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STEM CELL RESEARCH, PART 2

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

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STEM CELL RESEARCH, PART 2

THURSDAY, NOVEMBER 4, 1999

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

The subcommittee met at 12:07 p.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

STATEMENT OF DR. FRANK YOUNG, FORMER COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Ladies and gentlemen, we have been awaiting the arrival of some of our witnesses. We had the swearing in of Senator Chafee, Senator Lincoln Chafee, which has delayed some. I think we will proceed with the testimony of Dr. Young and Dr. Childress at this time, and when Senator Thurmond and Congressman Dickey arrive, we will proceed to interrupt the hearing to take them as soon as they do arrive.

This is the fourth hearing which this subcommittee is holding on the stem cell issue. Last November, the issue of stem cells burst upon the scene with disclosures that research at Johns Hopkins and the University of Wisconsin demonstrated the ability to grow stem cells taken from an embryo and modify them so that they could become different body parts, promising sensational breakthroughs in medical science.

There is a prohibition against Federal funding on embryos. The Department of Health and Human Services has a legal opinion saying that there may be research on stem cells which are extracted from embryos privately funded, and the subcommittee had inserted in the markup an elimination of that prohibition.

Not unexpectedly there was very strenuous opposition in the full committee and opposition likely on the floor. How it would have turned out is problematical, but in consultation with Senator Lott, the Majority Leader, and Senator Stevens, chairman of the full committee, the subcommittee decided to delete it in the full committee report so that we could proceed and get the appropriation bill passed. There would have been perhaps a filibuster and a lengthy proceeding on the Senate floor.

As a result of deleting that provision, we have not exactly moved expeditiously to get the bill anyway, a matter of ongoing struggle.

But Senator Lott did say that once removed from the appropriations bill, the issue would come up as a freestanding bill in February. We intended to have hearings on it to give people on both sides of the issue an opportunity to express themselves.

SUMMARY STATEMENT OF DR. FRANK YOUNG

So, at this time let us proceed with two of our witnesses who are here. Dr. Frank Young, former Commissioner of the Food and Drug Administration, 5 years, 1984 to 1989; previously served as Deputy Assistant Secretary for Health in the Bush administration, and as Director of HHS, Office of Emergency Preparedness. He was Dean of the University of Rochester Medical School, a microbiologist by training with an M.D. from NYU and Ph.D. from Case Western. He now serves as pastor of the Adult Ministries at the Fourth Presbyterian Church in Bethesda. Thank you for joining us, Dr. Young, and we look forward to your testimony.

In accordance with our practice, we have a 5-minute rule to allow maximum time for questions and answers. The floor is yours, Doctor.

Dr. YOUNG. Thank you, Mr. Chairman. It is a pleasure to see you again and to testify before you. I want to thank you for your steadfast work also in the field of weapons of mass destruction, which is the opportunity that I had to be with you at the last time as we were planning the medical response.

I also want to thank you for the work that you have done over the years in your support and this committee's support in the Department of Health and Human Services.

I find myself in a very different position today, having been an individual who was present at the Asilomar meeting. Then on every one of the bioethics panels, with the exception of up until the very last one, I have had a chance from the recombinant DNA advisory committee forward to look at this work, and as the Commissioner of the U.S. Food and Drug Administration, had the privilege of bringing on line the biotechnology industry that we have today. I am an advocate of and a devotee of molecular genetics.

So, therefore, at this present time I find myself in a rather unusual position because instead of being a complete advocate of pushing forward with stem cell research at this time, I raise a large caution. The very greatest concern that I had as Commissioner was to be sure that the public was fully supportive of the procedures, the processes, and the policies that we were bringing forward. Otherwise, the fruits of biotechnology were liable to rot on the laboratory bench.

In this particular case, though I compliment your hearing process and the many hearings that you have had, I believe that there are some serious concerns with the way the issue has been addressed before the public. It is imperative that any commission or group that we have is not only broadly representative, but strives for a consensus. As you said, sir, in your opening remarks, this is a controversial issue.

So, I bring forward to you today, if I may have my entire statement introduced for the record——

Senator SPECTER. It will be in the record, without objection.

Dr. YOUNG [continuing]. Some recommendations and a way, I think, out of this dilemma.

The first thing that I would say is that there is a need to develop an ethical framework.

Second, a need to gather the full and carefully analyzed results of the research, both on adult and embryonic stem cells. I have not had the privilege of seeing the final report of the committee, but I do know that the executive summary had raised some important issues. But I did not see a summary there of the research and the pros and cons. While it side-stepped the ethical issues, the compelling scientific reasons for choosing one versus the other was not apparent to me in the executive summary.

Therefore, I believe that this committee should support a very substantial focus on the alternatives, as well as the other recommendations.

One quote that I would like to give you at this time for perspective came from Professor Leff, a lawyer at Duke, in the Duke Journal, and he said something that I think you almost said in your opening remark. He said:

> I want to believe, and so do you, in a complete transcendent and imminent set of propositions set of propositions about right and wrong, findable rules that authoritatively and unambiguously direct us how to live righteously. I also want to believe, and so do you, in no such thing, but rather that we are wholly free, not only to choose for ourselves what we ought to do, but to decide for ourselves, individually and as a species, what we ought to be. What we want, heaven help us, is simultaneously to be perfectly ruled and perfectly free, that is, at the same time to discover the right and good and to create it.

I have listed some recommendations, which is for the establishment of a commission. I have given you some membership that I would propose for this, a commission built by both Congress, the House, Senate, and administration, that it have representatives from the public sector, people from science, theology, medicine, and law.

That in this time, we would have a moratorium for 3 years for this commission to work.

That it be funded in the way that would be appropriate for it to get its job done.

That the Food and Drug Administration be charged to examine whether or not the regulations and the resources are adequate because the commission aptly pointed out some regulatory conundrums, and I believe that the Congress has the responsibility to meet that.

PREPARED STATEMENT

Finally, I would hope there would be a way to communicate with the public to try to bring together the various diverse views. I have lived both as a scientist, a physician, and now as pastor, and just this morning I met with a woman who is having surgery at 6:45 in the morning. Her question was the meaning of life and how she would survive. Therefore, science speaks in one category, religion and theology in another. We need to bring both of these together to talk, to work, and to get a consensus.

Mr. Chairman, again I congratulate you for having this hearing, and I thank you for the privilege of appearing before you again.

Senator SPECTER. Well, thank you very much, Dr. Young.
[The statement follows:]

PREPARED STATEMENT OF DR. FRANK YOUNG

Mr. Chairman and Members of the Appropriations Subcommittee: Thank you for the opportunity of participating in this hearing concerning the controversial ethical issue of research on human embryos to optimize the procedures for harvesting embryonic stem cells and the federal funding of research on stem cells derived from human embryos. Allow me to state the question clearly: should we destroy living human embryos in order to experiment with their cells for the potential benefit of the living? The Executive Summary of the Report of the National Bioethics Advisory Committee (September 1999) aptly summarized the Congressional intent. "The current ban on embryo research is in the form of a rider to the appropriations bill for the Department of Health and Human Services (DHHS), of which the National Institutes of Health (NIH) is a part. The rider prohibits use of the appropriated funds to support any research 'in which the embryo [is] destroyed, discarded, or knowingly subjected to risk of injury greater than that allowed for research on fetuses in utero'". This is not an unexpected controversy. As early as 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report entitled "Splicing Life: A Report on the Social and Ethical Issues of Genetic Engineering with Human Beings.[1] Yet there has been little sustained development of consensus policies regarding the ethics of the new genetics and cell biology on the National level with the notable exception of recombinant DNA (rDNA) technology.

In 1999, the level of the intellectual and societal playing fields were changed by recent advances in the cloning of animals and manipulation of embryonic cells and by a decision of DHHS. On January 26, 1999, Dr. Varmis, in testimony before the Appropriations Subcommittee stated that the General Counsel of DHHS concluded that DHHS funds can be used to support research using human pluripotent cell derived from human embryos because the statutory ban does not apply. It was posited that "the statutory prohibition does not apply to research utilizing human pluripotent stem cells because pluripotent stem cells are not embryos." In response to this decision, early in 1999, 70 members of the Congress signed a letter that called upon DHHS to reverse the NIH Director's decision to allow funding for research on pluripotent stem cells. In a letter in Science, a group of 73 scientists offered support for the Director Varmus' decision to fund this research (Science 283:1849–1850, 1999) It is important to emphasize that this research on embryos one of the most controversial societal concerns today. It will be a proxy for our view of the essence of the meaning of life in the 21st century.

To understand the issues fully, we must clearly realize that while science measures and explores the known world, religion embodies a devotion to God and the meaning of life. Thus, there will be different worldviews within our society, and each one must be heard respectfully and considered carefully. As noted by Professor Gould, science and religion are two "Non-Overlapping Magisteria."[2] Both make major contributions to society. But these contributions are different.

In this testimony, I shall present an analysis of this dilemma and offer a recommendation to resolve it.

Throughout my scientific career as a molecular geneticist, I have been involved in the ethical issues confronting biotechnology and cellular biology as well as medical advances. I was present at the Asilomar Conference where 150 scientists from 18 nations first met to debate the safety of rDNA technology and also consider the ethics of the research. Careful attention to both safety and scientific inquiry was incorporated into the NIH Guidelines that resulted from the Asilomar meeting. A deliberately careful approach was taken to this research and the guidelines were relaxed as scientific and social concerns permitted. As a member of the first Recombinant DNA Advisory Committee, I participated in deliberation on the development of this technology and was keenly aware that public confidence in this new field of biotechnology was imperative. This rDNA research using microbes and animal cells to produce medicines led to the establishment of the biotechnology industry as we know it today. For many years, I participated in recombinant DNA research and in policy deliberations on implementation of guidelines for conducting rDNA research. As the Commissioner of the Food and Drug Administration, I led in the development

[1] Splicing Life: The Social and Ethical Issues of Genetic Engineering of Human Beings. November 1982, Library of Congress card number 83–600500.

[2] Stephen J. Gould, Rocks of Ages: Science and Religion in the Fullness of Life, Ballintine Publishing Group 1999.

of regulations nationally and internationally that ushered in the current era of biotechnology. However, I must emphasize that this research and industrial development did not involve the disintegration of human embryos. Instead it used or "enslaved" bacterial yeast and animal cells to produce large amounts of desired products. As Commissioner, I was conscious that the ethical considerations as well as safety and effectiveness must be considered carefully in order to ensure public support.

Today, we are considering embarking on an equally significant revolution in cellular biology. The use of stem cells to produce tissues such as blood vessels, brain cells and heart cells could result in the partial regeneration of organs. Unlike the development of biotechnology, which uses bacteria, yeast and adult tissue culture cells to produce products, the research on embryonic stem cells is dependent on disintegration of human embryos. Ethical problems abound. I contend that killing embryos by disintegration to harvest stem cells is illegal, immoral, and unnecessary.

ANALYSIS OF POSTULATED BENEFITS AND INHERENT LIABILITIES OF RESEARCH ON EMBRYONIC PLURIPOTENT STEM CELLS

(1) The potential benefits are clearly enunciated in the March 19, 1999 letter in *Science.* These hypothetical benefits range from research to clinical medicine. It must be emphasized that these abundant research promises have yet to be realized even in experimental animals on a broad scale. Furthermore, history is replete with over promises as evidenced by the "War on Cancer" and the rapid development of a vaccine for AIDS. The risks, however, are real. An embryo, which could have a chance to live, is destroyed.

(2) The Executive Summary of the Report of the National Bioethics Advisory Committee (September 1999), recommends that Embryonic Stem (ES) Cells be harvested from "excess or spare" embryos remaining after infertility treatments. Recommendation 2 states, "research involving the derivation and use of human ES cells from embryos remaining after infertility treatments should be eligible for federal funding. An exception should be made to the present statutory ban on federal funding of embryo research to permit federal agencies to fund research involving the derivation of human ES cells from this source under appropriate regulations that include public oversight and review." At first glance this looks to be an attractive option. Why not use an unwanted embryo to benefit the living? However, there are a number of objections. First, there are no existing regulations on In Vitro Fertilization procedures. Congress might wish to promulgate a law to regulate this industry including production of spare embryos, standards for preservation, record keeping and options for adoption. Second, serious consideration should be given to developing procedures for adoption of embryos. Third, there is enormous peer pressure in science to "support the current ethos or risk loss of funding or intellectual denigration." Therefore, objectors could be cautious in expressing contrary opinions.

(3) The NBAC proposed voluntary guidelines and possible regulations to cover this research. However, the safeguards recommenced by the NBAC are neither sufficient nor enforceable. The problem is clearly seen in a report in *The Washington Post* on November 3, 1999. In an article entitled "Gene Research Moves Toward Secrecy," Deborah Nelson and Rick Weiss reported that there were 8 deaths in gene therapy that were neither reported to patients nor properly communicated to the regulatory and scientific community. A loss of public confidence could drastically curtail research and development. In the early days of the recombinant research, there were reports of individuals leaving the country to find a location where research not approved in the United States could be conducted. Steps were rapidly taken to prevent these ethical infractions.

(4) The DHHS proposal and the NBAC recommendations enable the research to go forward expeditiously. However, there is an inherent conflict of interest when academicians comprise the vast majority of the membership. A special interest group that stands to "profit" through grants, industrial contracts, or research on the ethical concerns, thereby engendering notoriety, should not propose the recommendations. Any Commission that represents public interest should have broad participation including people with opposing views. Did the scientists learn from the rDNA regulations that public participation is cumbersome and should be avoided? Finally, once the research is initiated there is no turning back. An ethical position should be established first. While not challenging the credentials of any committee member, I contend that the NBAC was not sufficiently independent and sufficiently broad to fulfill this mandate.

(5) Recommendation 2 in the NBAC report implies that the extra embryos described have no legal status nor affords them any. This legal issue raises many questions that demand further analysis. For example, can the donors of the sperm

and egg that were used to produce an embryo legally give it away? Our Declaration of Independence states that "we hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness." I contend that the embryo should receive such protection no matter how it is conceived. It is important to note that the embryo is accorded legal protection in many states. Finally, the harvesting of an embryo and the subsequent use of its cells for research might violate the 14th Amendment. Throughout American history, our Nation has striven to protect the vulnerable. The Americans with Disabilities Act, our efforts in Kosovo, and the recent Clinton Administration's Conference on Mental Health are contemporary examples of our National commitment in this regard.

(6) The NBAC report focuses primarily on ES and Embryonic Germ (EG) cells. In science there is an ethos of the imperative, "if it can be done, try to do it," or, stated differently, "research is a 1st Amendment right." However, we live in a society where the cardinal principle is do no harm, whether in medicine or to the environment. Therefore, the use of adult stem cells should be fully explored and investigated prior to reversing the moratorium on human embryo research. Recent studies have demonstrated that these cells might be a suitable substitute for ES and EG cells.

We are at a critical junction in society and faced with a serious dilemma. The problem of conflicting human desires was stated clearly by Arthur A. Leff in the *Duke Law Journal* December 1979, pg. 1229. "I want to believe, and so do you, in a complete transcendent and immanent set of propositions about right and wrong, findable rules that authoritatively and unambiguously direct us how to live righteously. I also want to believe, and so do you, in no such thing, but rather that we are wholly free, not only to choose for ourselves what we ought to do, but to decide for ourselves, individually and as a species, what we ought to be. What we want, heaven help us, is simultaneously to be perfectly ruled and perfectly free, that is, at the same time to discover the right and good and to create it."

CONCLUSIONS AND RECOMMENDATIONS

The issues are contentious and difficult. Our population is divided on the ethical appropriateness of the use of ES cells. The scientific imperative impels us ever forward. But there are major costs. These are the same considerations that we had at FDA as we embarked on the approval of biotechnology products and developed regulatory policies. We need to have the confidence of the people and to be concerned for the social, religious, medical, environmental and scientific interests of our citizens. Once we lose credibility, all chance for acceptance of the adequacy of the public health system is eroded. Under such conditions, the fruits of biotechnology would have rotted in the laboratory. However, we succeeded admirably! Following the pattern of the successful development of the biotechnology industry, I contend that the rush to engage in embryonic pluripotent stem cell research is foolhardy. We need to settle the ethical concerns first.

Since I have moved from medicine into pastoral ministry, I have become more aware than ever of the need to ensure the dignity of each person. As a scientist, I am fascinated with the complexity of life and the capacity to develop medicines that can alleviate the suffering of mankind. As a physician, I an committed to promoting health and providing care to the living. Now as a pastor, I know that we are made in the image of God (Genesis 1: 26–27) and as image bearers we must respect the sanctity of life. Because each of us will die, it is imperative that we must know the meaning of life and live accordingly. Maintaining the endowment by the Creator "with certain unalienable rights, that among these are life, liberty and the pursuit of happiness" is as important for the embryo as for the adult. The utilitarian ethical stance of promoting the greatest good could lead to a new eugenics and the sacrifice of the vulnerable to relieve the pain and suffering and extend the life of the living.

Recommendations

(1) To ensure a broad representation of the citizens of the country, I recommend that Congress and the Administration appoint a Commission to review the current progress in ES, EG and Adult Stem cells. This Commission should be charged to hold public meetings and to report annually to Congress and the President. Additionally the Commission should develop an ethical framework for research with stem cells and propose a well-designed way to communicate with the public. The Commission should also recommend policy questions for analysis by the Administration and Congress. To ensure representation of all points of view, five members should be appointed by the President, five by the Senate and five by the House of Representatives. The membership should consist of at least two of each of the fol-

lowing: public representatives, scientists, physicians, ethicists and theologians. The term of service should be limited to three years.

(2) A moratorium for three years to enable the Commission to report to the Administration and Congress.

(3) The Commission should be adequately funded through an independent budget to accomplish its tasks.

(4) In the interim, as an added layer of safety, the FDA should examine whether additional guidelines and regulations are required for in vitro fertilization. FDA should report to Congress on the adequacy of regulations to meet the new responsibilities and the adequacy of the staff resources to accomplish the expectations of the public.

(5) In the meantime, there should be sufficient funding for research on human adult stem cells and animal embryonic and germinal stem cells to enable this technology to continue to be developed during the moratorium on human pluripotent stem cells.

I will be pleased to answer any questions you have regarding my testimony. If you wish, I shall provide more in depth recommendations about the proposed Commission and additional insights into the commercialization of biotechnology that occurred on my watch as Commissioner of FDA. Thank you for your attention and concern.

STATEMENT OF HON. JAY DICKEY, U.S. REPRESENTATIVE FROM ARKANSAS

Senator SPECTER. If Congressman Dickey would come forward. We have started the hearing in the absence of—you had to go to vote, as we understand, and Senator Thurmond I believe has been detained with the swearing in of our new colleague. In order to economize your time, Congressman Dickey, we will take you right now.

Mr. DICKEY. Oh, great, thank you.

Senator SPECTER. We do know that there are a few items on your agenda. You have to finish up the appropriations bills. Thank you for joining us, Congressman Dickey.

Jay Dickey represents the Fourth Congressional District in Arkansas, previously a practicing lawyer in Pine Bluff and served as City's Attorney, former State Chairman of the Christian Legal Society, currently in his fourth term, serves on the Appropriations Subcommittee of Labor, Health and Human Services, and Education where we have had a great many contacts, always cordial, not always in agreement, but always cordial. He had expressed opposition to removal of the restrictions in a discussion we had informally some time ago. So, we thought we would invite him to present his views here today. Welcome and the floor is yours.

Mr. DICKEY. Thank you, Mr. Specter, and thank you for having me here and for always listening to my views in particular, and I notice that other people who differ with you you will listen to them. I want to say this for the record that each time we have had a confrontation, if we want to call it friendly or otherwise, I always lose.

But maybe I will just keep trying and somehow my ideas will prevail.

I think we have got a serious——

Senator SPECTER. That drew a chuckle, as expected, Congressman Dickey, even though it is not exactly correct. The record will be burdened with a very long list of your victories when this hearing is over.

Mr. DICKEY. Thank you, sir. But I do appreciate your willingness to listen and consider all aspects of issues.

This particular one I think is unusual in that it has a broad umbrella of concern across the Nation, and the question comes down does science serve human beings or do human beings serve science. A little bit of look into history shows us that when governments or civilizations or whatever you might want to call it get this in reverse where human beings serve science, we have problems. Nazi Germany comes to mind where they considered those that were infirm in whatever way, youth, elderly, race, they were dispensable and science was put at center stage and human beings were, in fact, treated indifferently when compared to science.

In our own country, we had the experiment at Tuskegee. I think officially it is called the Tuskegee Study of Untreated Syphilis in the Negro Male where we did virtually the same thing, where we considered certain people proper subjects for scientific experiments without their knowing that they were being used as such. I think the outrage is sort of the basis for our opinion here, the outrage that came from that.

I am concerned personally that we are making a business out of terminating life in this particular case, that we are not treating life with the proper dignity. We are going to eventually get to where we are going to have a storehouse with prices on body parts. Science may be able to justify it. They may say, well, we will be able to save a life here, but in the process we are terminating lives.

But the big thing that we are going to have happen to us is that our conscience is going to be numbed. We are not going to understand the basis that our country was founded upon, and that is the consideration of life and the human dignity that it deserves.

Some people are drawn in the decision to support science from the standpoint that how can we go wrong if we are trying to improve our conditions. Everybody wants to be a part of that, particularly a legislator and particularly someone on the Appropriations Committee. I am the same way. I am no different than anybody else. If we get a breakthrough and I happen to be a part of voting for that, that is something that goes years and years and years down the road. It is certainly something that I would like to do, and I look closely in this committee work to doing that.

But I feel for myself I am stopped cold, just dead cold, when I find out that reaching for science has blinded me to the fact that we are trashing human life, that we are throwing human life aside and saying it does not matter. I think that is what has concerned me here.

We have Federal funds that we have prevented from being used in several different areas because our Nation just says it is all right if you want to do it privately. We may disagree, but we do not want to take tax receipts from people and then use them against their consciences. We have done that in the form of no Federal funds are used to destroy human embryos. That law was enacted in 1996. No Federal funds for abortions or even in some instances to subsidize programs that provide abortions, prohibiting the NIH for harmful research on human babies in the womb, even if the mother is going to get an abortion. That has sort of been our standard, our standard of conscience in our country.

Here we come with the stem cell research and all of this scientific language that sounds good, saying yes, this is different than

destroying a human embryo, when in fact the human embryo is a source of stem cells. There is no question we are sort of in the same argument that we had back in 1995, when we first started in this.

I want to say this. I want to point to a Terrence poll where 75 percent of those people polled opposed use of Federal funds for human embryo experimentation, or termination, as I like to say it.

I just think we have got to bring ourselves up and say, just what are we doing?

Are we stopping science? No. Adult stem cells can, in fact, be used. That is one source. We can take the stem cells from the person that is affected and we can bring that into some kind of useful scientific application.

We can also use fetal tissue. The law is already there. Fetal tissue is another way we can do it.

PREPARED STATEMENT

We could also let, as we have in the past, private industry do this, even though we would object to it. There is no question that I would be objecting to that, but that is their business and that is private funds. Here we are dealing with a trust of Federal funds, money that has been worked for and paid into the Government, and somehow we are saying, look, we know better than you do. The mind is going to overcome the heart in all instances, and we are going to replace your conclusions with ours and we are going to use your money to fund it.

[The statement follows:]

PREPARED STATEMENT OF HON. JAY DICKEY

Thank you, Mr. Chairman, and Members of the Subcommittee, for having me here today to testify regarding my moral and ethical concerns with embryonic stem cell research. I feel very strongly about this issue. Recently, there has been much discussion concerning federal funding of research in which human embryos are destroyed. In 1995, and every year since, Congress has passed an amendment to prohibit funding of "research in which" human embryos are destroyed or discarded.

However, in January of this year, the General Counsel at the Department of Health and Human Services (HHS) issued a memorandum to the director of the National Institutes of Health (NIH), Harold Varmus, claiming that taxpayer funds may be used for research on stem cells taken from living human embryos. (Stem cells are unspecialized cells with the capacity to develop into various body parts such as bone, skin, nerves, organs, and they exist in all human beings, whether embryos or adults.)

Shortly after this HHS determination, the NIH director Varmus announced that he would reverse current federal policy and begin funding research which relies on the mutilation and destruction of human embryos.

As the author of the law restricting taxpayer funding of experiments which harm living human embryos, I believe this decision is wrong and undermines the spirit and letter of the law. The General Counsel unilaterally narrowed the meaning of "research in which a human embryo or embryos are destroyed" and stated that it prohibits only direct federal funding of the specific act of destroying the embryo. While the act of destroying or injuring a human embryo would certainly be ineligible for Federal funding, the law has much broader application. It also bans the use of tax dollars to fund research which follows or depends upon the destruction of or injury to a human embryo. In the embryonic stem cell experiments which NIH proposes to fund, the timing, method and procedures for destroying the embryonic child would be determined solely by the federally funded researchers need for usable stem cells.

The HHS General Counsel also presumes to redefine what we mean by "human embryo," calling an entity an "embryo" only if one can show that it is capable, if implanted in the womb, of becoming a born "human being." This narrow definition has no support whatsoever in federal law, and it very clearly violates the foundation

on which the present law is based—respect for the lives of human beings from the very beginning. This new definition of human embryo, fabricated by HHS, would weaken even that part of the law supported by President Clinton which bars the use of federal funds to create human embryos for research purposes. Federally funded researchers might simply begin creating embryos with lethal defects.

Science can sometimes be used to hide other agendas and must have limits. So far, there is not any clear evidence that human embryo research is the best route to relieve human suffering. The private embryonic stem cell research which is presently being practiced and which is not prohibited by this law has yet to provide any definitive results that could justify using federal funds to accelerate such activities. Moreover, numerous reports over just the last few months have shown remarkable discoveries about the versatility and possible uses of stem cells found in adults.

For more than 20 years, Federal laws and regulations have protected the human embryo and fetus from harmful experimentation at the hands of the Federal government—regardless of whether the embryo is "perfect" or damaged, wanted or unwanted, intended for abortion or intended for live birth. This area of law has provided a barrier against government's misuse or exploitation of human beings in the name of medical progress. It would be a travesty for this Administration to attempt to unravel this accepted ethical standard.

FETAL TISSUE

Senator SPECTER. Congressman Dickey, when you raised the issue of fetal tissue, that was very contentious a few years back with some saying that the use of fetal tissue would promote abortions, others saying that fetal tissue would only be used where abortions were conducted otherwise. It was very contentious in the Senate until Senator Thurmond took a position in favor of use of fetal tissue, and he did so because his daughter suffered from diabetes. Senator Thurmond is going to be a witness here today. The votes were changed in the Senate from about 40 to about twice that number, 80, when Senator Thurmond testified in that way.

So, I am interested in your articulating fetal tissue as an alternative, and I would like to have you amplify, if you would, your feeling. I think you said you were still opposed to it, but how do you make a judgment as to the use of fetal tissue considering your sense of opposition?

Mr. DICKEY. I think that is a point well taken. Again, I am going to be countering your thoughts on this.

I want to say this. I voted against the fetal tissue. I thought it was going to encourage abortions, it would give an economic reason for abortions, for pregnancies to even occur, and then for abortions to take place. I am not aware of whether that has increased abortions or not, but I do not think it has. At least the increase has not been an issue that has been brought to my attention. It is the law. It is there and this source can be used even though I do not agree.

What happens with me, Senator Specter, is if I have to err, I am going to err on the side of life. I may err a lot because I do not know science or I am not up on it as much as I should. But that is what happened on the fetal tissue issue and that is what is happening here. I feel stronger about the stem cell because we have got the human embryo law in place and it has been there since 1996. We are now trying to marginalize the provisions of that law that were fought for both in the committee level of the House and the committee level in the Senate and the Senate.

Senator SPECTER. You do, though, as you have just testified, leave latitude for private research.

Mr. DICKEY. That is correct, even though I disagree with that. We need to start doing that. What I see is that private investment is a laboratory for us on this issue. If we are getting into this dangerous area where we are going to traumatize our Nation's conscience, we ought make sure, for certain, that scientifically it can happen, that it can bring some kind of benefit.

Senator SPECTER. Well, the General Counsel for the Department of Health and Human Services, as you know, has come down with an opinion that as long as the private funds are used to extract stem cells from the embryos, then public funds may be used for the research on the stem cells since it is not research on the embryos. What is your thinking on that interpretation?

Mr. DICKEY. It still terminates the human embryo.

Senator SPECTER. Well, I think the embryo has been terminated by the private research which extracts the stem cells. So, when it comes into the public expenditure, you have the stem cells without the embryo.

Mr. DICKEY. I understand. It is one of those this equals this equals this, but we are still terminating the embryo and we are being a part of it. It is like being an accomplice to a crime. You cannot just sit there and watch something happen and then encourage it by receiving the goods from it and then say I am innocent. I do not think we are innocent. I know I cannot do that in my own conscience and my own commitment to what I think is right and wrong.

But you have got an argument. Let me say this in all due respect. That is an argument of the mind. What I am talking about is a response from the heart, and I am just concerned about what we are going to do on the sidelines while we watch these things happen.

Senator, in graphic terms, I just do not want us to create a situation where we have a storeroom full of body parts that have price tags on them. That is an awfully tough thing for me to say because you are a gentleman. This is a discussion among friends, but I am just saying to you that that is what I am concerned about.

On the other side, I want to encourage people to fight for life, for the dignity of life, and I want to show them that the Federal Government is not going to use their funds to do that.

I am not trying to convince anybody to believe like I am believing. I am not trying to say that I want my will or my conclusions to be yours. All I am saying to you is that I believe the beginning of life is at conception. Our Nation is a godly Nation, and we are not going to win by forcing people to pay their money into the Federal Government and then disregard that conclusion that a great number of people in this country have, that life begins at conception.

Senator SPECTER. Well, Congressman Dickey, I very much appreciate your coming today and your views. I know that they are very sincerely held. When you make the distinction, speaking from the mind as opposed to the heart, I respect that. You and I have had quite a number of discussions formally on the record and we have had conferences between the House and the Senate on our subcommittee and informally as we have met and talked on many oc-

casions. This is an important subject to be discussed and to be advanced. We very much appreciate your coming over.

Mr. DICKEY. Thank you for having me.

Senator SPECTER. May the record show that you had paused, that I did interrupt you on your last statement. I want to be clear that you can have as much time as you like to say anything further.

Mr. DICKEY. No, I have concluded. Probably talked too long as it is.

Senator SPECTER. I think you have been very succinct and very direct and very illuminating.

Mr. DICKEY. Thank you, Senator.

Senator SPECTER. Thank you very much, Congressman.

Mr. DICKEY. Good to see you.

STATEMENT OF DR. JAMES CHILDRESS, COMMISSIONER, NATIONAL BIOETHICS ADVISORY COMMISSION; KYLE PROFESSOR OF RELIGIOUS STUDIES AND PROFESSOR OF MEDICAL EDUCATION, UNIVERSITY OF VIRGINIA

Senator SPECTER. Let us proceed now with the testimony of Dr. James Childress. Dr. Childress is Commissioner at the National Bioethics Advisory Commission, who directly participated in the commission's stem cell report. He is also the Kyle Professor of Religious Studies and Professor of Medical Education at the University of Virginia and the Co-director of the Virginia Health Policy Center. He earned his Ph.D. from Yale University.

Thank you for joining us, Dr. Childress, and the floor is yours. We are going to go back to our 5-minute rule.

Dr. CHILDRESS. Thank you very much, Mr. Chairman. My name is James Childress and I am a member, as you mentioned, of the National Bioethics Advisory Commission, NBAC, and I teach at the University of Virginia in religious ethics and biomedical ethics.

I am pleased to testify before you this morning on behalf of NBAC on the subject of its recent report, Ethical Issues in Human Stem Cell Research. Your subcommittee has previously received testimony that updated the status of this report. Today I will briefly describe the process we used to arrive at our 13 recommendations and summarize a few main points.

I would respectfully ask that the full text of my statement be included in the record.

Senator SPECTER. Without objection, it will be made a part of the record.

Dr. CHILDRESS. Copies of the executive summary of the report have been distributed to the committee and are also on NBAC's web site.

On November the 14, 1998, President Clinton asked NBAC to undertake a thorough review of the issues associated with human stem cell research balancing all ethical and medical considerations. From that point until we submitted the report in September of this year, we examined the full range of issues associated with this research in order to reach the best judgment we could about the appropriate balance of ethical and medical considerations and about the appropriate ethical and policy guidelines for such research in light of this great medical promise, but also in light of its morally controversial derivation and use of stem cells from fetal tissue fol-

lowing deliberate abortions or embryos remaining after in vitro fertilization.

In exploring these issues, we benefitted from broad and diverse testimony by experts and the public. All of NBAC's meetings are held in public and provide ample opportunity for public input. Our deliberations were informed throughout by perspectives provided by members of the public, as well as by interpreters of major religious traditions, philosophers, bioethicists, lawyers, scientists, physicians, and others.

For example, on May 7 of this year, NBAC convened a meeting at Georgetown University to hear presentations on religious perspectives relating to this research. Altogether 11 scholars in Roman Catholic, Jewish, Eastern Orthodox, Islamic, and Protestant traditions presented formal testimony that day, and two others made statements in the public comment period. The diversity of views, both across these traditions and within them, demonstrated that there are different perspectives from longstanding religious traditions, as well as other moral and ethical traditions, about the ethical acceptability of research on cadaveric fetal tissue and on the human embryo.

Over time we found widespread agreement that human embryos deserve respect as a form of human life, but we also found disagreements regarding both what form such respect should take and what level of protection is required at different stages of embryonic development. At the very least, this respect means that these sources should not be used unless they are necessary for important research, that alternative sources should be simultaneously pursued, and that cadaveric fetal tissue and embryos remaining after in vitro fertilization should not be bought or sold.

We concluded that it would be appropriate for the Federal Government to provide funds for the derivation and use of stem cells from cadaveric fetal tissue and from embryos remaining after infertility treatments if certain guidelines and safeguards are in place and if there is an appropriate and open system of national oversight and review.

First, we recommend that research involving the derivation and use of stem cells from cadaveric fetal tissue continue to be eligible for Federal funding and that the relevant statutes and regulations be amended to make clear that the ethical safeguards currently in place for fetal tissue transplantation also apply to this new research.

Second, we proposed that research involving the derivation and use of embryonic stem cells from embryos remaining after infertility treatments be eligible for Federal funding. Thus, we recommend on ethical grounds a limited exception to the current statutory ban on Federal funding of embryo research in part because, based on expert testimony, we came to the conclusion that it is a mistake to suppose that derivation and use can be neatly separated without damaging the development of scientific knowledge. For example, the methods for deriving stem cells may affect the properties of those cells.

We also recommended ethical guidelines to try to separate the decision to dispose of embryos from the decision to donate embryos for research.

We considered two other possible sources of stem cells. Again after balancing the ethical and medical considerations, we recommended against the deliberate creation of embryos for research at this time whether by IVF or by somatic cell nuclear transfer cloning.

PREPARED STATEMENT

We trust that this report will further stimulate and contribute to our society's important ongoing debate about the profound ethical issues regarding this potentially beneficial research.

Thank you, Mr. Chairman. I will gladly try to answer any questions that you or other members of the subcommittee may have.

Senator SPECTER. Well, thank you very much, Dr. Childress.

[The statement follows:]

PREPARED STATEMENT OF DR. JAMES CHILDRESS

Good morning, Mr. Chairman and members of the subcommittee. I am James Childress, a member of the National Bioethics Advisory Commission (NBAC) and the Kyle Professor of Religious Studies at the University of Virginia. I am pleased to testify before you this morning on behalf of NBAC on the subject of its recent report, Ethical Issues in Human Stem Cell Research. I know you are aware that on two previous occasions NBAC has testified before your subcommittee, providing updates on the status of this report. Today I will briefly describe the background and process we used to arrive at our recommendations, and summarize some of our major recommendations. Copies of the Executive Summary of the report have been distributed to the Committee and are also available on NBAC's website, at www.bioethics.gov.

BACKGROUND AND PROCESS

On November 14, 1998, President Clinton wrote to NBAC, requesting that we "undertake a thorough review of the issues associated with . . . human stem cell research, balancing all ethical and medical considerations." From then, until September 1999, when the commission submitted its report, we spent most of our time examining the full range of issues associated with human stem cell research in order to reach the best judgment we could about the appropriate balance of "ethical and medical considerations" and about the appropriate ethical and policy guidelines for such research.

We believed that it was necessary to get as clear a picture as possible about the science involved and about the possible medical benefits of research on human stem cells, in light of the reports about a year ago that researchers had isolated and cultured human embryonic stem cells (or ES cells) and embryonic germ cells (or EG cells). Our initial meetings included testimony from Dr. Harold Varmus, Dr. John Gearhart of Johns Hopkins University, Dr. Jamie Thomson of the University of Wisconsin, and others. It became clear to us that the published reports of isolating ES and EG cells generated considerable scientific and clinical interest because of the prospect that human stem cells could be used to produce more specialized cells or tissue to treat injuries or diseases such as Alzheimer's disease, Parkinson's disease, and heart disease. The research also could further the development of life-saving drugs and other therapies and increase our understanding of the earliest stages of human development.

While creating great excitement, particularly because of its medical promise, this research also raised serious ethical concerns, mainly because the major current sources of stem cells are cadaveric fetal tissue obtained from elective abortions, and embryonic tissue derived from embryos remaining after in vitro fertilization (IVF).

In exploring the scientific, medical, and ethical issues, NBAC benefited from broad and diverse testimony, in both oral and written form, by experts and the public. All of NBAC's meetings are held in public and provide ample opportunity for public input. Indeed, NBAC's deliberations about how to balance ethical and medical issues were informed throughout by perspectives provided by members of the public, as well as by interpreters of major religious traditions, philosophers, bioethicists, lawyers, scientists, physicians, and others. Of the many experts who provided valuable testimony to the Commission, one group offered particularly helpful perspectives. On May 7, 1999 NBAC convened a meeting at Georgetown University to hear

presentations on religious perspectives relating to human stem cell research. Altogether eleven scholars in Roman Catholic, Jewish, Eastern Orthodox, Islamic and Protestant traditions presented formal testimony that day, and two others made statements in the public comment period. The diversity of views, both across these traditions and within them, suggested to us that there are different perspectives, from longstanding religious traditions, about the ethical acceptability of research on cadaveric fetal tissue and on the human embryo.

With specific attention to the ethical issues, NBAC found widespread agreement that "human embryos deserve respect as a form of human life" (p. 90) but, at the same time, disagreements "regarding both what form such respect should take and what level of protection is required at different stages of embryonic development." At the very least this "respect" means that these sources should not be used unless they are necessary for research, that cadaveric fetal tissue and embryos remaining following IVF should not be bought or sold, and that alternative sources should simultaneously be explored. In addition, NBAC sought to show respect for the range of serious ethical concerns represented in various positions on stem cell research in our society.

NBAC's deliberations reflected the "tension" that many experience between the ethically grounded desire to realize the promise of therapeutic benefits of this research and the ethically grounded desire to treat the different sources of stem cells with appropriate respect. Because of these important ethical concerns, NBAC "wrestled" with the strong arguments presented for and against the derivation and use of stem cells from different sources in its efforts to formulate an acceptable public policy regarding federal funding of and guidelines for such research.

NBAC'S RECOMMENDATIONS

Our report made 13 recommendations in several areas.

We concluded that it would be appropriate for the federal government to provide funds for the derivation and use of EG and ES cells from cadaveric fetal tissue and from embryos remaining after infertility treatments. Building on current policies and practices relating to fetal tissue transplantation, NBAC recommends that research involving the derivation and use of human EG cells from cadaveric fetal tissue, following deliberate abortions, "should continue to be eligible for federal funding," and that the "relevant statutes and regulations should be amended to make clear that the ethical safeguards that exist for fetal tissue transplantation also apply to the derivation and use of human EG cells for research purposes" (Recommendation #1). These "ethical safeguards" were erected to prevent the use of fetal tissue in transplantation research from encouraging abortions. For example, they separate the consent process for abortion from the consent process for the donation of fetal tissue for research and prohibit the donor of fetal tissue from designating the recipient of the transplant. These guidelines appear to be sufficient in human fetal tissue transplantation research and should be extended to stem cell research as well.

A second source of stem cells—ES cells from embryos remaining after infertility treatments—is more controversial because the derivation of ES cells destroys the embryo. NBAC proposes that "research involving the derivation and use of human ES cells from embryos remaining after infertility treatments should be eligible for federal funding" (Recommendation #2). To this end, NBAC recommends a limited "exception" to the current statutory ban on federal funding of embryo research to permit research that involves the derivation of human ES cells from embryos remaining after IVF. Rather than attempting to resolve the debate about the interpretation of the statutory ban on embryo research, NBAC chose to focus on the ethical concerns involved.

Our conclusion that "it is ethically acceptable for the federal government to finance research that both derives cell lines from embryos remaining after infertility treatments and that uses those cell lines" reflects our judgment, based on expert testimony, that it is a mistake to suppose that derivation and use can be "neatly separated without affecting the expansion of scientific knowledge"—instead, there is a "close connection in practical terms." For instance, the methods for deriving stem cells may affect the properties of the ES cells, and increased understanding of the nature of ES cells may come in part from the process of derivation.

Several ethical concerns arise in the derivation and use of ES cells from embryos remaining after IVF, and some are similar to those that arise in the derivation and use of EG cells from cadaveric fetal tissue. NBAC proposes ways to separate, to the extent possible, donors' decisions to dispose of their embryos from their decisions to donate them for research, in order to reduce the possibility that "potential donors could be pressured or coerced into donating their embryos for stem cell research." We stress that "potential donors should be asked to provide embryos for research

only if they have decided to have those embryos discarded instead of donating them to another couple or storing them. If the decision to discard the embryos precedes the decision to donate them for research purposes, then the research determines only how the destruction occurs, not whether it occurs."

We also recommend (Recommendation #5) the disclosure of certain, specific information to those considering whether to donate their embryos for research. The informational components include: the ES cell research "is not intended to provide medical benefit to embryo donors"; a decision to donate or not to donate the embryos for research will not affect future care provided to the prospective donors; "the research will involve the destruction of the embryos"; and the "embryos used in research will not be transferred to a woman's uterus." In addition, we recommend (Recommendation #6) that, in federally funded research, researchers "may not promise donors that ES cells derived from their embryos will be used to treat patient-subjects specified by the donors."

NBAC identified another ethical constraint that needs to be in place for the derivation and use of stem cells from embryos remaining after IVF as well as for research involving cadaveric fetal tissue: "Embryos and cadaveric fetal tissue should not be bought or sold" (Recommendation #7). Federal statutes and regulations and state statutes should be examined to make sure that they or subsequent modifications achieve this end.

I should note that we considered two other possible sources of human ES cells, again balancing the relevant ethical and medical considerations. We recommend against the deliberate creation of embryos for research at this time, whether by IVF (Recommendation #3) or by somatic cell nuclear transfer cloning (Recommendation #4). In NBAC's judgment, the creation of research embryos could not be justified at this time either on the grounds that the supply is inadequate or on the grounds that matched tissue is needed for autologous cell replacement. However, the report notes that it may be appropriate to reconsider these issues in the future (p. 93).

Most of the remaining recommendations (#8–13) focus on the creation and functions of a National Stem Cell Oversight and Review Panel, a broad, multidisciplinary panel with public members, which NBAC recommends that the Department of Health and Human Services (DHHS) establish in order "to ensure that all federally funded research involving the derivation and/or use of human ES or EG cells is conducted in conformance with the ethical principles and recommendations contained in this report." (Recommendation #8).

CONCLUSION

In summary, NBAC concluded that it would be acceptable for the federal government to fund research that both derives and uses stem cells from cadaveric fetal tissue and from embryos remaining from fertility treatment, if certain guidelines and safeguards are in place and if there is an appropriate and open system of national oversight and review. However, at this time it recommends against federal funding for the creation of embryos for research by either IVF or somatic cell nuclear transfer cloning.

In part because of the evolving science and on-going societal conversation about ethical issues, NBAC did not suppose that it could offer the final word on the ethics of human stem cell research, on the best possible balance of ethical and medical considerations, or on how to resolve the tension between proper respect for cadaveric fetal tissue and embryos remaining after IVF, on the one hand, and promoting research that could relieve much human suffering, on the other hand. However, our recommendations reflect our considered judgment, based on an extensive, open, and public process of obtaining information and engaging various ethical, legal, and policy perspectives, about an "acceptable public policy" that reflects "widely shared views" about not foregoing the potential benefits of stem cell research and about respecting cadaveric fetal tissue and embryos remaining after IVF as well as avoiding undue pressure, coercion, and exploitation of potential donors. Throughout its deliberations, NBAC attempted to propose policies "that demonstrate respect for all reasonable alternative points of view and that focus, where possible, on the shared fundamental values that these divergent opinions, in their own ways, seek to affirm."

We hope that our report will further stimulate the important public debate about the profound ethical issues regarding this potentially beneficial research.

Thank you, Mr. Chairman. I would be glad to answer any questions you or the members of the Subcommittee may have.

NEW COMMISSION

Senator SPECTER. Dr. Young, beginning with a question to you, you have suggested a new commission be formed and that there be a moratorium of 3 years. What would you see the new commission doing, if anything, which the National Bioethics Advisory Commission has not already done?

Dr. YOUNG. Without any prejudice or concern about any individual on the commission, I would say these few things that I think are very important.

I practiced science for over a quarter of a century. I know the peer pressure that exists on straying outside of existing dogma. The penalties can be loss of research grants, professorships, and appearances at national meetings. When we set up the AIDS Commission, Admiral Watkins was chosen as chair, a Navy officer who did not have an affiliation with science. At the time that we did one of the early appointments at RAC, we moved to Representative Thornton who was again not involved or vested in this. Any university president, academician, scientist, physician that is engaged in this I believe has an inherent conflict of interest.

Second, I think that it is very important that it be balanced between just the Congress, Senate, House that is, and administration. If one has it as a handmaiden of any branch of government, I do not believe it is as broadly representative.

Third, we tried in the Recombinant DNA Advisory Committee to have on the committee representatives of the public that were very different in views. We deliberately selected those and also difference in background. That is why I suggested a richness of individuals of various persuasions and at least two from the public which had no vested concern.

I would urge that this group would also report to Congress, the administration, would raise policy concerns, and above all, try to reach some sort of a consensus. I do not believe that, as the Congressman said, there is enough consensus in the land about this research at this time.

Most importantly, I would like to see a very thorough catalog of the type of studies that could be used with adult versus the embryonic stem cells. The most recent literature, if I could include a few press clippings on the monkey studies for the record, show that adult stem cells might be able to be isolated from the carotid body in the brain of monkeys and utilized for treatment of Parkinson's disease.

Senator SPECTER. Dr. Young, when you look for consensus, it is going to be very difficult or more likely impossible to obtain because of the very deep-seated differences which are present here. It brings up the dichotomy, for want of better terms, of categorized pro life and pro choice. So, that is going to be very hard, as I say, perhaps really impossible, to do.

How would you compare this issue with the fetal tissue issue where the same considerations were present on both sides, and finally fetal tissue was approved because of the judgment that it did not encourage abortions, but would be used only after the abortions were completed, similar to the argument that stem cells are derived from embryos which are not going to be utilized for life?

Dr. YOUNG. If I could answer that question with an introductory answer.

At the time we first formed the Recombinant DNA Advisory Committee, there were just as grave concerns of whether we would be playing God, and we had to address by deliberately being more conservative and then gradually roll back.

But to answer your question immediately, one of the major concerns in the production of research on fetal tissue, or termed cadaveric tissue, was that it would be highly successful in the treatment of Parkinson's disease. Those aims that were touted widely in the use of cadaveric tissue have not proven to be highly successful at all. In fact, some of the work with adult stem cells is more efficacious by factors of 30 or 40 or so than actually the work that was done with cadaveric tissue.

I was in the Bush administration——

Senator SPECTER. Dr. Childress, let me ask you about the adult stem cells as an alternative, which has been suggested here today and by others. What is your view of that as a realistic alternative?

Dr. CHILDRESS. I am not a scientist, but the evidence that NBAC received and information that has appeared in the literature would suggest to us that it is important to pursue adult stem cells as a possibility, but there are limitations given what we currently know. Those limitations have to do with our inability so far, scientists' inability so far, to identify adult cardiac stem cells, for instance, or adult pancreatic eyelet stem cells. But in addition, often the stem cells that can be derived this way appear to be available only in small amounts and are hard to isolate and purify. Then there are other questions about whether, if it is a genetic error that is creating the problem, that would also be present in the stem cells. So, those are reasons at least for some caution while also supporting this particular avenue of research.

I think from NBAC's standpoint it was important not to view these as alternatives, but rather as avenues to be pursued simultaneously so that comparisons can be made about the effectiveness of tissue or cell therapies that might be developed accordingly.

Senator SPECTER. The commission came to the conclusion that Federal agencies should not fund research involving the derivation or use of human stem cells from embryos made solely for research purposes. Is that essentially a cloning conclusion?

Dr. CHILDRESS. In part, but also there would be two sources that we considered. One would be from in vitro fertilization, and the other would be from somatic cell nuclear transfer cloning. So, we considered both of those and argued against the creation of an embryo for research purposes by either means.

STATEMENT OF HON. STROM THURMOND, U.S. SENATOR FROM SOUTH CAROLINA

Senator SPECTER. We have been joined, as you see, by our distinguished President Pro Tempore of the U.S. Senate, the senior Senator from South Carolina, in the Senate since 1953 or 1954?

Senator THURMOND. 1954.

Senator SPECTER. Candidate for the presidency, chairman of the Judiciary Committee, chairman of the Armed Services Committee, my good friend. Senator Thurmond, we very much appreciate your

appearing here. Senator Thurmond had testified some time ago on a number of issues relating to diabetes. I saw Strom earlier today at the Judiciary Committee meeting. We welcome you here. We will interrupt our questioning of Dr. Childress and Dr. Young to turn to you.

Senator THURMOND. Thank you very much.

Mr. Chairman and members of the committee, it is a pleasure to be here today supporting Federal funding for stem cell research. I am hopeful that we are on the verge of discovering a whole new way of treating and curing diseases which for too long have led to pain and suffering in the lives of too many Americans.

Late last year, privately funded scientists made major breakthroughs in stem cell research. As you may know, stem cells are the body's basic cells from which all of a person's tissues and organs develop.

While a number of scientific challenges must be overcome before specific medical benefits might be realized, there is great potential in this research. Scientists believe that stem cells could be used to produce a supply of healthy cells and tissues that can be used for transplantation. By replacing existing damaged cells, new treatments and even cures for numerous diseases might be developed.

There is great optimism that lifesaving therapies might be produced. Cells and tissue capable for transplantation could include insulin producing cells to cure diabetes, heart cells to rebuild damaged hearts, or new brain cells for victims of Parkinson's disease or other neurological disorders.

As a father of a daughter with juvenile diabetes, I know firsthand the devastating nature of this disease. In addition, during my service in the Senate, I have heard the personal pleas of thousands of constituents who are affected by various diseases and disorders. Therefore, I have been a longtime supporter of medical research.

I recognize that many modern biotechnology developments are complex issues and are frequently controversial. A number of experts in medicine, religion, bioethics, and other disciplines have reviewed and continue to comment on these issues. I believe these discussions are beneficial as we seek to advance medical progress and the well-being of patients without demeaning the value of human life.

The National Institutes of Health have led the way in medical research and must be actively involved in stem cell research. NIH financial support of this basic research will allow us to move toward clinical applications.

PREPARED STATEMENT

I commend you, Mr. Chairman, for your leadership on this issue. I note this subcommittee has held a number of hearings on this topic. These hearings have provided an important forum for a broad discussion of the scientific, medical, and ethical matters related to this important breakthrough. I look forward to working with you and other colleagues to ensure adequate funding and appropriate Government support is available to our national medical research community.

Thank you very much.

Senator SPECTER. Thank you very much, Senator Thurmond, for coming and testifying.

[The statement follows:]

PREPARED STATEMENT OF SENATOR STROM THURMOND

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WOULD USE OF FETAL TISSUE ENCOURAGE ABORTIONS?

Senator SPECTER. I had commented earlier when Congressman Dickey was here and the subject of fetal tissue had come up that when you had supported the use of fetal tissue, that it was very influential with many of our colleagues in the Senate. The disagreement had arisen whether use of fetal tissue would encourage abortions or whether it would not encourage abortions, with use of fetal tissue for abortions already completed. Congressman Dickey commented that while he had not seen statistics on the subject, he did not think that fetal tissue had increased the number of abortions although, as I say, he commented that he had not seen statistics.

But I think, given your stature and your general approach to issues in the Senate, that your testimony will be very influential with our colleagues, as was your testimony and your vote some time ago on fetal tissue. So, thank you very much for coming, Senator Thurmond.

Senator THURMOND. Thank you, Mr. Chairman, for the fine work you are doing.

Senator SPECTER. Dr. Childress, you were in the middle of responding to the question about the commission concluding that the derivation or use of human stem cells from embryos should not be financed where they are made solely for research purposes.

Dr. CHILDRESS. Yes. I commented that we intended this to cover, in two separate recommendations, the creation of research embryos either by IVF, created specifically by IVF for research, or from somatic cell nuclear transfer cloning.

Senator SPECTER. When you say created specifically for——

Dr. CHILDRESS. Instead of using——

Senator SPECTER. Created specifically for?

Dr. CHILDRESS. For research.

Senator SPECTER. Embryos can be created scientifically by cloning?

Dr. CHILDRESS. If somatic cell nuclear transfer cloning could be used to create embryos in this way——

Senator SPECTER. If it could be.

Dr. CHILDRESS. I cannot speak to the scientific part of that at this point as to how soon this would be possible, but the intention NBAC had was to cover the creation of research embryos, embryos created solely for research purposes by either in vitro fertilization or somatic cell nuclear transfer cloning.

Senator SPECTER. Your commission further found that Federal agencies should not fund research involving the derivation or use of human stem cells from embryos made by the transfer of DNA from a regular body cell into a human egg. Is that correct?

Dr. CHILDRESS. Yes.

Senator SPECTER. What does all that mean?

Dr. CHILDRESS. Which recommendation are you referring to specifically? OK. That is a restatement of the somatic cell nuclear transfer point.

Senator SPECTER. The same thing?

Dr. CHILDRESS. Yes, same. OK. Sorry. I thought there might have been something there that I did not catch from the previous one.

Senator SPECTER. OK.

Dr. Young, you have had a fascinating career in Government, as I had noted, Commissioner of the Food and Drug Administration, in the Bush administration, HHS. You are both an M.D. and a Ph.D., and you now serve as Pastor of Adult Ministries at the Fourth Presbyterian Church in Bethesda, Maryland. If you do not mind my inquiring, that is quite an interesting career change. Why did you move in that direction? You do not have to answer that question or any other question, if you do not want to.

Dr. YOUNG. I would be happy to. I have felt over my life that the struggles that I was trying to deal with was to see the interrelationship between science and medicine and a belief in God. To me that was a dominant question. As I looked into this, one of the best answers that was given to this was when a group of individuals went to Jesus—it is described in Matthew—and asked him whether it is lawful to give taxes, to pay taxes. The question was then answered by asking for a coin and he said, render unto Caesar what is Caesar's and what is God's God. Through my life I tried to figure out what I should do and how I should live it.

In fact, those teachings were very helpful as I was Commissioner of the Food and Drug Administration and tried to represent all of the Nation in the development of a response to the HIV crisis.

Senator SPECTER. So, now you have turned, essentially, to the ministry.

Dr. YOUNG. Now I have found that as I look into the 21st century, the very struggle is what is the meaning of life. I have seen this play out in the question of violence, the question of treating people as parts and objects rather than as real individuals. Now the search for God and the meaning of life is most important.

Senator SPECTER. Well, you said that you were asked that question this morning at 6:45 when a woman was on her way to the operating room?

Dr. YOUNG. Yes.

Senator SPECTER. Well, that was a private conversation, but would you care to tell us what the answer was or, if not that answer, your answer?

Dr. YOUNG. No. The answer was actually from a psalm, and the psalm that I read to her was Psalm 146.

Senator SPECTER. Justice William O. Douglas always reached into his pocket and pulled out the Constitution, but you reached into your pocket, may the record show, and pulled out a psalm, or a Book of Psalms.

Dr. YOUNG. There were two. The one was: "Praise the Lord, O my soul. While I live I will praise the Lord: I will sing praises to my God while I have being."

The other one that I read to her was Psalm 27. "The Lord is my light, my life, and my salvation. Of whom then shall I fear?" The psalm goes on to say there is one thing that I ask that "I may dwell in the House of the Lord forever."

I think that people have both, as we look at this box called life, the need through science and medicine to understand life as we can see and measure it. Religion is different. Religion is a private, personal relationship with God. Now my responsibility is to help people understand ways to reach God and to be reached by God because it is that calling.

I would finally say that the most sacred time in an individual's life and in a minister's life is to help a person at the hour of death because that is the time when all of life comes into focus.

Therefore, I used to ask the medical students when I would interview them at Rochester, after first asking them what do they dislike, in the middle of the interview, I would say, would you please tell me what is so important for you that you would be willing to die for it? I asked that question to try to find out what was the inside conviction of a person, not for a selection or nonselection, but I submit that for each of us to live, for you serve, for me to serve in whatever the careers are, we must know what the very essence of life is.

I have found this to be the greatest challenge and greatest change in my life. I must admit I was very scared, more scared than an internship, to study for my ordination exams. They were very difficult.

Senator SPECTER. Dr. Childress, I note you too have a combination of approaches, a professor of medical education and professor

of religious studies. What was your Ph.D. from Yale in, Dr. Childress?

Dr. CHILDRESS. It was in religious ethics, specifically Christian ethics.

Senator SPECTER. What is your qualification or background for being a professor of medical education?

Dr. CHILDRESS. The work I do in biomedical ethics, looking at the relation between philosophical and religious perspectives on the one hand and what happens in the biological sciences, medicine, and health care on the other.

Senator SPECTER. But it is an ethical basis as opposed to telling you how to carve up cadavers, et cetera.

Dr. CHILDRESS. Yes, indeed.

Senator SPECTER. Well, thank you very much, gentlemen. Thank you very much.

At this point in the record we will insert Senator Feinstein's prepared statement.

[The statement follows:]

PREPARED STATEMENT OF SENATOR DIANNE FEINSTEIN

I want to thank Senators Specter and Harkin for scheduling today's hearing on stem cell research.

I believe Congressional attention like this is critical to supporting the research community's efforts to innovate and find new cures and treatments for many of the diseases and disabilities that plague humankind.

One of my constituents, Lawrence S. B. Goldstein at the University of California San Diego School of Medicine wrote on May 25, 1999:

"Why should we use federal funds for human pluripotent stem cell research? Ask Walter Payton and 12,000 other Americans who are waiting for liver transplants. If they are fortunate, new livers will be found and they may live; if not, they will die."

This week saw that sad prediction come true. We lost Walter Payton.

As NIH Director Dr. Harold Varmus testified before this subcommittee on December 2, 1998, by better understanding cell development, "research on stem cells could help us understand the complex events that occur during human development." He also explained quite eloquently how many diseases and disorders are the result of disruption of cellular function or destruction of tissues of the body and that some day in the future, stem cells could be a renewable source of replacement cells to treat a broad range of diseases. He said, for example that the transplant of healthy heart muscle cells could provide new hope for heart attack victims.

Similarly, the Biotechnology Industry Association has written that stem cell therapies could provide blood cells to treat anemia; skin cells for burn victims; nerve cells for treating Alzheimer's Disease; spinal cord cells for spinal cord trauma and paralysis; pancreas cells to treat diabetes; bone cells for treating osteoporosis. The National Coalition for Cancer Research has hailed the promise of this work. As my constituent, Dr. Thomas Okarma of Geron Corporation, Menlo Park, also testified before this subcommittee, "The human pluripotent stem cell has the potential to dramatically impact clinical medicine by introducing fundamentally new therapeutic technologies."

One important potential stem cells is that they may not be rejected by the human body the way donated organs and other tissues often are. Dr. Goldstein wrote: "Pluripotent human stem cells, unlike all other cells in the human body seem to 'remember' how to become almost any type of cell or organ."

Because stem cell research inevitably raises ethical concerns, I am pleased that the President asked the National Bioethics Advisory Commission for guidance and I look forward to their testimony this morning. We must demand the highest ethical standards, but we also must continue to advance medical research to find cures and treatments for the thousands of diseases that may affect us.

I look forward to a thoughtful public discussion on these important issues and to the witnesses testimony.

Again, I thank you for holding this hearing and I look forward to hearing the testimony this morning.

CONCLUSION OF HEARING

Senator Specter. 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 12:58 p.m., Thurday, November 4, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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