella of these guidelines? Would that be your understanding?

Dr. FISCHBACH. Senator, that is one reason I am proud to be at the NIH. I think the NIH sets the standard for the field and for the world, and I think you behave differently at some risk, and I think the guidelines will influence industry. Certainly the guidelines specify we will fund research using embryonic stem cells derived from human embryos only according to strict regulations and rules, and that will have a big influence.

Senator HARKIN. Again, for the lay person's mind like mine, would you again, as much as you can in lay person's terms, discuss the news that came out over the summer about the finding that they could use adult bone marrow cells, stem cells, that could differentiate into other cell lines, and once that came out some people said to me, well then, you do not need to use embryonic any more now we have this, and I think there is some confusion out there, because I talked to a lot of people and they said, well, you do not need the embryonic. We now know that we can take bone marrow cells, adult stem cells, and they can differentiate into, I think it was liver—neurological cells.

So please, explain what this is all about.

Dr. FISCHBACH. Again, we can both take a shot at that.

My understanding of that paper is that it is an important observation in that it does show that bone marrow, which we have known for 40 or 50 years has diverse developmental potential, and some of those cells—remember, bone cells are turning over all the time in our body, unlike nerve cells.

So there are stem cells in bone marrow to replace the marrow, especially during the war on radiation injury and marrow transplants, and this report pointed out that when the cells are treated in a certain way in tissue culture, that a few of the cells would begin to express—in other words, begin to manifest certain proteins that are characteristic of nerve cells, and they look a little bit like nerve cells under the microscope, but there is no demonstration yet that this will be a realistic supply of cells yet, and there is no demonstration that these cells will become the type of nerve cells that are needed. It is like an existence proof. Something can happen, but we do not know how far down the road they will go to be useful.

So while it is an interesting first step, I cannot tell whether it is 1 year, 5 years, 10 years, or a generation before those cells will be truly clinically useful, so I think it should not preclude—I do not agree with the statement that we have shown this, therefore you do not need human embryonic stem cells.

Dr. SPIEGEL. Since you asked in lay terms, let me try a sports analogy. We are talking in terms of human pluripotent stem cells capable of playing any position on a team, and having a limitless supply, a bench strength, that has incredible depth.

In terms of the adult stem cells, there is new evidence that they may not have the high degree of versatility of human pluripotent stem cells. If we use a baseball analogy, adult stem cells may be like a utility infielder who can play a couple of positions in the field, but it is not necessarily good at all positions. Much more research needs to be done to see whether adult stem cells can really play every position in the sense of combating multiple diseases. They do not have the same bench strength.

In embryonic stem cells from mice, there are several cell lines that are replicating, that is, dividing endlessly in many labs and being used in limitless supply. I think that is a critical difference.

When we think in terms of our goal, which is the treatment of disease and alleviating suffering, we have to think in terms of the range of disease possibility. The embryonic human pluripotent stem cells can address every one of these diseases. The adult stem cell research may, and we hope it will, be successful in certain areas, but not necessarily every area.

Senator SPECTER. There is a vote in process right now on the Senate floor, to be followed by another vote, and we are going to take a very brief recess. We will return as promptly as we can, and at that time we will turn to the next panel of distinguished witnesses, Dr. Prentice and Dr. Roth, and we would ask you, Dr. Fischbach and you, Dr. Spiegel, to stay, and after we hear the testimony from those expert witnesses we may want to have some interchange, and so we stand in recess for just a few minutes.

The subcommittee will resume.

Although both Senator Harkin and I have expressed our views on this subject by introducing legislation to remove the prohibition so that there may be funding on stem cell research, we have both had many contacts from constituents who have a different point of view, and whatever our personal views may be, the subcommittee considers it indispensable to hear all sides, and earlier in our hearings we had heard the leading opponents of stem cell research both in the Senate and in the House as witnesses before this subcommittee, and now we turn to two distinguished witnesses who are opposed to stem cell research, Dr. David A. Prentice and Micheline M. Mathews-Roth. Dr. Mathews-Roth, if you would step forward.

STATEMENT OF DAVID A. PRENTICE, M.D., Ph.D., PROFESSOR OF LIFE SCIENCES, INDIANA STATE UNIVERSITY

Senator SPECTER. We will hear first from Dr. Prentice, professor of life sciences, Indiana State University, and an adjunct professor of medicaid and molecular genetics for Indiana University School of Medicine. He also serves as science fellow for United States Sen-

ator Sam Brownback, who had testified earlier in opposition to stem cell research at one of our prior hearings.

Dr. Prentice is a founding member of Do No Harm, the Coalition of Americans for Research Ethics. He received his bachelor of science in cellular biology and his Ph.D in biochemistry from the University of Kansas, parenthetically, Dr. Prentice, my home State. We welcome you here and look forward to your testimony.

Dr. PRENTICE. Mr. Chairman, thanks for this opportunity to appear before you today to talk about this extremely important issue, stem cell research. Your colleague, Senator Brownback, has stated previously his position that federally funded human embryonic stem cell research is illegal, immoral, and unnecessary, and others have discussed at length the arguments related to illegal and immoral.

My point today would be to talk at some length about the unnecessary aspect, whether we should actually be doing human embryonic stem cell research, so I would like to spend some time talking about that, because I feel at times the statements that have been made are somewhat misleading.

Mr. Chairman, because embryonic stem cells are derived from very early embryos in the continuum of human development, they should have the ability to form virtually every tissue needed in the body. It is for this reason that many are anxious to see these cells used for possible clinical applications.

You are also well aware that production of human embryonic stem cells does require the destruction of human embryos. There are some scientific reasons why human embryonic stem cells may not be as desirable as adult stem cells. One is simply the fact that tissues generated by these cells will cause transplant rejection, the same as any normal organ transplant will require the use of toxic immunosuppressive drugs, possibly for the lifetime of the patient.

Now, one possible solution might be to clone the patient, destroy that embryo, essentially the patient's own twin to divide the cells, but this complicates the debate even more with an additional controversial technique.

Another possible problem may be control of differentiation of embryonic stem cells to form the desired tissue, rather than other tissues, or possibly even a tumor.

Senator SPECTER. What was it you just said, Dr. Prentice, your last point?

Dr. PRENTICE. Another problem might be precise control of the differentiation of the embryonic stem cell so that we get the desired tissue.

Now, one other concern that has come up in terms of embryonic stem cells, these have been termed pluripotent, able to form most, not necessarily all stem cell types, but actually published reports indicate that they are totipotent, able to form all tissues of the developing human, or possibly even an integral human embryo itself.

The publications regarding human or primate embryonic stem cells and their derivation note that, unlike mass embryonic stem cells, human and primate embryonic stem cells can form not only the tissues that become part of the human body, but also trophoblast tissue.

Now, you are probably well aware that it is the trophoblast tissue that surrounds what become the embryonic stem cells that allows the embryo to implant into the uterine wall and nurtures early development. This is the tissue layer of the embryo that is destroyed when the embryonic stem cells are derived.

Now, reformation of this tissue layer in cultures of embryonic stem cells could actually lead to reformation of complete human embryos in culture, able to survive if implanted into a womb. This means actually the possible production and destruction of thousands of new humans in culture created with Federal funds, which would be a direct violation of Federal law and NIH's own guidelines. Image of a virtual embryo body shop springs to mind.

If we could turn to my main goal here, talking about the ethical alternative of adult stem cells, there have been a number of statements critical of this alternative and their abilities, and I am somewhat mystified by these statements, Mr. Chairman, because they seem to have been made without a thorough reading of the scientific literature, especially within the last 1 to 2 years.

For example, it has been stated that embryonic stem cells will be in clinical use before adult stem cells, but to date there have been no publications regarding the current clinical use of human embryonic stem cells. The statement was made earlier about clinical use for Parkinson's and stroke, but those particular uses used transplants of fetal brain tissue, not embryonic stem cells.

I have, and I will be submitting for the record, a number of references regarding current clinical uses, including cancer, lupus, various other immune diseases, corneal scarring.

Another criticism that has been leveled is that there are only a few types, but more and more we are finding there are many different types of adult stem cells, and these essentially are pluripotent, just as has been claimed for the embryonic stem cells.

In fact, in June of this year, a group in Sweden performed an experiment with mice using adult neural stem cells, showing these cells are pluripotent. They repeated an experiment done in 1984 using mouse embryonic stem cells, an experiment, I might add, which has not been done and ethically should not be done with human embryonic stem cells.

The group stated that these studies suggest stem cells in different adult tissues may be more similar than previously thought, and perhaps in some cases have a developmental repertoire close to embryonic stem cells.

I realize I am short on time, Senator, and I will be introducing—

Senator SPECTER. Your red light is on, but you may proceed.

Dr. PRENTICE. Thank you, sir. If I could just hit a few of the high points, as we say, others have said adult neural stem cells can be stimulated to grow even while still within the brain if given sufficient signal. One report notes adult neural stem cells can be multiplied in culture and are, quote, similar to human embryonic stem cells, end quote.

Other adult stem cells have been identified in muscle, and just 2 days ago a report in the *Journal of Cell Biology* announced purification of adult stem cells from the muscle of a mouse model of Duchenne's muscular dystrophy. These cells were introduced intra-

venously injected back into the dystrophic mice, and resulted in muscle regeneration and partial restoration of dystrophon expression in the mice.

Diabetes, one of the leading killers in the United States, previous witnesses mentioned the use of adult stem cells from cadavers, and this is a very promising technique, but obviously the patient could use their own stem cells. This would be a distinct advantage.

In March of this year, adult pancreatic stem cells from mice were used to reverse diabetes in these animals. These animals are a model of Type I, or juvenile diabetes. After treatment the mice no longer needed insulin shots to survive.

Other criticisms are that the adult stem cells are hard to access. They do not multiply well in culture. In August, researchers showed that human adult bone marrow stem cells can take up a new job description, if you will, and be changed into neurons. The report notes that these grow readily in culture, are readily accessible, and provide a renewable population.

In July, two groups, one in the United States and one in the U.K., found human adult bone marrow stem cells could form liver and they noted, we could avoid problems with current liver transplants where the patient's body rejects the foreign organ. Another one said, this would suggest maybe we do not need any type of fetal stem cell at all, that our adult bodies continue to have stem cells that can do this stuff, perhaps not precise scientific language, Senator, but I think they make the point that we do seem to have within our bodies these cells, pluripotent adult stem cells, which can take care of organ and tissue regeneration.

Some have urged research on both types of stem cell should go forth, but the President's own National Bioethics Advisory Commission has said that because human embryos deserve respect as a developing form of human life, destroying them is, quote, justifiable only if no less morally problematic alternatives are available for advancing research, close quote.

Senators, the scientific literature overwhelmingly demonstrates that adult stem cells are already fulfilling the goals only hoped for with embryonic stem cells, making destruction of human embryos completely unjustifiable.

Mr. Chairman, essentially, and we are really talking about a human rights issue, it has been said that these human embryos targeted for destruction to derive embryonic stem cells will die anyway, so we should get some good out of them, possibly to benefit those with life-threatening diseases.

PREPARED STATEMENT

If we follow this path of devaluing human life and sacrificing one set of lives for the potential benefit of others, how long might it be before those patients with life-threatening diseases will hear the same phrase? They are going to die anyway. Let us get some good out of them. Whom will we choose to assign value, and who will dare to make those choices? I implore you not to follow this path.

I thank you once again for this opportunity to discuss this extraordinarily important topic with you, and I will be pleased to respond to any questions you might have.

[The statement follows:]

PREPARED STATEMENT OF DAVID A. PRENTICE

Mr. Chairman and Members of the Subcommittee, I thank you for this opportunity to appear before you today to talk about this extremely important issue of stem cell research. Your colleague, Senator Brownback, has stated previously his position that federally funded human embryonic stem cell research is "illegal, immoral, and unnecessary". Others have discussed at length the arguments related to the "illegal" and "immoral" aspects, but not enough has been said regarding the reasons that it is "unnecessary", and in fact it would appear at times that some of the information which has been brought forth is misleading. Therefore, I would like to spend some time with you today discussing this aspect in terms of an ethical alternative to embryonic stem cells, the so-called "adult stem cells", and the scientific information which indicates that this alternative actually does make destruction of human embryos completely unnecessary.

Mr. Chairman, while I am certain that you and the other Members of this Subcommittee are by now well aware of the basic information regarding stem cells, for the benefit of those in the audience who are relatively new to this debate I would like to give just a brief background. A stem cell is a cell that can proliferate with almost unlimited potential, maintaining a pool of growing and dividing cells, with the added ability that some of the daughter cells can differentiate into specific cell types. Thus, a stem cell allows for replenishment of itself while providing for specific functional tissues needed by the body. Stem cells have been known for many years, such as the blood stem cells in our bone marrow which continually replenish the red and white cells and platelets in our bloodstream. Embryonic stem cells (ES cells) have been isolated from mice for 20 years. In the fall of 1998, there were two reports on isolation of human embryonic stem cells; in Dr. John Gearhart's laboratory at Johns Hopkins, the workers actually isolated embryonic germ cells from early human fetuses after elective abortion, while Dr. James Thomson's laboratory in Wisconsin isolated true embryonic stem cells from human embryos a few days old. Because embryonic stem cells are derived from embryos quite early in the continuum of human development, they should have the ability to form virtually any tissue needed in the body. It is for this reason that many are anxious to use these cells for possible clinical applications in repair of damaged or diseased tissues. As you are also well aware, part of the debate revolves around the requisite destruction of the human embryos for derivation of these embryonic stem cells.

There are, however, some scientific reasons why use of these human embryonic stem cells is less desirable than use of adult stem cells. One is simply the fact that tissues generated by these cells will face transplant rejection, as would any normal organ transplant, and require use of toxic immunosuppressive drugs, perhaps for the lifetime of the patient. While one possible solution to this problem would be to clone the patient and destroy that embryo, the patient's "twin", to derive the cells, this complicates the debate even more with an additional controversial technique. Another possible problem may be control of the differentiation of these embryonic stem cells such that they form the desired tissue, and not other tissues or even a tumor.

One concern and potential problem is that while these embryonic stem cells have been termed "pluripotent", able to form most but not all cell types, published reports indicate that they are actually "totipotent", able to form all tissues of the developing human, or even the integral human embryo itself. The publications regarding human or primate embryonic stem cell derivation note that, unlike mouse embryonic stem cells, human and primate embryonic stem cells can form not only tissues which become part of the human body, but also trophoblast tissue. Trophoblast is the tissue layer of the early embryo that allows it to implant into the uterine wall, forms part of the placenta, and essentially nurtures early development. It is this layer which is removed in the destruction of the early embryo. Re-formation of this tissue layer in cultures of embryonic stem cells could lead to re-formation of complete human embryos in culture, able to survive if implanted into a womb. This means the possible production and destruction of thousands of new human embryos in culture, created with Federal funds, a direct violation of Federal law and NIH's own guidelines. The image of a virtual "embryo body shop" springs to mind. This concern certainly impacts the debate again in terms of the legal and moral aspects.

But now turning to the main topic, the ethical alternative of adult stem cells. Let me note for those unfamiliar with the terminology that these cells reside not only in adults but in all of our bodies from birth, one rich source being cord blood from the umbilical cords of newborns. There have been a number of statements critical of this alternative and the abilities of adult stem cells to fulfill the promise of tissue repair. I am somewhat mystified by these statements which malign the capabilities of adult stem cells, and can only assume that the statements have been made with-

out a thorough reading of the scientific literature, especially within the last 1-2 years.

For example, it has been stated that embryonic stem cells will be in clinical use before adult stem cells. To date, there have been no publications regarding the current clinical use of human embryonic stem cells. However, human adult stem cells have already been used successfully for several clinical treatments. There is a wealth of references on the use of stem cells as an adjunct in the treatment of numerous types of cancer, including brain tumors, ovarian cancer, various solid tumors, multiple myeloma, breast cancer, and non-Hodgkin's lymphoma. The adult stem cells are purified from bone marrow or circulating blood, preferably from the patient, and after treatment to destroy the cancer cells the patient is given back their own purified stem cells (an "autologous" transplant.)

Adult stem cells have also been used successfully to treat several autoimmune diseases such as multiple sclerosis, systemic lupus, juvenile rheumatoid arthritis, and rheumatoid arthritis, as well as anemias. A report in August noted one of the first uses of an adult neural stem cell line for treatment of stroke. This summer there were two reports of the use of corneal stem cells to restore vision to patients with corneal scarring in which normal corneal transplants would not work. Again, in most of the cases, the patient's own adult stem cells were used. Adult stem cells have been used to treat children with a condition which leads to bone and cartilage deformities. And, in April of this year, "adult" bone marrow stem cells were used in what seems to be the first successful example of human gene therapy, in which infants with a severe immunodeficiency seem to have been cured by giving them their own stem cells with the defective gene replaced.

One of the common criticisms leveled against adult stem cells is that there are only a few types, and they are not pluripotent, lacking the range of ability to differentiate into all tissues which is claimed for embryonic stem cells. In point of fact, human embryonic stem cells also have not been shown at this time to be able to generate all tissues in the body; nonetheless, it is presumed that they have pluripotent potential.

For adult stem cells, however, in June of this year a group in Sweden performed an experiment with mice using adult neural stem cells which shows that these adult cells are pluripotent. The study replicates an experiment done in 1984 using mouse embryonic stem cells, an experiment which has not been done-and ethically should not be done-with human embryonic stem cells. The Swedish group's results confirm that adult neural stem cells are pluripotent-the cells were able to participate in formation of heart, lung, intestine, liver, nervous system, muscle, and other tissues. The authors state that "—these studies suggest that stem cells in different adult tissues may be more similar than previously thought and perhaps in some cases have a developmental repertoire close to that of ES cells."

Other reports note that adult neural stem cells can be stimulated to grow even while still within the brain if given sufficient signal. Several sites within the human brain have been found to contain neural stem cells, and that these cells can be used in animals to repair spinal cord damage and other neural damage. One report notes that these human adult neural stem cells can be multiplied in culture, established as continuous cell lines, and are "similar to human embryonic stem cells." The authors of this study also note that "The fact that this revolutionary strategy uses autologous neuronal material means that it has all of the advantages of biosafety, histocompatibility, and neurophysiological efficiency. Furthermore, it does not raise the ethical and moral questions associated with the use of embryonic or heterologous material."

Other adult stem cells identified include those in muscle, and these cells also appear capable of reprogramming to form different cell types including blood, bone, and cartilage. Just 2 days ago a report in the *Journal of Cell Biology* announced purification of adult stem cells from muscle of a mouse model of Duchenne's muscular dystrophy. The cells were intravenously injected back into the dystrophic mice, and resulted in muscle regeneration and partial restoration of dystrophin expression in the mice. Transplantation of these cells engineered to secrete a bone protein resulted in the cells changing from muscle to bone cells, and accelerated healing of a skull defect in mice.

Diabetes is one of the leading killers in the United States. There have recently been reports of successful treatment using adult pancreatic stem cells from cadavers. Again, if a patient could use their own stem cells, there would be a distinct advantage. In this respect, in March of this year adult pancreatic stem cells from mice were used to reverse diabetes in these animals, employing their own stem cells. After treatment, the mice no longer needed insulin shots to survive.

Other criticisms of adult stem cells are that they are hard to access, and that they do not multiply well in culture. One of the most versatile and accessible adult stem

cell populations is in bone marrow. In August researchers showed that these human adult bone marrow stem cells can take up a "new job description" and be changed into neurons. The authors noted that this source could provide "a virtually limitless supply" of nerve cells. According to reports, the cells "grow rapidly in culture", "are readily accessible", and "provide a renewable population." They also add that "Autologous transplantation overcomes the ethical and immunological concerns associated with the use of fetal tissue."

In July, two groups, one in the U.S. and one in the U.K., found that human adult bone marrow stem cells could form liver. In considering the promising potential of these stem cells, one researcher noted, "We could avoid problems with current liver transplants where the patient's body rejects the foreign organ." Another said "This would suggest that maybe you don't need any type of fetal stem cell at all-that our adult bodies continue to have stem cells that can do this stuff."

Others have found that human adult bone marrow stem cells can be reprogrammed to form bone, cartilage, muscle, and fat cells. You might ask, "Why would I want fat cells?" Such tissues have significant applications in reconstructive surgery. Numerous reports in the last year demonstrate the significant proliferative capacity of adult stem cells in culture when given the proper signals.

And one more note on the tremendous potential of adult stem cells in terms of tissue engineering and reconstructive repair. There are now numerous reports where adult stem cells have been seeded onto polymer matrices. Testing these constructs in a sheep model system, autologous adult heart cells have been used to form heart valves and aorta.

Some have urged that research on both adult and embryonic stem cells should go forth. However, the President's own National Bioethics Advisory Commission has said that because human embryos deserve respect as a developing form of human life, destroying them "is justifiable only if no less morally problematic alternatives are available for advancing research." Senators, the scientific literature overwhelmingly demonstrates that adult stem cells are already fulfilling the goals only hoped for with embryonic stem cells, making destruction of human embryos completely unjustifiable.

Mr. Chairman, respected Members of this Subcommittee, it has been said that these human embryos targeted for destruction to derive embryonic stem cells will die anyway, and so we should get some good out of them, possibly to benefit those with life-threatening diseases. If we follow this path, devaluing human life and sacrificing one set of lives for the potential benefit of others, how long might it be before those patients with life-threatening diseases will hear the same phrase-"they're going to die anyway, let's get some good out of them?" To whom will we choose to assign value, and who will dare to make those choices? I implore you not to follow this path.

Thank you once again for this opportunity to discuss this extraordinarily important topic with you, and I would be pleased to respond to any questions you might have.

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

Senator SPECTER. Thank you very much, Dr. Prentice. We will come to questions as soon as we hear from Dr. Mathews-Roth, who is an associate professor of medicine at Harvard Medical School, and an associate physician at Brigham Women's Hospital. She performs basic science and clinical research and photobiology. Her clinical studies focus on developing photoprotective treatments for photosensitivity diseases. Dr. Mathews-Roth received her M.D. from New York University.

Thank you for joining us, Dr. Mathews-Roth, and we look forward to your testimony.

Dr. MATHEWS-ROTH. I just want to say I am not here as a representative of either the Brigham or Harvard Medical School, but as a physician who deals with patients with a genetic disease that is called erythropoietic protoporphyria. We call it EPP because nobody wants to say erythropoietic protoporphyria, and I am also concerned about the ethics involved in embryonic and fetal stem cell research.

I did leave a copy of my full testimony. I will try and summarize it. I also would like to leave two sets of clippings that describe some of the adult stem cell work as an appendix to my testimony, if that is okay.

Senator SPECTER. Dr. Roth, your full statement will be made a part of the record, as will the articles you referred to, without objection.

Dr. MATHEWS-ROTH. I think it is crucial for people and legislators alike to realize the only way to obtain embryonic stem cells is, as Dr. Prentice was saying, is to literally tear apart growing human embryos, and I brought a picture. This is the zona palusa, which sort of holds everybody together. This is the trophoblast layer that Dr. Prentice was talking about. These little guys here are the inner cell mass, or stem cells that people are interested in getting, so literally you have to break these guys apart to get it.

Now, what we all know is that the embryological fact is that we do know when a new life begins, and that is at fertilization, when egg and sperm join. Now, stem cells are not embryos, but as Dr. Prentice was pointing out, the human ones seem to be a little bit more totipotent than mouse embryo cells, but remember, you have to break apart an embryo to get the stem cells, and this is really the ethical objection, so I think we all have to ask ourselves, do we really want to allow the deliberate killing of even one of the youngest members of our species to help sick members of our own species also?

It is a tough ethical question, but again, can we really do this because we know ethically that a good end can never justify using a bad means, or an evil means to attain it.

The fact that the embryos which would be used for stem cell harvest are spares and would die or be destroyed anyway still does not justify killing them for their stem cells. I think there is a big difference between that and between people who sign organ donation cards. They make the informed decision. I have decided after I die a natural death, or am killed in an accident, or whatever, then I will donate my organs.

There is a heck of a lot of difference between that and deliberately killing a growing human to get organs, and again also I am concerned with the problem that Dr. Prentice mentioned of rejection, immunological rejections. What do we suggest? Adult stem cells, really emphasizing research on adult stem cells.

And also I would add, which I sort of forget to put in my testimony, the use of embryonic tissues from spontaneous abortions or miscarriages, I was talking to a physician, or a Ph.D. who does this kind of work, and yes, if you establish a network and let hospitals know that you are interested in doing this work, and there is no ethical problem here, these babies have died a natural death, their parents can say yeah, just like to a child or somebody who is killed in an accident, you may use the organs.

These are potential forms, or potential sources also of adult, quote-unquote, if you want to call them that, stem cells. Well, I guess the term is really fetal stem cells, so no, we are not leaving patients in the lurch. We are saying, look, there is so much promise for adult stem cells that really the research should be emphasizing those.

There is mounting evidence of the versatility of these adult stem cells that may make the use, as Dr. Prentice was saying, of fetal cells unnecessary, and really, I agree with this statement—well, actually it is the NBAC statement, if there was another morally and scientifically acceptable alternative, use it. Do not use the embryological stem cells.

I want to quote—I was going to, and I have in my testimony several examples, as Dr. Prentice did, of the use of adult stem cells. I just really want to quote one of those in a little bit more detail. “Adult bone marrow stem cells such as the marrow stromal cells have proven to be extremely versatile, as Woodberry, et al., in a paper describing the transformation of marrow stromal cells into nerve cells”—and I believe Dr. Fischbach referred to that, and so did Dr. Prentice.

He says the marrow cells are readily accessible, overcoming the risk of obtaining neural stem cells from the brain, and provide a renewable population. Autologous transplantation, that is, using the patient’s own cells, overcomes the ethical and immunological concerns associated with the use of fetal tissue.

Moreover, marrow stromal cells grow rapidly in culture, precluding the need for immortalization, and immortalization, I believe, adds a little foreign virus to the cells, and differentiates into neurons exclusively with the use of a simple protocol, and other scientists, Allison et al. reports that human hematopoietic stem cells can differentiate into liver cells in the tissues, in the livers of people receiving bone marrow transplant, so if they can do it in people receiving bone marrow transplants, they can also do it in people who need help with their liver.

The exciting thing about these bone marrow stem cells is that they are able to be transformed in all of the three original embryonic layers, the ectoderm—and this is the example for that, is the nervous tissue—mesoderm, muscle, fat, and bone cells, and endoderm, example is the liver cells, and it is just a matter of time that more things will be developed about them.

In my testimony I was going through the four objections that the NIH guidelines had suggested to liver cells, or to use of adult cells, so I am sort of briefly going through that. One of their objections is valid. They said that in diseases caused by genetic defect, the defect would also be present in the patient’s stem cell.

However, this problem can be solved by ex vivo gene therapy. That is gene therapy to cells that you take out of the person’s body, then you put them back in, adding the normal gene to bone marrow stem cells which are then treated to get them to develop into, say, whatever needed cells you need, like liver cells or muscle, fat, or bone, or nervous tissue.

Successful gene therapy to bone marrow cells has also been reported by French workers, who cured a severe combined immunodeficiency disease in children with gene therapy to the bone marrow, and I am happy to tell you my colleagues and I are also studying gene therapy using bone marrow cells. We have cured the mouse model of the genetic disease that I am studying, erythropoietic protoporphyria with ex vivo gene therapy.

Again, the advantage of that is that you—and obviously we are hoping to eventually develop it for people. The advantage of that

is, if you take the person's own stem cells, treat them, cure them with gene therapy, put them back into the patient, they are not going to get rejection and it is going to work.

So in summary, I just want to say the most ethical and scientifically appropriate steps for the Government to take concerning stem cell research are first to revoke the guidelines and to continue the ban on research on embryonic stem cells, and two, I would say also to impose a ban on research on stem cells obtained from induced aborted fetuses, because there is a danger of their potential of encouraging abortion to obtain these cells, and we have heard stories about doctors, well, sort of suggesting to patients, why don't you wait a week or two, or something like that.

I think there are problems here. However, on the other hand, approving research on fetal cells derived from miscarriages, and I think it is somewhat of a myth to say that this is not practical, having done this the Government must strongly encourage and fund research in adult stem cells as well as research on umbilical cord blood and placental stem cells. Although these latter ones may cause immunological problems they are probably still worth looking at.

So that the full potential of adult stem cells and possibly these other forms, certainly the fetal stem cells from aborted, from miscarried fetuses can be really looked at and explored to find out just how versatile these cells really are, and this way I think we are not deserting our patients, but we are doing things that would be ethically acceptable to everyone.

PREPARED STATEMENT

I would hate to have to tell my patients that, boy, I have to destroy a human life before I can treat you, and I do not think we have to do that. I think work on adult stem cells will avoid that awful problem.

Thank you, sir.

[The statement follows:]

PREPARED STATEMENT OF MICHELINE M. MATHEWS-ROTH

Dr. Mathews-Roth is an Associate Professor of Medicine at the Harvard Medical School, and a Physician at the Brigham & Women's Hospital, in Boston, Massachusetts. She performs clinical and basic research on the genetic disease, erythropoietic protoporphyria.

[NOTE.—The views presented here are Dr. Mathews-Roth's—she is NOT acting as a spokesperson for either the Harvard Medical School or the Brigham & Women's Hospital.]

The stated purpose of the Guidelines for Research Using Human Pluripotent Stem Cells issued by the National Institutes of Health is to “establish procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner”. However these guidelines, as presently written, are ethically very questionable. Since the guidelines deal with the beginnings of individual human lives, and thus an issue of great importance, American society cannot tolerate ethical and scientific errors concerning this issue. It is crucial for people to understand that the only way to obtain embryonic stem cells is to literally tear apart growing human embryos. Although the Guidelines state that “NIH funds may not be used to derive human pluripotent stem cells from human embryos” (though funds can be used to derive stem cells from fetal tissue), nevertheless, these guidelines are allowing scientists to let the youngest members of our species, even though their bodies consist of just a few cells, to grow for a few days, and then deliberately kill them by breaking them apart to obtain their stem cells. My understanding is that the bill, S. 2015

is similar in intent to the Guidelines, but would remove the restriction about deriving the stem cells from embryos. Good ethics hold that a good end can never justify evil means to attain it. Certainly killing a growing human (no matter what its age) is not an ethical means to obtain even a most desirable end such as curing disease. The fact that the embryos would die or be destroyed anyway does not justify the act of killing those whom we all know are the youngest members of our species. The Guidelines and S. 2015 condone the attitude of “they are going to die anyway, so why not use them?”: this attitude applies to the use of stem cells derived from fetal tissue as well as from embryos. This willingness to destroy the youngest of our species is a logical continuation of the “slippery slope” this country got on when it condoned killing of somewhat older members of our species by allowing abortion on demand. It is doubtful that the “safeguards” proposed in the Guidelines will totally prevent the abuses they are meant to prevent. The more ethical thing to do is to prohibit the production of embryonic or fetal stem cells.

In addition to the basic ethical problem with the Guidelines (and with S. 2015), there are scientific problems with the use of both embryonic and fetal pluripotent stem cells which may make their use unnecessary, which the Guidelines do not sufficiently address: the first is the use of adult stem cells instead of embryonic or fetal stem cells, and the second is the problem of immunological rejection of fetal/embryonic stem cell grafts by their recipients.

The Guidelines, in their responses to public comments that the ban on the use of embryonic stem cells remain in force and emphasis be placed on research of adult, placental and umbilical cord stem cells instead, seem to ignore the mounting evidence in the current scientific literature of the versatility of adult stem cells, which may make the use of embryonic stem cells unnecessary, and avoid the ethical problems of working with embryonic/fetal stem cells. Rather than simultaneously pursuing all lines of research, the most ethical thing to do is to thoroughly study adult/placental/umbilical cord stem cells to determine their full potential, and continue the ban on the study of embryo/fetal stem cells until this work is done.

The Guidelines state four reasons for not banning embryonic stem cell research in favor of work on adult stem cells (“Scope of Guidelines and General Issues” section, Paragraph 4; “Respondents . . . adult tissues.”) These reasons are not totally accurate in view of what is presently known about adult stem cells. Following are some examples from the recent medical literature to illustrate this point.

(1) The Guidelines state that adult stem cells may have more limited potential than embryonic stem cells, and that stem cells for all cell and tissue types have not yet been found in the adult human. On the contrary, after reviewing some other studies, Clarke et al. state that “. . . these studies suggest that stem cells in different adult tissues may be more similar than previously thought and perhaps in some cases have a developmental repertoire close to that of ES [embryonic stem] cells” (Science, vol. 288 page 1660, June 2, 2000). It is important to remember that studies on adult stem cells have not been going on for a particularly long time—much further progress can be expected with future studies. The guidelines mentioned that cardiac or pancreatic islet stem cells had not been found. It may not be necessary to find specific organ stem cells—there is evidence that bone marrow stromal cells or cells like them may be present in the heart and could be converted into heart muscle-like cells (see page 233 of Kessler & Byrne, Annual Review of Physiology, vol. 61, page 219, 1999) and also that ductal structures of the adult pancreas contain stem cells that differentiate into insulin-producing cells in an animal model (Ramiya et al., Nature Medicine, vol. 6, page 278, 2000).

(2) The Guidelines claim that stem cells of adults are only present in minute quantities, are difficult to purify and may decrease with age. Such a generalization should not be made. Bone-marrow stem cells such as marrow stromal cells have proved to be extremely versatile: recent research has demonstrated their ability to develop into neurons as well as other tissue cell types such as muscle, fat, bone, and even liver cells: and marrow stromal cells are easily obtainable and can be made to multiply in large numbers. As Woodbury et al., in a paper describing the transformation of marrow stromal cells into nerve cells, point out: “The marrow cells are readily accessible, overcoming the risks of obtaining neural stem cells from the brain, and provide a renewable population. Autologous transplantation [i.e. using the patient’s own cells] overcomes the ethical and immunological concerns associated with the use of fetal tissue. Moreover, marrow stromal cells grow rapidly in culture, precluding the need for immortalization, and differentiate into neurons exclusively with use of a simple protocol” (Journal of Neuroscience Research, vol. 61, page 364, 2000). These authors’ statement seems to refute the Guidelines’ expressed concerns about ease of isolation and obtaining sufficient quantities of cells. Additionally, Allison et al. report that human hematopoietic stem cells can differentiate into hepatocytes (liver cells) in the livers of people receiving bone marrow transplants

(Nature vol. 406, page 6793, 2000). The exciting thing about these bone-marrow stem cells is that they are able to be transformed into all of the three original embryonic layers, ectoderm (represented by nervous tissue), mesoderm (muscle, fat and bone cells) and endoderm, (liver cells).

(3) The Guidelines correctly state that in diseases caused by a genetic defect, the defect would also be present in the patient's stem cells. This is true, but this problem can be solved by ex vivo [outside the body] gene therapy, adding the normal gene to bone marrow stem cells, which are then treated to get them to develop into the needed cells. Successful gene therapy to marrow cells has already been reported by French workers who have cured severe combined immunodeficiency disease with gene therapy to the bone marrow (Cavazzana-Calvo et al., Science, vol. 288, page 669, 2000). My colleagues and I are also studying gene therapy using bone marrow stem cells for the treatment of a genetic disease: we have cured the mouse model of a human disease called erythropoietic protoporphyria with "ex-vivo" gene therapy (Pawliuk et al., Nature Medicine, vol. 5, page 768, 1999).

(4) The Guidelines also claim that there is evidence that the stem cells from adults may not have the same capacity to multiply as do younger cells. This does not seem to be true, since at least in the case of bone-marrow stem cells, adults can be successful bone marrow donors (Anderlini et al., British Journal of Hematology, vol. 97, p.485, 1997).

The Guidelines do not mention the main problem with the use of embryonic and fetal stem cells, that is the rejection of the grafts by the recipients. This serious immunological problem is the same as is encountered when people receive lung, kidney, heart or liver transplants from non-identical twin donors, necessitating the use of immunosuppressive drugs for the rest of the recipient's life. This immunological problem will not occur if stem cells from the person's own body are used—an important value of adult stem cells, derived from the recipient, and a strong reason in favor of exploring the full potential of adult stem cells.

In summary, the most ethical and scientifically appropriate steps for the Government to take concerning stem cell research are to: (1) revoke the "Guidelines" and to continue the ban on research on embryonic stem cells, and (2) impose a ban on research on stem cells obtained from aborted fetuses (in the latter case because of the potential of encouraging abortion to obtain these cells). Having done this, the Government must strongly encourage and fund research on adult stem cells, as well as research on umbilical cord blood and placental stem cells (although these latter two groups may cause immunological problems), so that the full potential of all of these other kinds of stem cells for generating tissue cells of various kinds can be fully determined.

Senator SPECTER. Thank you very much, Dr. Mathews-Roth.

Dr. Prentice, Dr. Mathews-Roth, supported the use of stem cells from fetal tissue except where there were induced aborted fetuses. Am I citing your testimony correctly, Dr. Roth?

Dr. MATHEWS-ROTH. Yes, and emphasize no induced abortions, just spontaneous.

Senator SPECTER. I said that, you excluded that, but otherwise fetal tissue. Dr. Roth has confirmed my statement that it is appropriate to use those stem cells. Do you agree with that, Dr. Prentice?

Dr. MATHEWS-ROTH. Excuse me, could I say one thing? I think that that research has been restricted to marrow stromal cells. I would not be in favor of using the germ line cells from the germ line fetal tissue.

Senator SPECTER. But there is fetal tissue you would approve?

Dr. MATHEWS-ROTH. I would say bone marrow stromal cells or other organ cells from the spontaneously aborted fetuses.

Senator SPECTER. But there is a form of stem cell from fetal tissue that you would approve of?

Dr. MATHEWS-ROTH. Yes.

Senator SPECTER. Dr. Prentice, do you agree with that?

Dr. PRENTICE. As far as I understand it, Senator, that would be an ethically as well as already legally acceptable choice, to use these spontaneously aborted fetuses.

Senator SPECTER. Well, I raise the issue because for a long time there had been a total objection to the use of fetal tissue at all, and that was on the basis that once you open the door, a slippery slope, you start to use fetal tissue even if they are from circumstances where the abortion was not made, it was going to happen anyway, so that at least so many people who had objected to the use of fetal tissue for some time have really reversed their position.

Senator Thurmond, interestingly, a very strong pro-life Senator, a model of conservatism, was against the use of fetal tissue, and then in his own family his daughter had juvenile diabetes, and Senator Thurmond testified many years ago before stem cells came up on the juvenile diabetes issue, and then he has testified now in favor of stem cells, but on the use of fetal tissue, when Senator Thurmond changed his vote it went from about 40 Senators in favor of using fetal tissue to about 80, and I raise that issue because of the potential similarities, where there had been an objection raised to fetal tissue, which has abated at least in some circumstances, as Dr. Roth would approve, and you concur, Dr. Prentice.

Dr. PRENTICE. Senator, if I might comment, that source, even though it might be acceptable, might still face some of the problems of the embryonic stem cell sources that we have mentioned, because unless we are using cells from the patient themselves, their own adult stem cells, we are still going to run this risk of immunological rejection.

The other difference between those arguments is, if we are using fetal tissue at that point, by current Federal regulations the embryo is already dead, to derive embryonic stem cells, we must actually wilfully destroy the embryo, so there is a difference.

Senator SPECTER. Well, let us take that point up, because that is really a core argument which has been made here, and Dr. Roth is very emphatic about destroying a human life, but where you have these embryos which have been created for in vitro fertilization and they are to be discarded, and the choice is just having them discarded, or using stem cells which may be derived from them to save lives, what is the balance of argument on destroying a human life when the issue arises as to what is the quality of a human life in the embryo, if any.

I understand your point about aging people. Are you going to kill them to help others? I do not think that follows, and the testimony that Senator Brownback advanced about the analogy to the Holocaust, aside from the issues of sensitivity, is just not, at least in my judgment, very sound, but come to grips with the destruction of a human life. When these embryos—how do you categorize them as a human life, and how do you justify letting them be destroyed collaterally by being discarded when there could be a use made?

I notice you nodding, Dr. Prentice, and we will turn to you first. Well, we can go to the ladies first. Dr. Roth, you go first.

Dr. MATHEWS-ROTH. Again, it was what I was trying to say before, between the difference of organ donation and taking a life of an embryo. I think there are some things that we just ethically

should not do, and I think that these extra embryos, if you cannot find adoptive parents for them that are willing to use them because they cannot have children—and there have been some reports of women applying to IVF clinics and saying, hey, have you got any spare embryos, if you can get permission from the original parents I would like them because my husband and I cannot do it, or whatever—I think ethically the best thing to do is let them die a natural death if you want to put it that way.

In spite of the fact that a good end would occur, I still think the means of destroying these embryos, of letting them grow for a few days and ripping them apart to take these stem cells, that is a bad means. I do not think ethically you can justify it.

Senator SPECTER. Dr. Roth, you referred to consent from the parents. Are you suggesting that if you had consent from the parents it would be appropriate to use the embryos?

Dr. MATHEWS-ROTH. I still would have a big problem with that, because it is direct killing. There is a difference when a child dies in an accident or of diabetes, or of overwhelming infection that we cannot cure, and this child dies a natural death, then I do not think there is a problem, if the organs obviously are suitable, for a parent to say, sure, take my child as an organ donor, or if there is a miscarriage, take my child as an organ donor, but with these embryos you have got to kill them, literally destroy them.

Senator SPECTER. Dr. Prentice, let us turn to you on the issue of human life, quality of human life contrasted with saving so many other lives.

Dr. PRENTICE. Actually, Senator, I am not sure that, from my own perspective, I could justify even discarding those embryos. I know that is a very—it is a sticky issue.

Senator SPECTER. You cannot justify what, sir?

Dr. PRENTICE. That I could justify discarding the embryos, either, and I realize, so what do we do with all of those embryos, and perhaps that is something that Congress itself should be looking at in terms of the IVF industry.

Senator SPECTER. Well, what would the alternative be?

Dr. PRENTICE. I am not certain, sir, until we can get them adopted, or what the answer might be.

Senator SPECTER. Well, they have to be carried to term. Are you suggesting that the Government would compel someone, a woman to carry them to term?

Dr. PRENTICE. I do not think we should be in the business of compelling anyone to carry these embryos to term or destroy them, either way.

Senator SPECTER. Well then, what would you do?

Dr. PRENTICE. I think it would have to be perhaps some sort of an adoption program, but that is not really the focus of the issue. The focus—

Senator SPECTER. I agree with you, but you brought it up, so I wanted to explore it if you care to. What would you do with them, if not discard them? If there were another alternative to discarding them, I think you have a very valid point.

This is a very sensitive and very difficult issue, when human life begins, and I understand your sincerity in saying that human life begins when you have a human embryo, and the next step up is

if you have human life, what is the quality of life, but if you can structure having them carried to term so that you have a baby after birth, then I think we would be in a very different realm. I would have a very different view.

I would not in any way suggest sacrificing a child who has been born for what benefit there may be to others from the child's body, but where you have an embryo which is going to be discarded, then it is a different matter. If you would care to pursue an alternative to what you do as opposed to discarding, I would be interested in hearing you.

Dr. PRENTICE. I have not really thought through the issue, Senator, but as we mentioned, one possibility might be some sort of adoption program.

Senator SPECTER. How would you structure an adoption program?

Dr. PRENTICE. I am not really certain. I have not really had time to think through the issue. It has really just come up.

Senator SPECTER. Well, in order to get to adoption, you have to have a child born.

Dr. PRENTICE. Well, no, sir.

Senator SPECTER. Excuse me, Dr. Roth.

Dr. MATHEWS-ROTH. You have to find a mother to carry it.

Senator SPECTER. That is what I was saying. You and I agree on this now, I want it noted.

Dr. MATHEWS-ROTH. One way you could avoid—through the adoption business is for IVF clinics to publicize the fact that they have got extra embryos up, quotes, for adoption, and if infertile couples, neither of whom are able to—the eggs of the women, she does not have enough eggs, or the man has no sperm, if they want to adopt one of these embryos fully made, implanted into a uterus, then this is possible. This is a way to go, and it is a matter of getting the news out there that these are available, but I personally find no way of justifying destroying an embryo even to help another person, I think ethically.

Senator SPECTER. I am advised by staff there are 100,000 frozen embryos in excess of what people propose to use by carrying to term.

Dr. MATHEWS-ROTH. I have also heard from IVF people that the tendency has been in the past, up until now, to make many more than actually needed. They seem now to want not to do this so much, so in the future there may not be that many extra embryos. I do not know what the figure is of infertile people who would like to adopt embryos.

Senator SPECTER. Dr. Roth, I wrote down one of your statements, that if there is a moral or ethical alternative then we should not use embryos. Do I quote you accurately?

Dr. MATHEWS-ROTH. I guess that was my paraphrase of what the NBAC was trying to say, that if there was a morally acceptable alternative to using fetal embryo, or fetal stem cells, then we should use it.

What we are both proposing, of course, is adult stem cells, and I am going one step further and saying hemopoietic stem cells, or possibly solid organ stem cells from spontaneously miscarried fetuses.

Senator SPECTER. The contention has been raised about adult stem cells being adequate to handle these issues, and if adult stem cells are not adequate, would you then be willing to use embryonic stem cells?

Dr. MATHEWS-ROTH. I do not think so, not if it requires killing. That is not good. I want to get away from killing people, even little, eensy-weensy tiny people. That is one of the reasons I do not like abortion, either. Abortion is direct killing.

Senator SPECTER. I want to be sure we have an adequate exploration of your views, and these green, yellow, and red lights are only guideposts, and the red light for Dr. Prentice was on, he noted, and I said go ahead, and yours was on a while, and I have questioned you fairly extensively, far beyond my customary time.

I would like now to have Dr. Fischbach and Dr. Spiegel come back with you, and I would like to have a discussion among the four of you scientists, and keep your seat, Dr. Prentice and Dr. Roth. They will surround you.

Dr. Fischbach, you have heard the testimony of Dr. Prentice, then Dr. Roth, about the potential applications for adult stem cells, and Dr. Prentice has been considerate enough to bring a chart along to illustrate his point. What is your view of what Dr. Prentice has said about the use of adult stem cells?

Dr. FISCHBACH. There were several things mentioned, and I think Dr. Spiegel and I both might comment. I think the notion that stem cells in bone marrow might be useful for replacing nerve cells is a hope we all share, and I think it is in the future.

The publication referred to demonstrated a very first step, a small first step, and that for a few hours in tissue culture cells from bone marrow appear to have some of the properties of nerve cells. It will take years to translate that into a useful therapy. I believe that studies of human, of embryonic stem cells are much closer to that goal now, but I think both efforts should be pursued vigorously.

Senator SPECTER. Are there things embryonic stem cells can do that adult stem cells cannot do?

Dr. FISCHBACH. I do not know any case where an adult stem cell derived from an adult animal has formed a nerve cell that can make and release dopamine, and can reverse the behavioral defect of Parkinson's disease. That may change with time, with years, but I feel differently about patients dying with devastating neurological disorders. I do not think we have that time to wait.

Senator SPECTER. Dr. Prentice, would you care to comment on Dr. Fischbach's statement?

Dr. PRENTICE. Mr. Chairman, I am not aware of currently a dopaminergic adult neural stem line, but there was a report in this month's *Experimental Neurology* where neurons were generated from adult stem cells, neural stem cells which formed functional glutamergic and gataenergic synapses in culture, so there is evidence the adult stem cells can form functional nerve connections and functional types of synapses in culture.

There have also been examples where in rat and mouse models the adult stem cells have been transplanted back into the animal and actually formed normal synapses in the animal.

Senator SPECTER. Dr. Spiegel, would you care to comment on this issue, as to overall, but in part responding to what Dr. Prentice has said?

Dr. SPIEGEL. I will not comment on the aspect of these cells because I am not an expert in that area.

Senator SPECTER. Well, before you leave it, would you care to comment on the issue of neuronal cells, Dr. Fischbach?

Dr. FISCHBACH. I think we shifted grounds in midstream from bone marrow to neural stem cells. I think the adult neural stem cells have promise, but I do not think they have yet reformed function to the extent of correcting a neurological defect.

Senator SPECTER. Dr. Spiegel, and Dr. Mathews-Roth, if you want to make a comment, go ahead.

Dr. MATHEWS-ROTH. I just want to say I think the bone marrow stromal cells are much more plastic than the bone marrow hemopoietic regenerative stem cells.

Senator SPECTER. Dr. Fischbach, for the record, would you respond or care to respond? I will study this later and try to figure it out.

Dr. FISCHBACH. I think one way to approach this is, there are many types of cells in bone marrow. Some cells are more germinal in the sense that they can give rise to many other types of cells. I agree that there are different types of cells in the bone marrow, and some have potential as stem cells for therapy.

Senator SPECTER. Do you think we should impose a requirement on Senators before being permitted to vote on this issue, that they know something about it, like these complex matters you are advancing here today, and you do not have to answer that, doctor. Dr. Spiegel, you were right in the middle of a response when we had a couple of interruptions. You have the floor.

Dr. SPIEGEL. Thank you, Mr. Chairman. I am not aware of a single report in which either bone marrow stromal cells or hematopoietic cells formed pancreatic islet cells. I am clearly aware of a report, for example, in "Nature Medicine" of mouse embryonic stem cells forming pancreatic beta cells and curing diabetes.

There are also reports of a diabetes breakthrough using adult stem cells from the pancreas, and this is what Dr. Mathews-Roth was showing as a clip. This is work we vigorously support, from the University of Florida, in which adult pancreatic stem cells were transplanted into mice with diabetes, with some positive effect.

There are also efforts to isolate human pancreatic ductile cells at the Joslin Diabetes Clinic. However, the numbers generated were clinically insufficient by two orders of magnitude, that is, they were only one-hundredth of the amount necessary for any kind of clinical utility. In the final analysis, as Senator Harkin said, we really need to pursue each of these avenues of embryonic and adult stem cell research to have the greatest possibility of success.

Dr. FISCHBACH. I want to underline that, if I can, that these involve quantitative statements. The question is not, can this happen, but the real issue is, can this happen in ways that we can control and make clinical use of, and I think that sets embryonic stem cells apart at the current time.

Senator SPECTER. Dr. Mathews-Roth, would you like to make a concluding statement?

Dr. MATHEWS-ROTH. I would just say—

Senator SPECTER. I am going to give each of you an opportunity to conclude here. Your turn comes first, Dr. Mathews-Roth.

Dr. MATHEWS-ROTH. I guess my concern is that there are some things that ethically we should not do. I am not convinced that it is going to take a terribly long time to get adult stem cells up to speed, because they have not been worked on as long as fetal stem cells, and I really think for the ethics involved, for the idea of yeah, it is okay to kill these little guys, even if they are very teeny, tiny humans, I think that is wrong, and that is why I think that ban should continue.

Look at adult stem cells. Look at stem cells, organ stem cells, maybe pancreatic ductile stem cells from spontaneously—spontaneously aborted, that is the medical terminology for miscarriages, miscarried babies may be a way to go, from stillborn children may be a way to go, but do not kill to do this.

Senator SPECTER. Dr. Spiegel, would you care to make a concluding statement?

Dr. SPIEGEL. The issue of transplant rejection and immune suppression has been raised, and this is a vigorous area of research that we are pursuing. This research is essential because of the many organ transplants we are already doing, and I am happy to say that there is really significant progress and potential success, which could address this issue.

As a physician, scientist, and public servant, I have tried to illuminate the terms of the debate, and to offer an objective view about the science. I hope I have contributed to that.

Senator SPECTER. Thank you, Dr. Spiegel.

Dr. Prentice, would you care to make a concluding statement?

Dr. PRENTICE. Thank you, Mr. Chairman. In the end, in a real sense, the question we are grappling with here is not a scientific question, whether adult or whether embryonic is the correct way to go, the only way to go and so on. I think you have heard evidence on both sides of the promise of both particular types of stem cells, but in the end this is really a moral and ethical question which you and the other Senators are going to have to grapple with, and it is my opinion that it has never been acceptable to sacrifice one set of human lives for the benefit of others.

Thank you, sir.

Senator SPECTER. Thank you, Dr. Prentice. Dr. Fischbach, would you like to sum up?

Dr. FISCHBACH. Senator, I think these are exciting times. Everything we have talked about today has been published or discussed for the first time in the last 2 years, most of it in the last year, and we are faced with issues of extraordinary promise, and revolutionary times.

I think these ethical issues are profound, and I think that is the very purpose of the NIH guidelines is to allow work to go forward under strict regulation and debate, and to allow it to proceed.

I would say that every time society has closed down avenues of investigation people have suffered, and I think the guidelines try to address that issue.

Senator SPECTER. Thank you very much, Dr. Fischbach, Dr. Mathews-Roth, Dr. Prentice, Dr. Spiegel. I believe this has been a

very productive hearing, unusually so. I think it is always useful when we have people who are knowledgeable advocate their positions, and especially when there is the kind of friendly but adversarial opposition that we have had here today.

I think it has been very constructive, and I know my colleagues in the Senate are very much concerned about this, and we will be studying the record so we can understand it, because a good bit of what has been testified to here today requires some definitions to work it through, but the exchanges I think have been very helpful in that regard.

CONCLUSION OF HEARING

Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 11:20 a.m., Thursday, September 7, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

STEM CELL RESEARCH

THURSDAY, SEPTEMBER 14, 2000

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:33 a.m., in room SH-216, Hart Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Harkin, and Reid.
Also present: Senator Wellstone.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hour of 9:30 having arrived, the Subcommittee on Labor, Health and Human Services, and Education for the Appropriations Committee will now proceed with this hearing, which is the seventh in a series of hearings on stem cells.

When the dramatic breakthrough occurred on stem cell research in November of 1998, this subcommittee undertook these hearings to focus on the prohibition which exists in the law saying that the Federal Government, the National Institutes of Health, may not engage in research to derive stem cells from embryos.

The potential for stem cells is virtually limitless, so we are told by the research community and by the people who are studying this subject. The stem cells pose a veritable fountain of youth, with already some tremendous inroads on Parkinson's Disease, prospects on Alzheimer's and stroke, potential for heart ailments and very vast potential in what we have found in a series of hearings which we have already conducted.

There are those who object to stem cell research on ethical, moral, perhaps religious grounds, with the contention that the embryo is a living being. We have invited people on both sides of the issue to testify so that we can have all of the positions presented, and that the Senate can be in the best place to make an informed judgment.

We have had leading opponents from the Senate and the House of Representatives testify before this subcommittee, and today we have a very distinguished panel of witnesses. Dr. Richard Hynes, director of the Center for Cancer Research from Massachusetts Institute of Technology, Dr. Darwin Prockop, director of the Center for Gene Therapy from Tulane University; in opposition we have Mr. Ron Heagy, president and founder of, quote, Life is an Attitude Foundation, Mr. Ron Saltzman, pastor of the Ruskin Heights Lu-

theran Church in Kansas City, Missouri, and Dr. Anton-Lewis Usala, chairman and chief technical officer for Encelle.

We have had assurances from the Majority Leader that the legislation which Senator Harkin and I have introduced will be called for a vote this month, so we are accelerating our efforts to present all facets of the issue.

We also have for our third panel Mr. Michael J. Fox, Ms. Mary Tyler Moore, Ms. Jennifer Estess, and Ms. Gina Gershon, and as frequently is the case, we have called on people who are well-known to the public, because when, candidly Michael J. Fox and Mary Tyler Moore testify about their ailments and the opportunity for stem cell research illustratively to cure Michael J. Fox from Parkinson's, that is a point of really great emphasis.

That is a brief summary of my formal opening statement which will be put in the record without objection, and now I yield to my distinguished colleague, Senator Harkin, Ranking Democrat for the subcommittee.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman, and my thanks to our distinguished panelists who are here today. As you said, Mr. Chairman, this is our seventh hearing on the issue of stem cell research. I want to commend you, Mr. Chairman, for the seriousness with which you take our responsibility over this important controversial issue. These hearings are part of a necessary dialogue on both the promise and the ethical implications of stem cell research.

Two years ago, researchers discovered and isolated the human pluripotent stem cells, the precursor of almost all of the cells in the human body, and demonstrated the ability to self-renew and differentiate into many different cell types.

As we have learned, they hold unprecedented potential for the treatment and cure of the terrible diseases and conditions that strike too many of our family members and friends, and so we are on, I think, the cusp of some really exciting research and discovery. No one knows what the potential for this is, but almost all of the scientists I have spoken to indicate that there could be tremendous, tremendous potential for the interventions and cures of some of our most disabling diseases.

There have been, obviously, ethical and moral considerations involving the use of these cells. For a couple of years the NIH, along with the commission, the President's Commission on Ethical Standards have been working to set up guidelines.

On August 23, NIH issued the final guidelines, and I believe these guidelines will permit the research to advance and move ahead within, I believe, fairly stringent and comprehensive ethical guidelines, and for the record I want to once again say what those are, because I keep hearing about how people are going to sell these cells, and they are going to patent, they are going to make money, and all that kind of stuff. Let me just read again what the guidelines are.

NIH will not fund the actual derivation of pluripotent stem cells.

NIH funds can be used only if the stem cells were derived from embryos in excess of need that were created as part of in vitro fertilization procedures.

Providers of stem cells cannot make a profit from supplying them to federally funded researchers.

And last, providers of stem cells must provide documentation of informed consent by the donors.

Those are the ethical guidelines. NIH will begin accepting grant applications for projects sometime early next year. Our legislation is pending and, as the chairman said, we hope that we can get it up before we leave here this year.

So that is just again the shortened part of my statement, Mr. Chairman, and again I want to thank you for your tremendous leadership on this very, very important issue.

Senator SPECTER. Senator Wellstone has joined us this morning. We welcome him here and would invite him to make whatever opening comments he makes here today.

STATEMENT OF SENATOR PAUL D. WELLSTONE

Senator WELLSTONE. Mr. Chairman, I appreciate your courtesy, and I know we need to get going with this hearing, a very important hearing. Let me just say to both Senator Specter and Senator Harkin that I come here to just show my strong interest and support for your work. I have done a lot of work with the Parkinson's community, but this legislation and your effort extends way beyond just one community. It is terribly important to many, many people, many, many families, many Americans, and I am here just as an indication of the strong support for your work.

I thank you.

Senator SPECTER. Senator Wellstone, at a previous hearing we made a tabulation, and stem cell research could affect 125 million Americans, just about half of the people in this country with a variety of ailments, which it may be able to deal with.

STATEMENT OF RICHARD O. HYNES, Ph.D, DIRECTOR, CENTER FOR CANCER RESEARCH, MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Senator SPECTER. We turn now to Dr. Richard Hynes, director of the Center for Cancer Research at Massachusetts Institute of Technology since 1991. He serves as president of the American Society for Cell Biology, and is a member of the National Academy of Sciences. Dr. Hynes received his M.A. in biochemistry from Cambridge University in England, and his Ph.D in biology from MIT. Welcome, Dr. Hynes, and in accordance with our standard practice the green light starts when you do, and it signifies 5 minutes, the yellow light gives you a minute, and the red light says stop.

The floor is yours.

Dr. HYNES. Thank you, Senator. I appreciate greatly the invitation to appear before you today, and I am here representing the American Society of Cell Biologists, 10,000 biomedical researchers, and many of our other colleagues in the biomedical research community, and I am here to explain to you and to your colleagues why our organization feels strongly that the full potential of human embryonic stem cell research must be realized.

On behalf of the society I want first to extend my deepest appreciation to you, Chairman Specter, to Ranking Member Harkin, and to members of the subcommittee for your visionary and courageous commitment to investment in biomedical research at the NIH. This funding is vitally important to allow our Nation's scientists and clinicians to exploit the tremendous opportunities offered by the current revolution in biomedical science in order to enhance public health.

I want to stress today that embryonic stem cell research is among the most promising of these new opportunities. We understand the ethical concerns that some have raised about this research, but we respectfully submit that appropriately regulated research on human embryonic stem cells can be conducted while taking these concerns into account.

We believe that this research will undoubtedly lead to new ways to treat disease and disability. Embryonic stem cells will allow creation of new healthy tissue to replace damaged or dead tissue. Examples include bone marrow for the treatment of cancer and sickle cell anemia, pancreatic cells for the treatment of diabetes, neuronal cells for the treatment of Parkinson's, Alzheimer's, and various brain and spinal disorders, and I could make a much longer list, but we do not have the time.

We are not alone in our conviction that this invaluable research must go forward. Attached to my testimony is a statement signed by 17 organizations around the country, including the American Medical Association, the Michael J. Fox Foundation for Parkinson's Research, the Juvenile Diabetes Foundation, the Christopher Reeve Paralysis Foundation, and the American Association for Cancer Research, among many others.

I also want to reiterate the support of the American Society for Cell Biology for the Stem cell Research Act of 2000 which you have introduced, that would allow not only the user but also the derivation of embryonic stem cell lines.

Some have argued that human embryonic stem cell research is illegal, unnecessary, and immoral. We respectfully disagree on all counts. On the contrary, we believe that it would be immoral not to pursue this great opportunity to improve the quality of life.

The charge of illegality is unfounded. As you know, various appropriations bills have restricted embryo research for several years, but these bills are silent on the use of embryonic stem cells. Such cells are not embryos, and they cannot independently develop into embryos.

The NIH guidelines set specific criteria governing the derivation of the stem cells, as Senator Harkin just pointed out, requiring informed consent, precluding payment, and prohibiting the creation of embryos for research purposes. Cells used for research must be derived solely from embryos generated for fertility treatments and in excess of clinical need. Such embryos would otherwise be discarded.

Previously, the use of embryonic stem cells was restricted to private and commercial entities which were not accountable to the public. NIH funding of stem cell research will allow Federal Government to exercise control over the standards for the use of stem cells and will encourage public input.

Second, critics argue that embryonic stem cell research is unnecessary because stem cells from adult tissues may be equally effective. I regret that this claim is ill-informed and misleading. Recent reports on adult stem cells are indeed encouraging, but this line of research is in its very early stages, and far from definitive at this point. We know little about the availability of adult stem cells, their differentiation, or their potential for prolonged maintenance outside the body.

While we strongly support continued research on adult stem cells, it is far too early to conclude that they will be as effective in treating and preventing disease as embryonic stem cells seem certain to be. If we hold up the progress on embryonic stem cells we may be very much at a loss in a few years time.

PREPARED STATEMENT

Finally, we believe it would be immoral not to pursue this embryonic stem cell research within the appropriate regulatory oversight, because it has such enormous potential to save human lives and to mitigate human suffering. I submit that if the issue is morality, using embryonic stem cells for life-saving research is greatly preferable to discarding them. I, along with many others, believe we should take advantage of the enormous life-saving potential of the thousands of embryos currently frozen and destined for destruction.

So I thank you for the opportunity to testify before you, Mr. Chairman, and I would be pleased to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF RICHARD O. HYNES

Mr. Chairman and members of the Subcommittee: I am Richard Hynes, Professor of Biology at the Massachusetts Institute of Technology, where I am also an investigator of the Howard Hughes Medical Institute and Director of the Center for Cancer Research. I am a member of the US National Academy of Sciences and of the Institute of Medicine. I am here today as President of the American Society for Cell Biology. The Society represents 10,000 basic biomedical researchers, most of whom work in our Nation's leading research universities and institutes. It is my great pleasure to appear before you to explain why our organization feels that it is so important that the full potential of human embryonic stem cell research be realized.

On behalf of the American Society for Cell Biology, I wish first to extend my deepest appreciation to you, Chairman Specter, to Ranking Member Harkin and to the members of the Subcommittee for the visionary and courageous commitment you have made through your investment in biomedical research at the NIH. We are extremely grateful that you have embraced the goal of doubling the NIH budget over five years and that we are halfway towards reaching that goal. This funding is vitally important to allow our nation's scientists and clinicians to exploit the tremendous opportunities offered by the current revolution in biomedical research to enhance the health of the American public.

We believe deeply that this investment in biomedical research will be most effectively used if embryonic stem cell research is included among the innovative methods used to develop treatments and preventions for disease. We understand the ethical concerns that some have raised about this research but we respectfully submit that appropriately regulated research on human embryonic stem cells can be conducted while taking into account those concerns. The Guidelines recently released by the National Institutes of Health enable federally funded scientists to conduct research using pluripotent human embryonic stem cell lines. We believe that this research will undoubtedly lead to new ways to treat disease and disability. Embryonic stem cells will allow the creation of new, healthy tissue to replace damaged or dead tissue, such as bone marrow for the treatment of cancers, sickle cell anemia and thalassemis; pancreatic cells for the treatment of diabetes, and neuronal cells for the treatment of Parkinson's disease, Alzheimer's and various brain and spinal cord injuries and disorders. The prospects offered by this research are analogous to,

but will likely far surpass, the benefits realized by organ transplantation over recent decades.

We do not stand alone in our determination that this invaluable research must go forward. Attached to my testimony is a statement signed by 70 American organizations, including the American Medical Association, the Michael J. Fox Foundation for Parkinson's Research, the Juvenile Diabetes Foundation International, the Christopher Reeve Paralysis Foundation, the American Association for Cancer Research, and the Federation of American Societies of Experimental Biology which I respectfully request be submitted for the record.

I also want to reiterate the support of the American Society for Cell Biology for S. 2015, "The Stem Cell Research Act of 2000" which you have introduced, that would allow federally-funded scientists not only to use, but also to derive embryonic stem cell lines for research purposes.

Some have argued that human embryonic stem cell research is "illegal, unnecessary and immoral." We respectfully disagree on all counts. On the contrary, we believe that it would be immoral not to pursue this great opportunity to improve the quality of human life.

First, the charge that the NIH has acted illegally is unfounded. As you well know, the Labor, Health & Human Services and Education Appropriations bills have restricted embryo research for the last several years, but these bills are silent on the use of embryonic stem cells. These cells are not embryos and they cannot independently develop into embryos. The NIH Guidelines prohibit the use of NIH funds to create embryos for experimental purposes and they set specific criteria governing the sources from which embryonic stem cells can be obtained. These guidelines require the informed consent of the donors, preclude any possible direct benefit to such donors, and prohibit the creation of embryos for research purposes. Cells used for research must be derived solely from embryos generated for fertility treatments and in excess of clinical need. Such embryos would otherwise be discarded. A critical element of the NIH Guidelines is that the federal government will oversee the use of embryonic stem cells. Heretofore, this valuable resource was available exclusively to private and commercial entities, which were not accountable to the public. By funding human embryonic stem cell research, the federal government may exercise control over standards for use of stem cells. This provision will facilitate open debate and encourage public input into the appropriate uses of this important scientific opportunity.

Second, critics argue that embryonic stem cell research is unnecessary because stem cells derived from adult tissues may be used with equal effectiveness. I regret that this claim is ill-informed and misleading. Scientists are indeed guardedly encouraged by recent reports of plasticity of some adult stem cells, but this line of research is in its very early stages and far from definitive. We know little about the availability of adult stem cells, their differentiation, or their potential for prolonged maintenance outside the body. While we strongly support continued research on adult stem cells, it is far too early to conclude that they will be as effective in treating and preventing disease as embryonic stem cells seem certain to be. If embryonic stem cell research were to be halted based on that hope, it is entirely possible that years would pass before scientists determine whether or not adult stem cells are of equivalent value. During those years embryonic stem cell research can and should be pursued in parallel, to the great benefit of many of our fellow citizens. This possibility was emphasized in a letter to Chairman Specter in May from some of this Nation's leading researchers investigating adult stem cells who stated: "We are . . . dismayed that our research . . . is being used as a justification to hinder or prohibit research with embryonic stem cells. It is simply incorrect to use the future promise of adult stem cell research as an argument that embryonic stem cell research is not critical and essential." Again, I respectfully request that you submit their letters for the record.

Finally, given these facts, we believe it would be immoral not to pursue embryonic stem cell research, within the appropriate regulatory oversight mandated by the NIH Guidelines, because this research has enormous potential to save human lives and to mitigate human suffering. The embryos in question would be obtained from in vitro fertilization clinics only from those in excess of clinical need. I submit that, if the issue is morality, using embryonic cells for potentially life-saving research is greatly preferable to discarding them. Surely we should take advantage of the enormous life-saving potential of the thousands of embryos that are currently frozen and destined for destruction?

Great Britain has recognized the value of stem cell research, having strongly recommended the use of embryonic stem cells, and is now considering enabling publicly funded researchers to establish new embryonic stem cell lines. Other European countries are moving in the same direction. I do not believe that the Europeans are

less moral or ethical than we. I also do not believe that they are less sensitive to the sanctity of life. I do believe that they have acted appropriately to enact by law the generation of new sources for stem cells in order to save lives and reduce suffering of the living and I believe we should do the same in this country.

In conclusion, The American Society for Cell Biology strongly endorses the NIH Guidelines which will enable federally-funded scientists to pursue embryonic stem cell research. We also endorse S. 2015, "The Stem Cell Research Act of 2000". We feel that, for the sake of humanity, studies using all forms of stem cells—embryonic, fetal and adult—should be pursued vigorously. We owe it to all those who are suffering to explore all possible avenues that could lead to the prevention of, and remedies for, disease.

I thank you for the opportunity to testify before you, Mr. Chairman. I would be pleased to answer any questions.

Senator SPECTER. Well, thank you very much, Dr. Hynes. You point out that there is no law prohibiting Federal funding on the stem cells once they have been extracted from the embryos, which I think is an important distinction to make clear, as you have, but the existing prohibition is on the use of Federal funding to take the embryos themselves and to extract the stem cells.

Once they have been extracted by somebody else, then Federal funding may be used, and I think the point you make on the discarding of the embryos is very important. The embryos were created for in vitro fertilization, and those which are not used will be discarded.

When we dealt with the issue of fetal tissue many years ago, objections were raised that fetal tissue would promote abortions, and finally that argument was discarded, but I think it is important to focus on those couple of additional factors at this juncture.

STATEMENT OF DARWIN J. PROCKOP, M.D., Ph.D, DIRECTOR, CENTER FOR GENE THERAPY, TULANE UNIVERSITY MEDICAL CENTER

Senator SPECTER. Now we would like to turn to the testimony of Dr. Darwin Prockop, who as of March of this year was appointed director of the Center for Gene Therapy at Tulane University Medical Center. Prior to that time, he was director of gene therapy at Hanneman University School of Medicine.

Dr. Prockop discovered the gene defect that causes brittle bone disease, and his most recent work involves successfully converting stem cells taken from adult bone marrow into nerve cells. He received his M.D. from the University of Pennsylvania and his Ph.D in biochemistry from George Washington University, so I guess we have to call you doctor, Dr. Prockop.

The floor is yours, sir.

Dr. PROCKOP. Thank you very much, Senator Specter. It is a real privilege to appear before this subcommittee.

I think I have been asked to speak to you today because Tulane Center for Gene Therapy is focusing on using adult stem cells, and developing these cells as a way of treating a number of diseases.

These adult stem cells were discovered over 20 years ago, the ones we are dealing with, and have been shown to have a number of remarkable qualities. One is that they can be easily obtained from a patient, and that means that we can use these cells from the same patient who is going to be treated without the use of embryonic tissues or cells. Another feature is that we can grow them very rapidly in the laboratory. The technical consequence of that is, we do not need viruses to work with these cells.

The third and most remarkable feature of these cells is that they can become many of the hundreds of kinds of cells one finds in the human body, and they seem to be part of us, as a kind of repairing tissue, so for example, a few years ago we discovered that if one takes these cells from an experimental animal and puts them into a vein of the same animal, the cells go to many, many tissues, and they seem to take part in the repair of those tissues. They form the new cells of those tissues.

So, for example, some of the cells go to bone and become new bone cells. The implication of that observation for therapy of bone disease is very broad. In fact, Drs. Edwin Horowitz and Malcolm Brenner and others at St. Jude's Hospital, with whom we are collaborating now, have recently reported some remarkable results in children with very brittle bones, children whose bones are so brittle they break a rib rolling over in bed.

Some of the cells, after infusion in animals, go to lungs, and so the possibility is there of using these cells to repair the lung in cystic fibrosis.

Some of the cells go to cartilage and joints. The possibility is there of using these cells to treat the damaged cartilage and joints that occurs as a result of arthritis.

Some of the cells go to muscle, particularly if the muscle is damaged, so the possibility is there of using the cells to treat muscular dystrophy.

In fact, at this point we are not quite sure what the whole spectrum is of diseases that could be treated. We cannot rule out the possibility of using these cells for diabetes, for heart disease, and kidneys. We simply do not know.

But one of the most remarkable features of these cells is that when you put them in the brain of an experimental animal, they become new brain cells. The discovery was made in our laboratory by Dr. Asum Azizi and Donald Phinney some 2, 3 years ago. It is extended now by the work of Ira Black at Robert Wood Johnson Medical School, and two other investigators at other medical schools.

They will become, in fact, some new brain cells, not all possible brain cells, and those observations have led us and others now to pursue the possibility of using these cells to treat Parkinsonism. In fact, we published a few months ago some very promising results in a rat model for Parkinson's.

We are also thinking about using the cells to treat Alzheimer's disease, and stroke, even multiple sclerosis and spinal cord repair, so the prospects here are really very exciting.

But I would like to close by making two points. Yes, all these things have been documented, the things I have just said. The possibility is there of using adult stem cells to treat these diseases, and we do not need therefore to use fetal tissues, and we do not need to put any foreign cells into a patient, and also we probably do not need to use a virus.

But the second point I would like to stress is, we are not there yet. We have a very long way to go. For example, we are working very hard in using these cells, adult stem cells for Parkinsonism, but we are at least 2 years, maybe 3 years away from the first trial in patients.

PREPARED STATEMENT

We need a lot of further work, we need continuing support from the National Institutes of Health, other sources such as the Louisiana State Consortium for Gene Therapy. We have to build up the data we need from animal experiments before we can try that. I think it would be a grave mistake to say, because of the work we have done and others have done with adult stem cells, one should now stop the kind of work with fetal tissues and cells as called for under the NIH guidelines.

Thank you very much.
[The statement follows:]

PREPARED STATEMENT OF DARWIN J. PROCKOP

Good Morning: My name is Darwin Prockop. I am currently the Director of the Center for Gene Therapy of Tulane University Health Sciences Center in New Orleans, Louisiana. I have an M.D. degree, a Ph.D. degree and two honorary doctoral degrees. In addition, I am a member of the National Academy of Sciences and the Institute of Medicine. I have published over 400 scientific articles. My work has been continuously supported by the National Institutes of Health. In addition, the Tulane Center for Gene Therapy that I now head is supported by funds from Tulane University, the Columbia Healthcare Association and the State of Louisiana Consortium for Gene Therapy.

Our Tulane Center for Gene Therapy is carrying out research on a special class of adult stem cells that we think can potentially be used for the treatment of a number of devastating diseases. The adult stem cells we are using were first discovered 20 years ago, and we now know they have a number of truly remarkable features. One remarkable feature is that they can easily be obtained from a small sample of bone marrow from the same patient who is to be treated. Therefore if our therapies work, we will not need fetal tissues nor will we need to introduce foreign cells into a patient. Another important feature of the cells is that we can grow them rapidly in the laboratory. A technical consequence of this fact is that we can introduce new genes without the use of a virus. But the cells are of special interest primarily because they can change into a large number of the many different types of cells found in the human body. For example, we discovered several years ago that if the cells are isolated from the bone marrow of an animal, and then injected back into the blood stream of the same experimental animal from which the cells were obtained, they travel to a number of different organs and tissues. Moreover, when they reach a given organ or tissue they become new cells of the same kind that are normally found in that organ or tissue. In effect, the cells can repair and rejuvenate the organ or tissue.

These features of the cells raise some exciting possibilities for using them in the therapy of diseases. For example, after infusion into a vein, some of the cells go to bone and become new bone cells. Therefore, the cells can potentially be used to treat diseases of bone such as osteoporosis. In fact, Drs. Edwin Horowitz, Malcolm Brenner and others at St. Jude's Children's Hospital in Memphis have recently reported promising results with the cells in treating children with severe brittle bone disease. Some of the cells go to lung and become lung cells. Therefore, they can potentially be useful in treating diseases of the lung such as cystic fibrosis. Some of the cells go to joints and cartilage and become cells of joints and cartilage. Therefore, they can potentially be used to treat diseases of the joint such as arthritis. Some preliminary data suggest that in the future the cells may also be useful in treating additional diseases such as diabetes, heart disease and kidney disease. One of the most dramatic observations about such cells is that they can become new cells of the brain. The first observations here were made one and two years ago in my laboratory primarily by Dr. Asum Azizi and Dr. Donald Phinney. In the past several months these observations have been extended by Dr. Ira Black and his associates at the Robert Wood Johnson Medical School and by research groups at two other medical schools. Because the cells can become some of the cells of the central nervous system, my laboratory and others are currently trying to see if they can be used to treat disease of the central nervous system such as Parkinsonism, Alzheimer's disease, stroke, spinal cord injury and multiple sclerosis. In fact, we have recently published some promising results using the cells in a rat model of Parkinsonism.

In closing I would like to make two general statements. One is, yes, it is true that if the work that my laboratory and many others are now doing continues to be suc-

cessful, it will open the possibility of using stem cells from adults, or even from the patient himself or herself, to treat a large number of terrible diseases. If successful, the therapies will not use any fetal tissues and probably will not use any viruses.

However, I would like to stress the second very important point: we are not there yet. We have a long way to go. In my estimation, it will be at least two years before the first adult stem cells can be tested in patients with diseases such as Parkinsonism. It will probably be much longer for testing the cells in patients with the other diseases I have mentioned. We simply cannot be certain in advance which therapies will work and which will not. We need several years of hard work and we need continuing support from sources such as the National Institutes of Health and other sources such as the Louisiana State Consortium for Gene Therapy and the Columbia Healthcare Association that are currently supporting the Tulane Center for Gene Therapy. In my opinion, it would be a serious mistake to stop all research on human embryonic cells and tissues because of the exciting discoveries my laboratory and others have recently made about adult stem cells. We are simply not ready for a moon shot-like strategy in which we place all our bets on adult stem cells. I think it would be a mistake to tell the millions and millions of people whose lives are being destroyed by these terrible diseases that they to wait three, four, five years or even longer until we see the results obtained with adult stem cells before we even begin doing research on the other kinds of tissues and cells that may cure their diseases. I myself would be extremely sorry to see this sub committee or any other group decide that because of the work we and others have done on marrow stem cells, the kinds of research called for in the new NIH guidelines should be stopped.

Senator SPECTER. Thank you, Dr. Prockop.

Picking up on one of your last statements about the prospects for having stem cells utilized in humans in Parkinson's, would you elaborate first of all why—2 to 3 years is pretty good. We press with some frequency the people who appear here, especially those from NIH, where Senator Harkin and I have led the way for very material increases. In the last four appropriations periods we have increased the funding by some \$7 billion, so that the current projection for next year will be in excess of \$20 billion. What do you anticipate in 2 to 3 years with respect to stem cells and Parkinson's?

Dr. PROCKOP. Well, I can give you the best case scenario. If our experiments now being conducted in animals come out right in terms of efficacy, in toxicity, we think we may be able to begin the very first clinical trials in patients with Parkinsonism in 2 or 3 years. That is our best case scenario.

Senator SPECTER. Why not sooner, Dr. Prockop?

Dr. PROCKOP. Senator Specter, we have to be safe about this. We have to be sure we are not going to do more damage than we are going to help the patients.

Senator SPECTER. What sort of experimentation do you anticipate between now and 2 to 3 years, when you are using the stem cells on people who have Parkinson's?

Dr. PROCKOP. First we have to go to animal models of the disease, and there are models in rats and monkeys that are pretty close to what people suffer from in this disease, and we have to do the tests there. It is not a test one does for a day or a week. One has to do the treatment and then wait out 3 months, or 6 months, or 9 months to be certain there is not some unfortunate consequence of what you are doing. It takes that, and one does not go from small animals to the more expensive tests in monkeys until one has those.

Senator SPECTER. All right. You move to 2 or 3 years. You make the use of stem cells with people who have Parkinson's. Do you

have a projection as to what your expectation is once that treatment starts, how long it would take from there, how long from there to cure Parkinson's?

Dr. PROCKOP. Well, we have to go through the FDA regulations on this, and it turns out that is a new chapter. The stage of stem cells in people is a new chapter for the kinds of regulations the Federal Drug Administration should set up, and a beginning dialogue has already started between people working with stem cells and the FDA.

What do you need in the way of safety and tests of efficacy before it is appropriate to go to a patient? It would just be terrible, and there are many examples in medicine, as you know, where a drug that looks very good on preliminary tests has some disastrous results in the first few patients.

Senator SPECTER. Well, you are going to have to qualify with the Food and Drug Administration, understandably so, important precautions, but my question goes to, do you have a projection as to how long it will take to cure Parkinson's?

Dr. PROCKOP. Senator Specter, I am an optimist, all right. One has to be an optimist to do research. I think it is somewhere in the order of 4 or 5 years. I am saying it is 2 or 3 years for the first few patients, carefully controlled studies and a very carefully controlled environment. I am hoping it goes fast after that.

Senator SPECTER. I appreciate your optimism, and there are many people hanging on, really hanging on your every word, people who have Parkinson's. One of my constituents from Pittsburgh has an hourglass. Whenever I see him he turns it upside down to remind me that every hour is slipping away, and that if something is not done soon it will be too late for him, so these time parameters are closely watched.

Dr. PROCKOP. These, as you know, are very difficult judgments, when you can make the jump from the laboratory to the patient. It is not an easy decision, particularly when introducing something so new as stem cells into people.

Senator SPECTER. Dr. Hynes, you had started to say that there would be a longer list than the itemized diseases which you thought could be dealt with by stem cells. Let me move to the issue of cancer, which is your specialty. What is your thinking about the potential for stem cells on cancer?

Dr. HYNES. Well, a third of the people in this room are going to get cancer at some point in their lives, and so a large proportion of the American public needs treatment for this disease.

Senator SPECTER. How many of the people in the room did you say would get cancer?

Dr. HYNES. 1 in 3. We are making some progress on that, but we desperately need new approaches, and the application of stem cells to variations on bone marrow stem cell transportation is certainly one of the opportunities that I think is going to be very valuable—the replenishment of tissues that are damaged during therapy, the replacement of tissues that have to be removed.

These stem cells are likely to be able to give rise to a large proportion of the tissues of the body, as are adult stem cells. I think that we need to work on both of them, and I think the opportunities from both of them approaching cancer are considerable.

Senator SPECTER. You said it would take a long time to list all of the ailments which might be affected by stem cells. I think it is worth the time. Tell us what you have in mind.

Dr. HYNES. Well, let me give you several more. For instance, replenishment of heart muscle tissue. We know from studies of embryonic stem cells in mice that one of the easy cells to derive from those is functional beating heart muscle cells, so that is a source of cells that could be used to repair damaged heart tissue. That will take a while, obviously. It is a complicated issue, but I think it is a definite prospect.

Multiple sclerosis, the loss of the cells that ensheath neurons, glial cells. Glial cells can be derived from embryonic stem cells, as can neurons, and so I already mentioned the neuronal diseases that affect the neurons themselves, but the accessory cells such as glia are also damaged in many diseases.

Juvenile diabetes, the ability to make islet cells that make insulin, that one we are not so close to, I do not think, because I do not think there is so much evidence yet as to how to derive those cells from any source, but I think there is a very good chance that that will come about, so that is three more examples for you.

Senator SPECTER. OK. Thank you very much.

I yield now to my distinguished colleague, Senator Harkin.

Senator HARKIN. Mr. Chairman, you have covered all the points that I think need to be covered here. I just want to thank you two witnesses for being here. I just want to make it clear as to sort of the summation of what your testimony is, and that first of all, am I right in assuming that you both feel that the ethical guidelines that are published by NIH are sound and will permit the Federal funding of stem cell research within good, ethical and moral guidelines? Do you feel that they are strong guidelines?

Dr. HYNES. I firmly believe that, that they separate the decisions about the embryos themselves from the science that goes forward from them, and I think that is a clear, clean separation. I think the ethical concerns are important and have been addressed by these guidelines.

Senator HARKIN. Dr. Prockop.

Dr. PROCKOP. I think the guidelines are really a very good plan for us to move ahead.

Senator HARKIN. Second, it is both your positions that—especially you, Dr. Prockop. You said that in my opinion it would be a serious mistake to stop all research on human embryonic cells and tissues because of the exciting discoveries in my laboratory, in other words, recently made about adult stem cells. We are simply not ready for a moon-shot-like strategy in which we place all our bets on adult stem cells.

So your position is that the research ought to go forward on all the fronts. Is that basically what you are saying?

Dr. PROCKOP. Absolutely. Absolutely, Senator Harkin. I really think it would be very unwise to do anything else at this time.

Senator HARKIN. Is that your feeling, too, doctor?

Dr. HYNES. That is absolutely my opinion, too. Each of these approaches is likely to produce useful insights. They will not be identical, they will be complementary, and we should proceed on all fronts, adult, fetal, and embryonic stem cells.

Senator HARKIN. Thank you both very much.

Senator SPECTER. Well, thank you very much, Dr. Hynes and Dr. Prockop. We appreciate the work you are doing. It is avant garde. This subcommittee and the full Congress is committed to research help. We have put in this year's budget \$2.7 billion increase in NIH funding, which was on top of \$2.3 billion last year, which had been reduced to \$2.2 billion on an across-the-board cut. We put in \$2 billion the year before. We put in almost a billion the year before that, so the total is right at \$8 billion in increases because of our determination to see this kind of phenomenal research advance, and the scientific community has performed magnificently, and the Congress would like to, if not perform magnificently, at least perform a supporting role, so we thank you.

Dr. HYNES. Well, Senator, we thank you very much for your support, and we will do our best to make good use of it.

Senator SPECTER. Thank you. I call our next panel, Dr. Ronald Heagy, Mr. Russell Saltzman, Dr. Anton-Lewis Usala.

STATEMENT OF RON HEAGY, PRESIDENT AND FOUNDER OF THE LIFE IS AN ATTITUDE FOUNDATION

Senator SPECTER. Our first witness, Dr. Ronald Heagy, is president and founder of the Life is an Attitude Foundation. He became a quadriplegic at the age of 17 when he was injured while surfing. He is a motivational speaker and the author of his autobiography, *Life is an Attitude*.

In 1995, he received the Disabled Oregonian of the Year Award, and he received his master's degree in social work from San Diego State University.

Mr. Heagy, we welcome you here. Let the record show that Mr. Heagy appears in a wheelchair with a microphone close to his lips and his hands.

Mr. HEAGY. A chin-operated wheelchair.

Senator SPECTER. Thank you very much, and the floor is yours.

Mr. HEAGY. Thank you very much, and I appreciate this opportunity as a citizen of America and a resident of Oregon. I went through quite an adventure to get here, and the natives from the West Coast bring greetings to you.

I have accomplished a number of things. My disability occurred as a result of my choice. We know that choices and consequences occur, and I ended up at 17 in a wheelchair, paralyzed from the neck down, a quadriplegic on a ventilator machine. Thank God I am no longer on a ventilator machine. I had a choice to make, whether I go on in life or I give up, and I chose to go on. I learned how to write with a pencil in my mouth, a stick in my teeth.

I type, and I entered college. I was placed on welfare, started out with no income, had no support in college. I worked hard without the State support a lot of people assume that folks like myself get. I am interested in seeing some of those programs be developed, of course.

I accomplished a master's degree at Seneca State University, and went out to try to get a job. I went through 20 different interviews, did not get a job, so I started my own job, became a speaker. I spoke at my own high school, my first speech, and I have spoken to 2 million high school students in this Nation. I just finished

speaking yesterday to 1,000 middle school children, and my emphasis is on life, and here I think we have an issue that focuses not on life.

Of course, I hear everyone make assumptions, and there are opinions, and mine is an opinion, but we have no idea what this can do, we have no idea the ramifications that this sends out to our country.

Who determines the quality of life? My life did not begin until I ended up in a wheelchair. Prior to this, I had a scholarship to play at Oregon State, I was a proud and arrogant person, lived for myself. I am now building camps across America for kids with disabilities to go out and enjoy the forest and the trees. I encourage them to be all that they can be, and I have seen the effect that a disabled person can have on others, including myself.

You look at my web site, go over on .com, read my guestbook, I have thousands of entries from students, high school students across the Nation who have been encouraged not to commit suicide. I could read them here, but for the sake of time—if someone chooses to live as a result of my disability, I think it is encouraging to me to continue on.

Life happens. Sometimes life dumps on you. You have got a couple of choices, get bitter or better, get negative or positive, and there is more than just Parkinson's here, and I know that we are all talking about some celebrity status, and I do not hold a celebrity status, but I do hold an opinion that a lot of my little disabled friends also hold.

I am opposed to this on moral grounds, No. 1. No. 2, it forces financial support from taxpayers that may have opposition to this, who they would have no choice but for their dollars to go towards this.

No. 3, what happens if we do find a cure using this type of procedure? Am I going to be forced to take the cure? If you say to me, well, we are not going to support you through medicare or medicaid any more because we have a cure for you, and I say, I cannot take it because it came through this procedure that I do not believe in, that is not just for me. That could be millions of Americans. There are 61 million Americans with disabilities that I am aware of, and it sounds like the numbers have changed, and not every one of them are on Prozac.

There is life after disability, and I visited last week here to speak before some of the Federal Government leaders encouraging them. They asked me, they paid me to come speak to encourage them. I visited the Holocaust—I think this is the beginning of the end, and I am opposed to it.

The other day I had a young man tell me at a school that he appreciated me talking about life, because there was so much shooting in America. What am I going to tell the kids—I am going to Denver, Colorado next week. What am I going to tell them, that we are deciding to take life, any form of life for the purpose of bettering somebody else's life?

Isn't that exactly what these students are doing? I am trying to talk against that. If you get in my way, I am going to take you out, because my life would be better if you were not here. This is just a—it is appalling to myself, and I would appreciate this country

considering other means in order for folks like myself to be bettered, and I believe that my quality of life is determined by my attitude and not my circumstance.

Thank you.

Senator SPECTER. Well, thank you very much, Mr. Heagy, for your comments, your testimony, your approach to the subject. We turn now to Pastor Russell Saltzman of the Ruskin Heights Lutheran Church in Kansas City, Missouri. Pastor Saltzman has served in other parishes in Omaha, Chicago, Charleston, South Carolina. In 1995 he was diagnosed with diabetes, so has some special insights. He received his master's in divinity from Trinity Lutheran Seminary in Columbus, Ohio.

Welcome, Pastor Saltzman, and we look forward to your testimony.

STATEMENT OF RUSSELL SALTZMAN, PASTOR, RUSKIN HEIGHTS LUTHERAN CHURCH, KANSAS CITY, MO

Mr. SALTZMAN. Thank you, Mr. Chairman, Senator, for the opportunity to appear before this subcommittee. I count it as a privilege. I once worked for a Member of Congress and I know the energy and the time you bring to this work, and how difficult your decisions sometimes are, and you are to be thanked for your efforts.

This is my second visit to the Capitol grounds since I left Washington, and I left January 20, 1973, and that was the day Richard Nixon was inaugurated for his second term. I like pointing this out. I left Washington and he had to resign later. My wife hates that joke. Evidently she is right.

Mr. SALTZMAN. I am here appearing as a person with diabetes to testify against the use of human embryonic stem cell research. First, though, I will reveal something of myself. I am the adopted child of Harry and Lola Saltzman. My parents, who live yet in the house my father built, and where I was raised in Olathe, Kansas, and since I am an adopted child you might guess accurately that the circumstances of my conception were not ideal.

When I was conceived in the summer of 1946 I was an unplanned and an unwanted pregnancy. My parents, birth parents, were members of the same family. In fact, they were step-siblings, and very possibly my conception was the result not only of step-sibling incest but step-sibling rape.

There is no question in my mind, given the circumstances today, that my birth mother would have been urged to accept abortion, and very likely would have sought one as the means of solving the dilemma I represented. I am unable to look at these issues in any light except that of my origin, and when I say that appearing here is a privilege, I hope I also convey my sense of the miraculous, for had my conception occurred after 1972 I would not be here at all.

And suddenly it comes to mind that, having been aborted, the fetal parts that were once me might have become research material for somebody's investigation into the very disease I have come here to discuss, so I say at the outset, this is a terrible thing we undertake in these discussions, not only because the matter touches me so personally, but also because I know our common origin, our core humanity that links us one to another, whatever our stage of development of maturity. We all spring once from an act of union be-

tween egg and sperm. We all once were human embryos. We all once were fetuses, quickening in our mother's wombs. We are all each human life.

We may hope that all of us were conceived in love, but in my case that matters to me not at all whether I was conceived in love or in violence. What is important for me is the fact that I am here in the first place, and my existence, by itself, has some considerable consequence for other people, not least for my seven children, two of whom are adopted.

I suffer from diabetes, and since my diagnosis I have learned that the burden of chronic illness is a genuine burden, and I have experienced the progression of this illness from a time when simple diet alterations controlled it to the point now where I require oral and insulin injections, and it is the chronic part that constitutes the real burden, knowing I will never be rid of it, and yet I cannot consent to stem cell therapy, and what I find disturbing about this is that no technique at present has produced a pancreatic cell.

It comes to a question, is the human embryo human life, or is it a mere bit of research material, and if it is mere research material, then why should any human life at any stage of development, yours or mine, carry any special privilege?

But if the embryo is human life, then we should have in place some restraint that cautions the strong against using the weak for their own purposes.

PREPARED STATEMENT

If a cure for diabetes and a host of other ailments require the production and destruction of human embryos, then I beg you to consider the possibility that some diseases are better than their cure.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF RUSSELL E. SALTZMAN

Thank you, Mr. Chairman and Senators, for the opportunity to appear before this subcommittee this morning. I count it as a privilege, I once worked for a Member of Congress and I know the energy and the time you bring to this work and how difficult your decisions sometimes are, and you are to be thanked for your efforts. This is my first visit to the Capitol grounds since I left Washington on January 20, 1973. That was the day Richard Nixon was inaugurated for his second term. I don't want to make too much of it, but I do enjoy pointing out that I left Washington and the president had to resign.

I am here as a person with diabetes to testify against the use of human embryonic stem cell research. But I shall first reveal something of myself. I am the adopted child of Harry and Lola Saltzman, my parents who live yet in the home where I was raised in Olathe, Kansas.

Since I am an adopted child, you might guess, accurately, that the circumstances of my conception were not ideal. In the summer of 1946, I was an unplanned, unwanted pregnancy. My birth parents were members of the same family. In fact they were step-siblings. Very possibly my conception was the result not only of step-sibling incest, but step-sibling rape.

There is no question in my mind—given the circumstances current these days—that my birth mother would have been urged to accept abortion and very likely would have sought one as the means of solving the dilemma I represented. I am unable to look at abortion in any light except those of my origin. When I say that appearing here is a privilege, I hope I also convey my sense of the miraculous, for had my conception occurred after 1972, I would not be here at all.

And suddenly it comes to mind that—having been aborted—the fetal parts that were once me might have become research material for somebody's investigation into the very disease I have come here to discuss.

So at the outset, I say it is a terrible thing we undertake in these discussions, not only because the matter touches me so personally, but also because I know our common origin, the base humanity that links us one to another, whatever our stage of development or maturity. We all once sprang from an act of union between egg and sperm. We all once were human embryos. We all once were fetuses quickening in our mothers' wombs. We are all, each, human life. We may hope that all of us were conceived in love, but in my case that matters not at all. Whether I was conceived in love or in violence, what is important for me is the fact that I am here in the first place. My existence by itself has some considerable consequence for other people, not least for my seven children, two of whom are adopted.

I suffer from diabetes. Since my diagnosis in 1995, I have learned that the burden of a chronic illness is a real burden. I have experienced the progression of this illness from a time when simple diet alterations controlled it, to the point now where I require both oral medication and insulin injections. It is the chronic part that constitutes the real burden, knowing I shall never be rid of it, knowing my life will always be governed by diet and injection schedules, and knowing, too, that my death probably will be the result of some diabetic complication. When I say I wish I did not have it, I am saying there is almost anything I would do to get rid of it.

Almost.

The prospect of stem cell therapy derived from human embryonic research—involving the destruction of a human embryo—touches me in a most profound way. I would never consent to any treatment for my diabetes that directly or indirectly came about as the result of destroying a human embryo. What I find disturbing about this incessant rush to harvest stem cells from embryos is the fact that no researcher to date has been able to develop a pancreatic cell from the techniques presently used, this while there are several promising avenues of research that do not involve destruction of a human embryo.

Most recently, I have learned about investigations by Canadian researchers that employed pancreatic islet cells from cadavers. The technique successfully eliminated insulin-dependence of several diabetics who received the procedure. The procedure is subject to further trials and it must be nuanced in application. But this holds greater promise for a diabetic cure than anything else I have heard about—and islet cell transplant is ethically neutral. It has no moral implications associated with it. Yet, we here in the United States seem in a rush to use what is arguably the most ethically objectionable method available, while other morally neutral medical technologies virtually are at hand. The President's own National Bioethics Advisory Commission has said that because human embryos deserve respect as a developing form of human life, destroying them "is justifiable only if no less morally problematic alternatives are available for advancing research." The fact is, those alternatives exist.

It comes to a question. Is the human embryo human life, or is it a mere bit of research material? If it is mere research material, then why should any human life at any stage of development—yours or mine—carry any special privilege? But if the embryo is human life, then we should have in place some restraint that cautions the strong against using the weak for their own purposes.

I would commend to your reading Aldous Huxley's *Brave New World*. Writing in 1933 Huxley, with astonishing prophetic foresight, created a world of genetic clones and what he called "decanted babies." All this arose because in the world of his novel, the human embryo was merely research material. He worried that science was being twisted all around. Where once, as with the sabbath, science was made for Man, he foresaw a time when Man would be made for science. In Huxley's fictionalized world the process that turned science around was methodical and deliberate, and without moral regard. In our own world, the process going on is less tidy but no less deliberate, and, I fear, with equally little moral regard.

If a cure for diabetes and a host of other ailments require the production and destruction of human embryos, then I beg you to consider the possibility that some diseases are better than their cure.

Senator SPECTER. Thank you very much, Pastor Saltzman.

We will have questions when we conclude the full panel, and we now turn to the third and final member of the panel, Dr. Anton-Lewis Usala, founder, chairman, and chief scientific officer for Encelle, a biomedical device transplantation company located in Greenville, North Carolina. He received his medical degree from

Jefferson Medical College in Philadelphia. Welcome, Dr. Usala. The floor is yours.

STATEMENT OF ANTON-LEWIS USALA, M.D., CHAIRMAN/CHIEF TECHNICAL OFFICER, ENCELLE, INC., GREENVILLE, NC

Dr. USALA. Senators, I come as a medical scientist, a person who has had diabetes 41 of my 42 years, and a concerned citizen of the United States. I was asked to present the approach my company has developed for the treatment of type I diabetes and other diseases states that require replacement of nonfunctioning tissues.

The premise of our approach is to replace as physiologically as possible the insulin-producing cells that have been destroyed in children with diabetes. This effort requires large numbers of replacement cells, as there are approximately 1 million patients with type I diabetes in the United States, and since only several thousand human pancreases are available to provide a resource for these cells, developing a method for preventing rejection of animal-derived cells has become the focus of our effort.

Our most promising approach to solving the problem of cross-species transplantation has involved culturing tissue from pig pancreases and proprietary hydrogel material derived from pig skin. The cells in this material are then injected in a diabetic animal without using any immunosuppression. The material is a copolymer designed to simulate the structure of connective tissue present during the first few months of fetal development.

Connective tissue is the scaffolding the cells attach to, and during phylogenesis the connective tissue is quite different in appearance than later in life.

Stem cells are attractive as a therapy because they are responsive to embryonic signals and are thereby differentiable. That is, they can differentiate into many different kinds of tissue. Our biopolymer material has been used for its ability to directly simulate host tissue differentiation, regeneration and repair without the need for stem cell transplantation.

Last Thursday, the Food and Drug Administration authorized the commencement of human clinical trials utilizing our material in the treatment of diabetic foot ulcers. We have demonstrated that a single injection of the material induces complete reconstruction of chronic and acute skin wounds in rabbits, dogs, and pigs. This includes reconstruction of skin architecture that is normally only made during fetal development. Blood vessels, hair follicles, and dermal structures are integrated in a scarless healing after a single injection of the material.

Replication of specific tissue requires cells to receive an enormous number of specific signals. What defines a human life is cellular mass able to produce and integrate this enormous number of sequences, and this occurs shortly after fertilization. The cascade of specific cellular differentiation begins and continues throughout the adult life of the person. It can be argued when the reasoning of the fetal organism begins. It cannot be argued when it is human.

Cells from a human embryonic donor can be induced to this degree. Severed from the intricate and specific environment in which they are made, totipotent or pluripotent cells require the signals from thousands of sources. While knowledge would undoubtedly be

gained from this research, this is different from development of a treatment, and there are different approaches that do not require using human embryonic cells.

Whether or not our approach will induce recreation of complex tissue structures in human patients will be known very shortly. I hope what we have observed in preclinical studies will also be the case in patients with diabetic foot ulcers. If so, variations on this approach will be researched by others for the ability to induce other types of tissue repair such as nerves, utilizing the patient's own regenerative capabilities.

I am 42 years old, and have had diabetes 41 years. I have seen the therapy for diabetes dramatically change over this time. Prior to the manufacture of disposable needles, which appeared when I was 8 years old, I recall my mother sharpening reusable hypodermic needles on a stone to make the injections less painful. During my childhood, adolescence and young adulthood, the medical community nearly unanimously concurred that blood sugar control made no difference in the development of diabetic complications, and thousands of children with diabetes died prematurely as a result.

Clearly, embryonic stem cell research will require enormous resources to define a usable path to treatment, if such a path exists. While many respected scientists are understandably enthused about the possibilities, human embryonic stem cells may not provide a viable path, and as the path adopted for treatment of diabetes for 40 years, just as this treatment was also not viable.

Senators, I am not sure that my experience gives me any more legitimacy in my views than any of the other 1 million patients with diabetes or any other conditions, but the more fundamental issue is not whether embryonic stem cells will provide a better path for a cure. It is whether or not this line of research should be entertained by society.

All societies are based on law, even unjust societies. The difference between a just and an unjust society is the premises it accepts to begin establishment of legal precedents. The United States, in my view, is a uniquely just society because of the first 10 amendments to its Constitution. These amendments for the first time in human history established a system where the rights of the individual supersede the perceived right of the State, implicitly defining the individual as the most valued entity within the society.

History has amply demonstrated the ghastly consequences when Government arbitrarily defines what constitutes human life. The law is based on precedent, and once the United States allows the individual human embryo to be sacrificed for a perceived greater good, the greatest defense for the rights of individuals will have been eroded. For the first time, the perceived right of the Government will supersede the right of the individual.

PREPARED STATEMENT

The pain and suffering endured by those with disease must be addressed, and the means to providing solutions encouraged. The decision to allow human embryonic stem cell research, however, must not be made solely on the basis of its utility in curing disease. It must be considered in the context of its potential to initiate an

insidious disease in our society's values and its potential to erode the foundation that the United States provides for all individuals. Alternative methods and cures must be pursued on both scientific and societal grounds.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF ANTON-LEWIS USALA

Senators: I come as a medical scientist, a person who has had diabetes 41 of my 42 years, and a concerned citizen of the United States. I was asked to present the approach my company has developed for the treatment of Type I diabetes, and other disease states that require replacement of non-functioning tissues. The premise of our approach is to replace, as naturally and physiologically as possible, the insulin producing cells that are destroyed in children with diabetes. This effort would require large numbers of replacement cells, as there are approximately one million patients with Type I diabetes in the United States. Since only several thousand human pancreases are available to provide a source of these cells, developing a method of preventing rejection of animal derived insulin producing cells has become the focus of our effort.

Our most promising approach to solving the problem of cross species transplantation has involved culturing tissue from pig pancreases in a proprietary hydrogel material derived from pig skin. The cells in this material are then injected in a diabetic animal, without using any immunosuppression. The material is a co-polymer designed to simulate the structure of connective tissue present during the first few months of fetal development. Connective tissue is the scaffolding that cells attach to, and during fetogenesis, the connective tissue is quite different in appearance than later in life.

My hypothesis was that during embryogenesis, undifferentiated cells must first bind to this connective tissue in order to properly communicate, integrate, and mature with surrounding cells. If this were true, then perhaps allowing mature cells to bind to a similar connective structure would induce de-differentiation, allowing them to receive local signals from the area in which they were transplanted. This de-differentiation apparently reduces the ability of the patient to recognize the tissue as foreign. When we have placed pig pancreatic cells in our biopolymer material, and injected them into either the muscle or liver of diabetic dogs, the animals' diabetes control is greatly improved. Furthermore, we have demonstrated that the pig tissue survives, and integrates within the dog tissue, without the need for immunosuppressive drugs. This is not yet a cure, but does demonstrate the ability to keep foreign tissue alive and partially functional without the need for either human embryonic tissues or immunosuppression.

Stem cells are attractive as a therapy because they are responsive to embryonic signals and are thereby "differentiable" into many different kinds of tissue. Our biopolymer material has been used for its ability to directly stimulate host tissue de-differentiation, regeneration and repair, without the need for stem cell transplantation. Last Thursday, the Food and Drug Administration authorized the commencement of human clinical trials utilizing our material in the treatment of diabetic foot ulcers. We have demonstrated that a single injection of the material induces complete reconstruction of chronic and acute skin wounds in rabbits, dogs, and pigs. This includes reconstruction of skin architecture that is normally only made during fetal development. Blood vessels, hair follicles, and dermal structures are integrated in a scarless, rapid healing after a single injection of the material. While the complete mechanism of action is not known, we believe these findings result from the following:

Upon injection, the biopolymer binds to the patient tissue with which it comes in contact. Upon binding to this fetal-like connective tissue biopolymer, the host cells de-differentiate into a fetal shape, resembling pluripotent mesenchymal tissue. Over time, we have observed these de-differentiated cells apparently differentiating into specific structures required in the wound areas. Thus, the host cells are again receptive to local signals that enable re-creation of specialized structures after binding to the biopolymer. Thus far, the material is limited in its ability to induce recreation to skin and related structures.

Replication of specific tissue requires cells to receive an enormous number of specific signals. What defines a human life is the cellular mass that is able to produce and integrate this enormous number of sequences, that occurs shortly after fertilization. The cascade specific cellular differentiation begins, and continues throughout

the adult life of the person. It can be argued when the reasoning of the fetal organism begins; it cannot be argued when it is human.

While the developing embryo is equipped to orchestrate the timing of these millions of signals, it is not at all clear how taking totipotent or pluripotent cells from a human embryonic donor can be induced to this degree. Severed from the intricate and specific environment in which they are made, totipotent or pluripotent cells require the signals from thousands of sources. While knowledge would undoubtedly be gained from this research, this is different from development of a treatment, and there are different approaches that do not require using human embryonic cells.

Whether or not our approach will induce recreation of complex tissue structures in human patients will be known shortly. I hope what we have observed in animal studies will also be the case in patients with diabetic foot ulcers. If so, variations on this approach will be researched by others for the ability to induce other types of tissue repair, such as nerves, utilizing the patient's own regenerative abilities.

Often, the highly regarded scientific and medical community will take a position based on their collective interpretation of data that is incorrect. Differing opinions are not heard, because they are outside the mainstream thinking. In the treatment of diabetes, this has had chilling results. I am 42 years old, and have had diabetes 41 years. Prior to the manufacturing of disposable needles when I was 8 years old, I recall my mother sharpening the re-useable hypodermic needles on a stone to make the insulin injection less painful. During my childhood, adolescence, and young adulthood, the medical community nearly unanimously concurred that blood sugar control made no difference in the development of diabetic complications. In 1968, the life expectancy of a child who developed diabetes before the age of ten was approximately 30 years, as most would die of kidney failure. When I was 10, it seemed to me that nature keeps blood sugars within a very tight range for some reason, and it accomplishes this by releasing insulin from the pancreas whenever a person eats food. Shortly thereafter, I began to surreptitiously take injections of fast acting insulin before or immediately after eating. My intent was to try to replicate nature by providing insulin when it was required to normalize blood sugar after eating.

I sit here today able to talk about the mistakes. Most of the children I grew up with that have diabetes are no longer alive, as their physicians practiced the state of the art medical doctrine, which was that control of blood sugar was not important. Throughout my medical school training, this is what was taught. It wasn't until the early 1990's that the medical community finally reversed its view, after hundreds of thousands of children had died from complications of poorly controlled diabetes. Clearly, embryonic stem cell research will require enormous resources to define a useable path to treatment—if such a path exists. While many respected scientists are understandably enthused about their possibility, human embryonic stem cells may not provide a viable path, as the path adopted for treatment of diabetes for forty years was also not viable.

Senators, I am not sure that my experience gives me any more legitimacy in my views than any of the other one million patients with diabetes. But the more fundamental issue is not whether embryonic stem cells will provide a better path for a cure or not; it is whether or not this line of research should be entertained in our society.

All societies are based on law, even unjust societies. The difference between a just and an unjust society is the premises it accepts to begin establishment of legal precedents. The United States, in my view, is a uniquely just society because of the First Ten Amendments to its Constitution. These Amendments, for the first time in human history, established a system where the rights of the individual supercede the perceived right of the State, implicitly defining the individual as the most valued entity within the society.

History has amply demonstrated the ghastly consequences when government arbitrarily defines what constitutes human life. I am not suggesting that those who want to use human embryonic tissue are of the same mind. However, the law is based on precedent, and once the United States allows the individual human embryo to be sacrificed for a perceived greater good, the greatest defense for the rights of individuals will have been eroded. For the first time, the perceived right of the government will supercede the right of the individual. The pain and suffering endured by those with disease must be addressed, and the means to providing solutions encouraged. The decision to allow human embryonic stem cell research, however, must not be made solely on the basis of its utility in curing disease. It must be considered in the context of its potential to initiate an insidious disease in our society's values, and its potential to erode the foundation of the United States' protection of all individuals. Alternative methods and cures must be pursued, on both scientific and societal grounds.

Senator SPECTER. Thank you very much, Dr. Usala.

I will begin the questioning with you, Mr. Heagy, and you obviously have undergone great trauma, and interestingly make the comment that your life began on the day when you were disabled, and you talk about the quality of life, and Dr. Usala talks about sacrificing human embryos.

What we are considering here in a sense is the availability of stem cells from embryos to cure very horrible illnesses, Parkinson's, Alzheimer's, stroke, perhaps cancer, and we have the embryo, which Dr. Usala defines as human embryos, but what is your evaluation of the quality of life, on the assumption that the human embryo is living, or with the conclusion that the human embryo is living, with the ability of those stem cells to cure so many people from dreaded diseases?

Mr. HEAGY. I think the difference in my opinion would be federally funding programs and the ramifications of the future that we do not have control of. At this point we all are here, but eventually we will all die and new people will come forward, and this I think is the beginning of some serious decay in respect to human life.

Senator SPECTER. The embryos are going to be destroyed, as we all know, if they are not used in in vitro fertilization, and being discarded, they will not live, again assuming life, and how do you evaluate their being discarded and the quality of life which they have as embryos contrasted with the good that may be done to people who have Parkinson's or other diseases?

Mr. HEAGY. I believe that that is another issue that this Nation has determined was an okay procedure, and it is a different subject. We are talking about a new set of laws, a new set of procedures, and utilizing that and funding that through taxpayer's dollars. I am not opposed to research. I am not opposed to walking again. I am just opposed to the process that we are discussing here and the funding source, and the good people in this Nation that have serious negative implications to this process. Forcing them to fund this is—it goes against what I know about America.

Senator SPECTER. Let me ask the same essential question, Dr. Usala. You talk about sacrificing human embryos. To what extent would you say that you have a human embryo, given the status of the embryo in in vitro fertilization and the consequence of its being discarded, so it either—it ceases to exist, or cannot help people who have horrible illness, what do you think?

Dr. USALA. I think you have crystallized, Senator, the dilemma. I think that some of what I have learned is from the result of not elective, but research that was done on abortuses, and so some of what we were able to do to stimulate the regeneration, and I am talking total regeneration and reconstruction, was coming from that kind of, taking an infant that was prematurely born and died, we were able to get some knowledge from that.

But Senator, what I am concerned about is the paradigm shift that is occurring here. We all know what happens once the precedent is that, well, taking a human embryo and using it for research is okay. What I am very much concerned about is the paradigm shift and its effect on the United States Constitution. I am very, very concerned about that.

Senator SPECTER. You say you think it is okay to use the human embryo? You are concerned about what that may lead to?

Dr. USALA. What we know it will lead to, Senator.

Senator SPECTER. Well, what do you know it will lead to?

Dr. USALA. Well, for instance, for in vitro fertilization they can create embryos and—

Senator SPECTER. I am going to go a little over my 5 minutes here, because I want you to have a full opportunity to set forth your viewpoints here.

Dr. USALA. Thank you, Senator. What we know will happen is that with in vitro fertilization, if we have these embryos, science is an all-consuming fire. What will happen is, maybe a few more embryos will be fertilized so that we could give the embryos to justifiably sound science for development.

Senator SPECTER. So you think they will be creating embryos for scientific research.

Dr. USALA. It will lead to that, if we state as the precedent that the use of these embryos in this way is in and of itself okay.

Senator SPECTER. But if we could certify, guarantee that embryos would not be created except for genuine purposes of in vitro fertilization, and it is a medical decision as to how many you need to create and what you will do with them, but you do not create them specifically for scientific research, if that could be done, would that satisfy you?

Dr. USALA. It cannot be. I am a medical scientist, and I know what happens. What happens is, as I say, science is an all-consuming fire, and the need to know is all-consuming, and what will happen is, well, let us say we need to do, arbitrarily, 10 embryos to have a reasonable success at in vitro fertilization. What will happen, I assure you, is that for medical reasons is they will say, well, we should probably do 20, because that way we can get a better feel for this. It will happen, Senator, there is no doubt. It cannot be legislated.

Senator SPECTER. Well, the guidelines prohibit it. Specifically, quote, the ban on Federal funding involves the prohibition of Federal funding for creation of a human embryo, or embryos for research purposes, but I understand your point of view, and we are very interested in it.

Pastor Saltzman, you and I have the same home State. I grew up in Russell, Kansas.

Mr. SALTZMAN. We were at opposite ends.

Senator SPECTER. Not quite. Russell is about half-way across the State, and Olathe, of course, is in the eastern part of the State. When you were 1 year old I was graduating from high school, so I have seniority on you. I want you to understand that.

Mr. SALTZMAN. I am happy to hear it.

Senator SPECTER. Pastor Saltzman, you talk about, if aborted you might have had your fetal tissue as part of someone else. Do you oppose the use of fetal tissue for medical purposes?

Mr. SALTZMAN. By and large, yes. I think the present system we have is subject to far too much abuse. We have had examples in the Kansas City area of tissue extraction companies playing things with the fees and such as that.

Senator SPECTER. Tissue extraction companies, fees?

Mr. SALTZMAN. Yes.

Senator SPECTER. Well, there had been the concern expressed by many that use of fetal tissue would promote abortions. That concern has pretty much receded. We had an interesting vote in the Senate when Senator Thurmond, who is a very strong conservative and strong right-to-life, had opposed the use of fetal tissue, and then his daughter had juvenile diabetes, so he testified in favor of use of fetal tissue, and instead of 40 Senators favoring fetal tissue, the number jumped to 80, and parenthetically it is worth observing that Senator Thurmond believes in the use of stem cells.

Mr. SALTZMAN. If you are speaking of fetal material derived innocently—

Senator SPECTER. Yes.

Mr. SALTZMAN. Spontaneous miscarriage, that removes the moral dilemma for me.

Senator SPECTER. Well, but suppose you have fetal tissue, or however you designate it, terminology, from an abortion which is being done not to create fetal tissue but for many other reasons why they are performed, do you object to the use of that tissue?

Mr. SALTZMAN. I do.

Mr. HEAGY. Could I make a comment on that, Senator?

Senator SPECTER. We would be interested in your views on the life or quality of life of embryos. You said we were all once embryos, but the general pattern is that we are embryos having been created by in most cases by a wife and a husband and then carried to term, as you and I were, but what about these embryos which are frozen, created for purposes of in vitro fertilization and then—

Mr. SALTZMAN. I think if you are asking about their disposition—

Senator SPECTER. Disposition, quality of life—

Mr. SALTZMAN. I think that is a separate issue, and it needs to be addressed separately. What I do know is that we should not use human life for the benefit of ourselves. If these embryos are going to be discarded anyway—I know the argument goes—why not go ahead and use them? We have prisoners on death row that are going to be executed anyway. Why not get some use out of them before they are dead?

All of this cheapens, I think, human life and our respect for it. We have decided that some may be used by others for their own purposes. Is this what we are saying?

If the embryo was human life, as the President's own advisory bioethics commission said, if the embryo is human life, then it deserves the respect owing to human life, and the commission also said then that when it comes to research in these areas we need to find the least morally objectionable method to advance our research, and that is the President's own commission, and this is all I am saying, too.

Senator SPECTER. Well, it is a matter of where you draw the line. If you have convicts who are serving life sentences—

Mr. SALTZMAN. Where do you draw the line? Where do you make the distinction? The convict is bigger and the embryo is not?

Senator SPECTER. Well, I would draw the line that a convict is a living person, and although he may have the death penalty, or

she may have the death penalty, they may have a DNA test tomorrow and they may be exonerated, but at any rate, they are living people, and this comes back to the issue of the quality of life which is articulated of the embryo and the contrast as to what can be done by way of saving a lot of people from greater diseases.

Senator Harkin—Pastor Saltzman, I did not want to cut you off if you want to say something more.

Senator HARKIN. Thank you, Mr. Chairman. I have listened closely to your line of questioning and the answers and I again—I do not think anyone should—I know Senator Specter well, we know each other well. I do not think anyone should get the misimpression that we do not wrestle with the ethical and moral implications of what this is all about.

We push very hard a couple of years ago, 2, 3 years ago to get the bioethics commission. We had them here to testify to get them to move on this, to examine in depth the ethical and moral implications of this, and to give us some recommendations—I am not an ethicist. There are people that understand these things much better than I do. You, for example—but try to get as much of an input as possible into this to advise us on what would be—if there is an ethical and moral way of doing this, and if there is, how? Well, they came back and said yes there is, and here is how, and they put these guidelines out, and I guess we get back to the point that—the dividing point on this seems to me to be whether or not one—you see, I think if one is opposed to in vitro fertilization as a procedure, just totally opposed to that.

Then I can understand how logically from that one might say that the use of any of these embryos from that is immoral. If the first act is immoral, the other acts are immoral, so I guess we have to first find out whether or not the person thinks in vitro fertilization is an ethical or moral act.

Second, then it seems to me that once you have in vitro fertilization, you have got all these frozen embryos—I guess we have got 100,000, I guess, that are frozen now in nitrogen, liquid nitrogen—that they are going to be discarded. They are just not going to be kept forever and ever and ever and ever. They are going to be discarded.

So if they are going to be discarded, is it more ethical and moral, then, to use these in a method that might reduce human suffering, prolong life, make our quality of life better? Is it more ethical and moral to do that than it is to discard them? That seems to me where we are coming, where we are sort of at the balance point here.

Mr. SALTZMAN. Let me pose a question to you, Senator, if I may. We have 100,000 frozen embryos at present on hand, roughly.

Senator HARKIN. Yes.

Mr. SALTZMAN. We use those up. We go ahead with our stem cell research, and we use those up. We need more. Are we not stimulating the production of human embryos for the purpose of experimentation? We are not going to stop at 100,000.

Senator HARKIN. Well, let me just say this. No, under the guidelines, again, unless you just say the guidelines are worthless, but I do not think they are worthless. They are saying that—

Mr. SALTZMAN. Can they be amended? They will be.

Senator HARKIN. Well, it says here that providers of stem cells cannot make a profit. You cannot sell them, and you have to have informed consent.

For example, if I am a donor through in vitro fertilization, I say no, you cannot use those embryos for that, you cannot use them. You have to have the informed consent of the donors themselves, and they have to be derived in excess of those needed for in vitro fertilization, so if someone goes in for in vitro fertilization, embryos are created, one is implanted, and that embryo develops into a human being and a child, then you have the other embryos that are frozen, I mean, how can you say you are producing the embryos for research when in fact it is a couple going in for in vitro fertilization? They are not going in saying, we want to donate for research. They are donating it for in vitro fertilization.

Mr. SALTZMAN. Why would the fertility clinic—I presume the Federal money would be spent paying the fertility clinic for the embryos that have been donated, is that not so?

Senator HARKIN. I am not—say that again. What is that?

Mr. SALTZMAN. When a couple goes in, they make 10 embryos, they use one, there is 9 left over, the Federal Government will pay the fertility clinic for the 9 embryos, will they not?

Senator HARKIN. I do not think so.

Mr. SALTZMAN. No?

Senator HARKIN. Two things. Under the guidelines, they cannot pay for them. They can pay for the cost of transportation, storage and transportation, but they cannot make a profit from them. They cannot sell them. Second, the guidelines specifically require the separation of the donation and the generation.

Mr. SALTZMAN. I think that is a bookkeeping thing, you know.

Senator HARKIN. Well, let me ask you this. Are you opposed to in vitro fertilization?

Mr. SALTZMAN. Personally?

Senator HARKIN. Well, I do not know, I mean personally, philosophically, ethically, morally, are you opposed to it?

Mr. SALTZMAN. No. I believe that is morally neutral. It raises a host of questions afterwards, though, and that is why we are having these discussions today. What do you do with these embryos that are left?

Senator HARKIN. Well, that is right. I keep saying that is the balance point.

Mr. SALTZMAN. I do not know what to do with them. I know what not to do.

Senator HARKIN. Well, do you think they should—I mean, if they are going to be destroyed, I mean, again, what do you do?

Mr. SALTZMAN. I cannot—we are going to die, all of us.

Senator HARKIN. We are all going to die, that is true.

Mr. SALTZMAN. But you know, I once said, just because we say this thing is going to happen anyway does not allow us to do another thing first.

Senator HARKIN. Well, again I think I can understand if you were opposed to in vitro fertilization, then I can see it, but if you are for it, then you have got to say, okay, what do you do with these left-over—and if you have strict guidelines that separate it out, you cannot pay for them, you cannot generate it for that pur-

pose, it seems to me that—to me, anyway, that the morally and ethically responsible thing would be to say how can—if there is a promise, in terms of research under ethical guidelines, to use them to alleviate human suffering, that is where I come down. I come down on that side of it, I guess.

Mr. SALTZMAN. You are familiar with the old argument, does good actually derive from evil means? It does not. I believe that human embryonic research, the production and use of human embryos for those purposes—

Senator HARKIN. But we are not doing that. These are in excess of in vitro fertilization. I keep saying that we are not producing them for this purpose. The guidelines are very, very specific on that.

Well, obviously we can go on and discuss this for a long time.

Mr. SALTZMAN. Have you ever read *Brave New World*, by Aldous Huxley?

Senator HARKIN. Sure, when I was in college, and I read it once again later on.

Mr. SALTZMAN. Read it again—three times. He wrote it in 1933. He first saw genetic cloning in what he called decanted babies.

Senator HARKIN. Yes.

Mr. SALTZMAN. What he worried about then is what we need to worry about today. He foresaw a time, as with the Sabbath, when science was made for man and instead we have come to a day when man is being made for science, and somehow things have been twisted all around.

Senator HARKIN. I do not agree with that. I mean, I do not think that is where we are at this point. I happen to think that our scientists are working to try to find interventions and cures for diseases and illnesses that affect humankind. There may be other new illnesses and diseases that arise in the future that we do not even know about, and we are going to continually need to do the research necessary to try to intervene on those.

I guess I am not a fatalist. I do not believe in, I guess—maybe because of my religious background, I do not believe in predestination. I do not believe in—I am not a fatalist. I do not believe that just because a person has had an accident, or because they were born a certain way, or have an illness, that that is how it must be forever and ever. If there are medical ways of intervening to relieve suffering or to make a life more whole, I think that is what we ought to be about.

I think that is the humane, moral approach that we ought to be about as a society. It is not demeaning human life. I think it is enhancing human life and making human life better. Of course we are all going to die, but I do not think that it is a necessary lot in life that people have to suffer from debilitating diseases. If that is so, we never would have cured polio. If that is so, we would not have called smallpox, or the other things that we have overcome. Now we are looking at other things that we can overcome.

Mr. SALTZMAN. No one seated here is opposed to research. All we are saying is there are less ethically objectionable methods to do the same kind of research.

Senator HARKIN. Well, I do not know. I mean, obviously I think—I agree we ought to do the adult stem cell research, as Dr. Hynes

and Dr. Prockop said before, but that does not mean we should do that and not do the other ones. I think we ought to advance on all these fronts.

But I am taking a lot of time to engage in a polemic exercise here, and I apologize to you for it, but it is an important aspect, and it is something that we wrestle with all the time.

Mr. SALTZMAN. I have enjoyed the exchange. Thank you.

Senator SPECTER. Thank you very much, Senator Harkin. I think it is very useful to spend extra time on those who are opposed to stem cell research, we have a complete record and give every opportunity to state your position, because we put on the record that we have introduced legislation in favor of research, but in so doing we want to be sure that these hearings are conducted in a very fair and evenhanded way to give you a full opportunity to express all of the opposing views.

Senator HARKIN. I am sorry, I have one other thing if you do not mind, Mr. Chairman. I was so involved with Dr. Saltzman.

Mr. Heagy said something that I wanted to respond to. If you know anything about my background, you know I worked for a long time in the area of disability rights, American Disabilities Act, which I was the chief sponsor of. You made a mention of something about, does this mean that we are going to back off on support for community services and things for people with disabilities. I just want to answer that, and the answer is absolutely not.

In fact, Senator Specter and I are both sponsor and cosponsor of the MCASSA bill—I can never remember what it means—Medicaid Community Attendance Services and Supports Act, which reforms Medicaid to enable and empower people with disabilities to decide exactly how they want their support services delivered, in a community setting, at home, with personal attendance services, or in an institutional setting.

Mr. HEAGY. In my State I—yes. For 18 years of my life I received in-home support services so that I did not have to be in a nursing home, that I could go out and try to make a life for myself, but it has been recently that we have implemented an initiative for disabled folks to go to work and continue to get those benefits, because I require 24-hour care, which I would have to make \$100,000 a year just to be able to afford my caretakers.

Senator HARKIN. I just wanted to respond that we are not backing off of that.

Mr. HEAGY. I appreciate that, but there is a whole lot that we needed to do to get here. There was hardly any transportation. I mean, I had to roll from the hotel to here, and the fact that these services are not accessible, it is just difficult. There are issues in life that we need to address and spend more time, and the money that we are spending.

And I just wanted to ask concerning, real quick, the frozen embryos are potential human life right now. If you farm them out and let them die, then they are dead, correct, and prisoners, and like—what we were discussing, yes, they have a voice right now, but once they are executed they are dead, so why can we not take their parts. It is the same thought process in my mind, and do we seek permission from the folks that gave up those 100,000 frozen embryos to see if they morally agree with this? You are talking about

the future, but what about where those came from? Are those donors okay with this?

Senator SPECTER. Mr. Heagy, I am advised that consent has been obtained from the donors, that we have some 100,000 unused embryos, and the NIH guideline requires informed consent from the donors, including the statement that embryos or fetal tissue will be used to derive stem cells, so that that has been obtained.

We have been joined by Senator Reid, who is a member of the subcommittee. Senator Wellstone has rejoined us, but let us turn to Senator Reid now, and Senator Wellstone, we will come back to you if you wish to ask questions.

Senator REID. Mr. Chairman, thank you very much. I have to be at the Senate when it opens, so I thank you very much for allowing me to say just a few words. I first of all am continuing to be the biggest cheerleaders that you and Senator Harkin have. I greatly appreciate the work that you have done in this area. This hearing is also part of the ongoing work that you are doing, and I cannot give you enough accolades for the work that you are doing and have done.

Let me just say, briefly, that I come at this hearing and the work that you have done in this area not because of statistics and philosophy, but because people that I know that I have hope that work that we are doing here and work being done in the scientific community will help them.

Steve Ragazio is a young man who has Lou Gehrig's disease. He is the president of the largest utility we have in Nevada, and every day he gets up his condition is worse. I hope that the work that is being done is going to help Steve, that he can play with his children and do things that he could do a few months ago. He cannot do it now.

I hope that Molly Singer, who is a little 11-year-old girl that I have known since she was a baby, who is a twin, we can do something about her diabetic condition as a result of the work that is being done because of the emphasis that you, Senators Specter and Harkin, have focused on this issue, and the money that has come from this subcommittee to allow research to continue.

So we have made progress. Again, I am not here to philosophize. I am here to help Molly and Steve get well, and I hope that we can do that.

Senator HARKIN. Thank you very much.

Senator REID. I will ask permission of the committee to be excused to go to the Senate. We are opening at 11 a.m.

Senator SPECTER. Thank you very much for joining us, Senator Reid, and thank you very much for those very complimentary—

Senator REID. The one thing I did want to say, also I want to thank Michael J. Fox, Jennifer Estess, and Mary Tyler Moore. It is wonderful that they are willing to put their celebrity status on the line to help us with this project.

Senator SPECTER. I agree with you, Senator Reid.

Senator Wellstone.

Senator WELLSTONE. Fine, Mr. Chairman. I thank the panel. I came in at the very end, so I do not have the context. I am just here right now. Thank you.

Senator SPECTER. We are going to take a very brief recess. Thank you very much for coming in, Mr. Heagy, Pastor Saltzman, and Dr. Usala. Your testimony is very helpful in putting on the record the articulated views in opposition to stem cell research, which have been very cogently stated, so thank you.

The hearing will now resume, and we call Ms. Gina Gershon, Ms. Jennifer Estess, Ms. Mary Tyler Moore, Mr. Michael J. Fox. We very much appreciate your coming in, and to comment briefly on a statement I made at the outset of the hearing, when people understand the impact of these illnesses, when Americans understand the impact of these illnesses on people they know, there tends to be a greater public awareness and more public support, so after hearing from the scientists, and after hearing from people who were in opposition on a variety of grounds to stem cell research, we do thank you for joining us.

We have Jennifer Estess who is coming in, but in the interim we will proceed with the testimony of Ms. Gina Gershon, who has enjoyed a wide-ranging career in film, television, and on the stage. She most recently was seen in the Academy Award-nominated film, *The Insider* with Al Pacino, and for the past 20 years Ms. Gershon has been a close friend to Ms. Estess.

Ms. Gershon met Ms. Estess while studying for her bachelor of arts degree in New York University. We are going to be joined here by Ms. Estess momentarily. Let us wait just a moment or two. She is coming through the main door because of the logistics of the situation.

While Ms. Jennifer Estess is coming in, and we thank her for joining us again today, she is president of the project, amyotrophic lateral sclerosis, which she founded in 1998 after being diagnosed with the disease in 1997 at the age of 35. Since that time, she has been working with the corporate entertainment communities to help raise funds to find a cure for ALS, also known as Lou Gehrig's disease. She was the producing director of the off-stage Broadway theater company *Naked Angels*, and is currently the executive producer of CBS movie based on her life, scheduled to air early next year.

This is Ms. Estess' second appearance before the subcommittee, having testified last time with Mr. Christopher Reeves back in April 26 of this year.

Ms. Gershon, we turn to you. We have lights, with the green one indicating 5 minutes, the yellow 1 minute, and the red, stop, so you may proceed.

STATEMENT OF GINA GERSHON, ACTRESS

Ms. GERSHON. Honored chairman, distinguished members of the committee, I want to first thank you for giving me the opportunity to speak to you today on behalf of my friend, Jennifer Estess, and her work with Project ALS.

Jennifer and I met as freshmen in college, and we both spent our twenties in New York City planning our futures and building a theater company together. In a group of passionately independent young people, it was always inevitably Jennifer who took it upon herself to focus our work, who, despite our energetic and often con-

flicting ambitions always managed to keep the bigger picture in sight for us.

So it was no surprise to me, or any of us who knew her, that when she was diagnosed with ALS, when she was told that she had, at most, 5 years to live, Jennifer instinctively turned her attention from her own condition to the larger goal. She was scared. We were all scared, but once again she asked us to look beyond ourselves to help her find a cure.

That search led her and her sisters to the stem cell research being conducted independently at some of the Nation's leading research institutions. She brought these doctors together, encouraged them to share their research, and asked how she could help. When they said they needed more money, she and her sisters and friends created Project ALS and began raising money, over \$4 million so far, almost all of which has gone directly to equipment and research, and that research has already produced amazing results.

As you know, ALS is a singularly destructive disease, striking randomly, methodically paralyzing its victims muscle by muscle until they can no longer breathe. It now seems possible that embryonic stem cells have the potential to stop or even reverse that process. We do not know for certain, but to not find out, to not get every possibility of finding out, seems like an agonizingly cruel decision.

While there are some people here today who feel that some diseases are better than the cure, I am positive that many people would feel that a cure is much preferable to having the disease. People should be allowed to have that choice.

Mr. Chairman, members of the committee, I cannot pretend to be an expert on this subject. It is complex and controversial. I know that. My friend here is dying, and I have to do everything I can to help her, and to help her find a cure, if not in her lifetime, perhaps in our own.

Thank you.

Senator SPECTER. Well, thank you very much, Ms. Gershon. Amyotrophic lateral sclerosis is certainly a dreaded disease. It came into very sharp public view with Lou Gehrig, who was stricken with amyotrophic lateral sclerosis and disabled, and died shortly thereafter.

Ms. Estess, we appreciate your being with us again, and we look forward to your testimony.

STATEMENT OF JENNIFER ESTESS, ACTOR/PRODUCER

Ms. ESTESS. Thank you so much. I also wanted to thank Gina, and I feel honored to be on the panel with Michael and Mary, and good afternoon to Chairman Specter and the members of this committee. I want to thank you for inviting me to come back to speak to you again.

My name is Jennifer Estess, and I have ALS, a disease which is always fatal. 5 months ago I came here to tell you about my story, my work, and to ask for your help. Since that time, while we wait, I have come to rely on this ventilator. That is because ALS is destroying the muscles I use to breathe.

Three years ago I was a healthy woman who worked hard and who dreamed of starting a family. Today, I cannot walk, brush my

own hair, or hold my nieces or nephews. But although my body has deteriorated, I am proud to report that stem cell research funded by Project ALS has progressed with stunning results.

When I was first diagnosed, I turned to the medical community for help. They told me that I was beyond the reach of science and medicine. There was not one drug to slow or stop my disease. A cure was unimaginable. But we now know about stem cells and their amazing medical potential.

We know that they instinctively migrate to the area of injury in the brain and spine. We know that they transform into healthy new cells. We know that they may eventually repair the damaged nervous system. Every indication from our distinguished team of doctors is that there will be a treatment, even a cure for ALS, that stem cell therapy will work on humans, but we need your help.

We need your funding. We need your funding to capitalize on the tremendous success that Project ALS and other organizations have realized in the private sector. We need Government control so that no one will abuse stem cell research, and we need the Federal Government to ensure that this life-saving work is carried out in the safest, most responsible way.

Since we last met, I have taken what would have previously been a vacation to the beaches of Southern California. As you might imagine, it was quite a trick for me to get to the shore. It took literally a team of people, my sisters, my friends, my health aides, to carry me to the water's edge. I lay on a beach chair as they lifted me up, and we all moved as a group into the water, and it struck me that the only way we will ever beat ALS is to work together like this to further the promise of stem cells, because we are running out of time.

Millions of Americans with ALS, Parkinson's, Alzheimer's, are running out of time. The children who love them are running out of time.

Mr. Chairman, I know that good science makes no promises and I am under no illusion that the potential rewards of this research will save my life, but while I am still able to breathe, I cannot sit silently as the hope for millions of other Americans stalls or stagnates or dies, and so although I am still unaccustomed to asking for help, I am urging you today to pass the Stem Cell Research Act of 2000.

On behalf of Project ALS and the millions of Americans living and dying with ALS, Parkinson's, Alzheimer's, and childhood brain diseases, I implore you to move this legislation forward with a renewed sense of urgency, to let this opportunity not slip away, to let us save our friends, our families, and ourselves now, because we can.

Thank you very much.

Senator SPECTER. Thank you very much, Ms. Estess. We appreciate you coming back today. We know it is very difficult for you to do that, and since you were here in April our subcommittee came forward with a recommendation of \$2.7 billion of additional NIH funding. That is the largest amount it increased. The year before we recommended \$2.3 billion, the year before \$2 billion, and the year before that, a billion, which are vastly increased sums over what had been done.

So within the last four appropriations cycles we have added some \$8 billion to NIH funding on top of \$12 billion, so you can see that kind of an increase, we are determined to double the research funding, and when the stem cell issue was disclosed in November of 1998, Senator Harkin and I introduced legislation so that we could use the Federal funding to extract stem cells from embryos. There has been a ruling that Federal funding may be used on the stem cells once they are extracted, but it is very important not to have the limitation on the Federal funding to extract the stem cells, so we are moving forward and anticipate a vote on it in the Senate yet this month.

So we appreciate your coming in and providing this testimony, and we not only hear you, but we have acted on it.

Ms. ESTESS. Thank you, sir.

Senator SPECTER. Our next witness is the distinguished star of radio, stage and screen, Ms. Mary Tyler Moore, who has been an active advocate for more than a decade, to my personal knowledge, about the time Senator Harkin was made a subcommittee member, honorary subcommittee member at least, probably best known for her television roles in the Dick Van Dyke Show and the Mary Tyler Moore Show, received an Emmy in 1992 for her role in Stolen Babies, and was nominated for an Oscar in Ordinary People. Broadway honored Ms. Moore with a special Tony for Whose Life Is It Anyway.

She has lived with diabetes for over 30 years, and has worked to raise public and congressional awareness for this disease. For the last 16 years she has served as the international chairman of the Juvenile Diabetes Foundation, and last week I saw her leading an entourage on the first floor of the Hart Senate Office Building on her lobbying ways, and—did she come to see you then, Tom? Me neither.

Ms. Moore, you have the floor.

**STATEMENT OF MARY TYLER MOORE, INTERNATIONAL CHAIRMAN,
JUVENILE DIABETES FOUNDATION**

Ms. MOORE. Thank you, Mr. Chairman. Senator Harkin, Mr. Chairman, members of the subcommittee, I thank you for the opportunity today to discuss stem cell research, an issue that could have enormous impact in the fight for a cure for diabetes.

I am here today as the international chairman of the Juvenile Diabetes Foundation, JDF, an organization whose mission is to find a cure for diabetes and its complications, a disease that affects a total of 16 million Americans, and costs more than \$100 billion per year.

Since its founding in 1970, JDF has grown to become the largest private not-for-profit supporter of diabetes research in the world. This year, JDF will fund up to \$120 million worth of diabetes research, with all of this funding coming from privately raised resources.

I want to thank the subcommittee for its extraordinarily strong support for Federal funding for the National Institutes of Health. I vividly recall several years ago my joining many of you in a kickoff press conference for the bipartisan effort to double the budget of the NIH, and that would be over 5 years. Well, I am so appre-

ciative of that work, and been so glad to see that you have brought us to the almost end of that 5-year period.

However, despite the increases in research funding, our mission to find a cure for diabetes may not happen unless scientists are free to use funds to explore some of the most promising avenues leading to a cure. Stem cell research is an integral part of finding a cure for this disease.

Many of you know that I have had juvenile diabetes for more than 30 years. The disease alone is always difficult to live with. Trying to balance blood sugar levels and insulin injections is hard enough, but adding to that the severe complications of diabetes makes things frightening. I know too well the fears that arise from this part of the disease, and I know as well as anyone that insulin is not a cure.

In many ways I have been more fortunate than others who have diabetes. While I have almost faced blindness due to the diabetic retinopathy, I am still able to see. While I have faced the possibility of amputation, I am still able to walk. But things could have turned the other way, as they have for millions of Americans, and the future of any person with diabetes is always uncertain.

But Mr. Chairman, there is evidence of a cure that is within our grasp. Earlier this year, in a study at the University of Alberta, Canada, 12 individuals with juvenile diabetes received a successful transplantation of insulin-producing cells, and they no longer require insulin.

The transplants involve a minimally invasive injection procedure which does not involve surgery. The cells are placed into the portal vein. They then migrate to the liver, where, even though they are not in the pancreas, they take root and produce sufficient insulin, and almost perfect control of blood sugar.

However, one of the major drawbacks of this study is that two cadaver pancreases are needed for each transplantation, and fewer than 2,000 are available each year. With millions of Americans having diabetes, including nearly 2 million with juvenile diabetes, you can see that even if this procedure is perfected, as we hope it will be, there are not nearly enough organs to cure everybody.

Stem cell research offers a tremendous amount of hope for this research. Scientists believe that one day stem cells will develop into any human tissue or organ. When scientists are able to specialize these cells to become insulin-producing islet cells, lines could be developed to produce an unlimited number of insulin-producing cells. This would effectively solve the supply issue.

Well, I do understand that some people have heartfelt concerns about this research. I believe that, given the safeguards developed within the National Institutes of Health, and considering that the embryos and fetal tissue used in this life-saving science would be destroyed, I believe that stem cell research should be pursued vigorously and is appropriate for Federal funding.

PREPARED STATEMENT

Mr. Chairman, every year thousands upon thousands of children in this country are diagnosed with juvenile diabetes, and one American dies from diabetes every 3 minutes. We owe it to these children and the 16 million Americans with the disease to pursue

all promising research avenues, including stem cell research, within the ethical framework established by the Federal Government.

I thank you for hearing this plea, and I will to the best of my ability answer any questions that you might have.

[The statement follows:]

PREPARED STATEMENT OF MARY TYLER MOORE

Mr. Chairman, Senator Harkin, and members of the Subcommittee, thank you for the opportunity today to discuss stem cell research, an issue that could have an enormous impact in the fight to find a cure for diabetes.

I am here today as International Chairman of the Juvenile Diabetes Foundation (JDF), an organization whose mission is to find a cure for diabetes and its complications, a disease that affects a total of 16 million Americans and costs more than \$100 billion per year. Since its founding in 1970, JDF has grown to become the largest private, non-profit supporter of diabetes research in the world. This year, JDF will fund up to \$120 million worth of diabetes research, with all of this funding coming from privately raised resources.

And I want to thank the Subcommittee for its extraordinarily strong support for federal funding for the National Institutes of Health. I vividly recall several years ago joining many of you in a kick off press conference for the bipartisan effort to double the budget of the NIH over five years. I am so appreciative of the work that you have done so far to get us almost through year three of this effort.

However, despite these increases in research funding, our mission to find a cure for diabetes may not happen unless scientists are free to use federal funds to explore some of the most promising avenues toward a cure. And stem cell research is an integral part of finding a cure for the disease.

Many of you know that I have had juvenile diabetes for more than thirty years. The disease alone is always difficult to live with—trying to balance blood sugar levels and insulin injections is hard enough—but adding to that the severe complications of diabetes makes things much scarier. I know too well the fears that arise from this part of the disease. And, I know as well as anyone that insulin is not a cure.

In many ways I have been more fortunate than others who have diabetes. While I have almost faced blindness from diabetic retinopathy, I am still able to see. While I have faced the possibility of amputation, I am still able to walk. But, things could have turned out differently for me as they have for millions of Americans, and the future of any person with diabetes is always uncertain.

However, Mr. Chairman, there is hope for a cure. In fact, earlier this year, in a study at the University of Alberta, Canada, seven individuals with juvenile diabetes received a successful transplantation of insulin producing cells and no longer require injections of insulin.

The transplants involve a minimally invasive injection procedure which does not require surgery. The cells are placed into the liver through the portal vein. The cells then migrate to the liver where, even though they are not in the pancreas, take root and produce sufficient insulin and almost perfect control of blood sugar. However, one of the major drawbacks of this study is that two cadaver pancreata are needed for each transplantation, and less than 2,000 are available each year. With millions of Americans with diabetes, including nearly two million with juvenile diabetes, you can see that even if this procedure is perfected—as we hope it will—there are not nearly enough organs to cure everyone.

However, stem cell research offers a tremendous amount of hope for this research. Scientists believe that one day stem cells will develop into any human tissue or organ. When scientists are able to specialize these cells to become insulin-producing islet cells, cell lines could be developed to produce an unlimited number of insulin-producing cells. This would effectively solve the supply problem.

While I do understand that some people have heartfelt concerns about this research, I believe that given the safeguards developed within the National Institutes of Health's recently released guidelines, and considering that the embryos and fetal tissue used in this research would be destroyed if not donated to this life-saving science, I believe that stem cell research should be pursued vigorously and is appropriate for federal funding.

Mr. Chairman, every day, 35 children in this country are diagnosed with juvenile diabetes, and one American dies from diabetes every three minutes. We owe it to these children and the 16 million Americans with the disease to pursue all promising research avenues, including stem cell research, within the ethical framework established by the federal government.

I would be happy to answer any questions, and I would like to introduce Dr. Marc Hurlbert from the Juvenile Diabetes Foundation, if you have any scientific questions about this research.

Senator SPECTER. Thank you very much, Ms. Moore, for your very poignant and moving testimony. When you talk about what could happen to you with diabetes, blindness or amputation, that is really laying it on the line, and when you talk about somebody dying every 3 minutes, 2 people have died since we started your introduction, and that is why there are many of us who are so determined to make use of embryos which will be discarded anyway—

Ms. MOORE. Exactly.

Senator SPECTER [continuing]. To save lives and stop human suffering.

We now turn to Mr. Michael J. Fox, who has had a spectacular career, first as Alex B. Keaton on the television series, *Family Ties*, later in a number of movies, including *Back to the Future*, and most recently on television again in the highly acclaimed *Spin City*. This past week, Mr. Fox won an Emmy award for best actor in a comedy series for his work in *Spin City*.

He was diagnosed with Parkinson's in 1991 at the age of 30, and since announcing his retirement from *Spin City*, he has been devoting his time to the Michael J. Fox Foundation for Parkinson's Research, and I might comment that he even came to the Republican convention in Philadelphia.

Mr. FOX. I was in Los Angeles as well, sir.

Senator SPECTER. Well, when you—Senator Harkin mentions that you hit them both. I was not at the other one. What was the other one, did you say?

Mr. FOX. As you said, sir, it is a nonpartisan problem that will take a bipartisan solution.

Senator SPECTER. Well, we are bipartisan here, as the Democrat and Republican representation on the podium suggests, but here again, spectacular work, and from time to time questions are raised about celebrities appearing at congressional hearings.

In fact, it is even more than questions. There is some pretty severe criticism about it, but we make no apologies, because we need public awareness of issues like stem cells, which could cure Parkinson's, or amyotrophic lateral sclerosis, or Alzheimer's, and when public attention is focused on Michael J. Fox because the American people know you, Michael, it is a great use of your talent and celebrity status to let people know what is going on and get public support for this kind of a measure.

So we thank your for your time and your efforts, and we know how debilitating the illness is, and we are just very hopeful that soon—we had the testimony from the scientists this morning—in 2 or 3 years there will be ready for use with people, and that you will be back on ABC TV—I do not want to say that in derogation of the other networks, which are here, but back—well, you choose where you go back. We just want you back.

Mr. FOX. I will be open to all offers.

Senator SPECTER. The floor is yours, Mr. Fox.

STATEMENT OF MICHAEL J. FOX, FOUNDATION FOR PARKINSON'S RESEARCH

Mr. FOX. Thank you, Mr. Chairman and Senator Harkin. Thank you for inviting me to testify, and good morning.

It is hard to believe that—I should say thank you to my fellow panelists. I am honored to be in your company, and let us hope it is for the good.

It is hard to believe an entire year has passed since I first appeared before the subcommittee and addressed the need to increase Federal funding for Parkinson's research. I am grateful for that opportunity to speak on behalf of the Parkinson's community about the reality of living with this disease.

It was during a hearing in September 1999 that Senators provided exciting testimony as to just how close we may be to a cure for Parkinson's. In pursuit of that cure, I am back this year to lend my voice and that of the Michael J. Fox Foundation for Parkinson's Research to support Federal funding for pluripotent stem cell research, including that research covered by the NIH guidelines announced on August 23.

I do not intend to become a professional witness. I am not a politician, nor I am a doctor, nor a research scientist. You do not need me to explain embryonic stem cell research or its medical applications, so what does qualify me to be at this table?

The answer is simple. I am one of a million involuntary experts on Parkinson's disease in the United States battling its destructive nature as we wait for a cure. We need a rescue, and the country should know it.

I am also here because I am a guy with PD who happens to be on TV. Because of that, many people have felt comfortable reaching out to me. By now, many of you have heard my story, but you have not heard this story, about a 38-year-old senior editor whose PD caused her to lose her job at a publishing house, plunging her from New York's middle class into poverty. She is now forced to exist on medicare and SSDI benefits, which are nearly consumed by her monthly medication costs alone.

Nor have you heard about my new friend, a former lawyer, now living on disability, who corresponds with me regularly. Two weeks ago his friends and family watched in horror as he disappeared into stony immobility while waiting for a prescription delivery that had been delayed. This demonstrated dramatically just how tenuous normalcy is.

And you have never heard about Brenda, a 53-year-old former computer specialist. Recently her drugs failed to kick in, and she found herself frozen in the bathtub with no one to help her. She remained there for hours until enough medication had reached her brain to allow her to crawl out of the tub. By this time she was suffering a panic attack and could not speak. She could only reach her computer to contact friends for help. Her biggest regret, she says now, was that CNN was not there to provide live, up-to-the-minute coverage of her predicament.

None of these people mind that I get more attention than they do. They simply say that if I get a shot at this microphone, that I start talking, so here I am again.

For 2 years, you have had a parade of witnesses, scientists, ethicists, theologians of every school, and some celebrities, discussing every nuance of stem cell research. You have given time to all sides of the issue, including a few very vocal opponents, but the consistent and inescapable conclusion is that this research offers the potential to eliminate diseases, literally save millions of lives.

So while I applaud your fairness, I cannot help but say respectfully, enough. It is time to act on what we have learned. Sadly, we have lost 2 years' progress towards a cure. Further delay will come at a high price. That is why I am back before this committee today. Every day funding is delayed means that a person with Parkinson's is getting closer to total loss of independence, or slipping slowly toward the progressive inevitability of this disease. These delays have real human consequences that are measured in human suffering and loss of life.

The pioneers in stem cell research, Drs. Gerhardt, Thompson, and West, told this committee in December 1998 that Parkinson's would be one of the first diseases to benefit from the use of stem cells. Still researchers have testified that it will take at least 3 years from the time they received funding to the development of the first stem cell therapies for Parkinson's.

Even at the fastest possible pace under the newly released NIH guidelines, the first scientists to receive Federal funding will not begin working until late next year, which all means that we are still years away from our rescue. Please, help us to not wait any longer than we have to.

I am not here solely to represent the benefits of stem cell research for Parkinson's patients. There are many other promising applications, from heart disease, to blindness, to Alzheimer's, to burn victims, to cancer, to HIV/AIDS, to stroke, to autism, to deafness, to schizophrenia, to diabetes, to MS and ALS.

Stem cell research could also help those with spinal cord injuries. My friend Christopher Reeve sends his regrets that he could not be here today to emphasize the urgency that we both feel. His testimony has been submitted for the record, but I would like to share a few of his words with you now.

Since its inception, a fundamental principle of our Government has been to respond to the needs of people. Now, a major scientific breakthrough has given us the opportunity to uphold another principle of our Government, to do the greatest good for the greatest number of people. I am referring, of course, to the recent discovery of the miraculous discovery of stem cells.

Now, those of us who are privileged to testify before our representatives, though suffering individually from specific conditions, have the unique opportunity to speak on behalf of an entire population, both at home and in every corner of the global village, who suffer from almost every conceivable form of debilitation.

Thank you, Christopher.

The NIH is ready. Extensive and meticulous guidelines for stem cell research have been written and approved. We urge you to not let politics interfere and needlessly delay this critical research. For 2 years, I have been watching this debate. To me, this is not theoretical. There are real consequences here. As I said earlier, I do not profess to be an ethicist, but I do consider myself a good and decent

man, a loving father and husband. I would not claim any benefit that I believe was made possible by harm done to another person. That is not the reality here.

I am not a political scientist, either, but I have an immigrant's love for my country, and I am humbled to participate in this process. I see a need for our politicians to act on our behalf, and for them not to politicize a wonderful medical advance.

So that is what I ask of the people who are touched by this issue. Those afflicted and affected, every patient, as well as every mother, father, brother, sister, grandchild, uncle, aunt, teacher, coach, friend, or neighbor of a person with Parkinson's, in addition to the even wider circle of those with related illnesses and their families and loved ones, which ultimately include every person in this country, you all have a stake in the outcome, and I ask those of you who are watching today to join me in the conversation, study the record, visit the NIH web site, add your voice. These good men and women are your representatives. Ask them to tell you where they stand.

I am confident that the vast majority of you would want this research funded, and quickly. I see in these cells a chance for a medical miracle. The Government has done its work. We ask you now to release our tax dollars so the scientists can do theirs.

I thank you.

Senator SPECTER. Thank you very much, Mr. Fox, for that very compelling testimony.

Mr. FOX. That red light is very—

Senator SPECTER. The red light was on, but it has been on on other occasions for longer periods of time with people not stopping talking, and it is OK. It is a parameter and a guideline. It is not absolute.

You made a statement, Mr. Fox, saying, quote, you would not claim any benefit that did any harm to another person, and that leads me to the critical question on this issue, which will be up for a vote, and the Congress, the Senate, decides questions for public policy, and we have to make decisions weighing the arguments on one side, and weighing the arguments on the other side, and the argument on one side in opposition to Federal funding for taking stem cells from embryos is that we are dealing with a human entity, which is alive.

At the same time, it is acknowledged that the 100,000 stem cells which are now being discarded with the consent of the donors will not be used for any purpose, but will be discarded, and any semblance of life will be ended.

On the other side, those argue that with 125 million Americans being affected by the long list of diseases, thousands with Parkinson's, thousands with ALS, what would your message be to the United States Senate as to how you balance the contention of destroying an embryo, which is living but soon to be discarded, with the benefit to people who suffer from Parkinson's, as you do.

Mr. FOX. Well, I think obviously that aspect of it is part of a grave debate, which there are passionate opinions and feelings on either side, and it is a debate that in a sense does not relate specifically to this, but I will address it. As you said, those cells that are undifferentiated, pluripotent in the sense that they have not

been assigned to be things, they do not know what they want to be, they are very early in development, they are pluripotent in the sense that they can be anything, are being destroyed.

It is a separate argument, why they are being destroyed, whether they should be destroyed, and like I said, there are finer minds than mine that can debate that. The fact is, they are being destroyed, they are being wasted, and the potential to change the health of this country and this world is something that it just seems to me the loss of that in the face of this potential is great, and it is a chance to do good and to do well.

Senator SPECTER. Thank you very much, Mr. Fox.

Let me turn to you next, Ms. Estess, since you suffer from amyotrophic lateral sclerosis, and as you commented, and as is well-known, it is always fatal, a question of how long, medical research I have seen, 2 to 7 years. What would your message be to the Senators who will be saying aye or nay on the contrast between the contention of embryos being alive, but soon to be discarded, contrasted with what might be done to save your life?

Ms. ESTESS. I think that the focus is not that, it is our responsibility as Americans to protect each other, and Michael said while he was speaking with you that every single person in this room is going to be touched by one of these illnesses, and I also think that often we do not want to look at things that are destroying lives, such as ALS and Parkinson's and diabetes that Mary spoke about.

I think it is our responsibility as Americans to push this forward so we can get treatments to these people so they can be with their families and loved ones.

Senator SPECTER. Ms. Moore, same question. It is the critical issue, the choice between the embryos, where the contention is made that they are living, although there is agreement they will be discarded, contrasted with healing and saving lives.

Ms. MOORE. The embryos that are being discussed, according to science, bears as much resemblance to a human being as a goldfish, I think makes the answer clear. We are dealing with flesh and blood people now who feel pain, feel fear, feel debilitation, and our obligation is to those who are here.

Senator SPECTER. Very cogently and movingly stated.

Ms. Gershon, we will give you the last word. It is a pretty hard act to follow.

Ms. GERSHON. Well, I think Mary just said it. I mean, that is perfect. All I know is, when I look at, you know, my friend and people that I know, suffering, to have the choice to help them or not help them, there should be no question.

Senator SPECTER. Easy choice.

Ms. GERSHON. Easy choice. To me that is pro-life. Let these people live.

Senator SPECTER. The pro-life position is to let Ms. Estess live.

Ms. GERSHON. Yes.

Senator SPECTER. And others.

Senator HARKIN. And others. Thank you, Mr. Chairman. I just want to thank all of you for not only being here today, but for your continuing efforts to get the public more knowledgeable about what we are about.

I could not help, Mary, when you were talking about resembling—I did this once before. I held up a piece of paper. Can you tell me what is on that piece of paper?

Ms. MOORE. You have got to be joking. No.

Senator HARKIN. There is a little, teeny little pencil dot that I put on there that you cannot even see. That is the size of the embryos we are talking about. I think a lot of people get confused, thinking an embryo is something, almost like a fetus or something like that, fully developed fetus. We are talking about something less than the size of a pencil dot—

Ms. MOORE. Yes.

Senator HARKIN [continuing]. That contains the cells, the undifferentiated cells that Michael Fox was talking about, so somehow to equate this with a fully developed human being I think is stretching credulity quite a bit.

Anyway, I just thank you, because we need your help. I think the bill that Senator Specter has authored, I am cosponsor of, that we have the assurances of the Majority Leader that we will have a vote on it—

Senator SPECTER. That is correct, this month.

Senator HARKIN [continuing]. Before we leave here this month. I do not know the outcome of that vote. I believe we have the votes. I hope we have the votes. But your being here today and your continued efforts in the public realm to just focus attention on this, to bring it out of the shadows and put the sunshine on it, does more to help us get this through than anything else. I am consciously optimistic that we can get it passed, and I am even more than consciously optimistic that in the next few years we are going to see tremendous breakthroughs using stem cells in addressing these illnesses and diseases, so again I just thank you very much for your efforts.

Senator SPECTER. Thank you, Senator Harkin, and thank you, Ms. Gershon, Ms. Estess, Ms. Moore, and Mr. Fox.

Mr. FOX. Thank you.

CONCLUSION OF HEARING

Senator SPECTER. Thank you for being here. That concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 11:43 a.m., Thursday, September 14, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]