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CLONING, 2001

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COMMITTEE ON APPROPRIATIONS

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CLONING, 2001

TUESDAY, DECEMBER 4, 2001

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 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Specter, and DeWine.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. This hearing of the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee will now come to order. Three years ago, Dr. Michael West of Advanced Cell Technology testified before this committee about a new plan to transplant a patient's DNA into a human egg, grow some stem cells, and then use those cells to cure devastating diseases. It was a plan that brought hope to millions of Americans suffering from Alzheimer's, Parkinson's, spinal cord injuries, diabetes, and many other diseases and debilitating conditions. Late last month Dr. West announced that he had taken the first step toward reaching that goal. Dr. West's announcement received a great deal of media attention, but it has also started an avalanche of disinformation about what this advance means and whether or not it will lead to human cloning. I think it's time to spend more time on the facts and less on the fiction. That's why Senator Specter and I decided to invite Dr. West to join us once again today.

One thing has become very clear in this debate: as long as the opponents of stem cell research can wave the flag of human cloning, science will be inhibited. The proposition of human cloning worries most Americans, as it should. Some choose to feed these worries. That's why I think it's important forever to separate the issue of human cloning from the science of stem cell research.

Soon I will be introducing legislation that will ban human cloning, and impose strict criminal and civil penalties on any misguided person who would conduct this type of procedure. This legislation would draw what I call an "iron curtain" between responsible research and misguided attempts to pursue human cloning. At the same time that this "iron curtain" shields us from a reckless few, it protects responsible scientists, allows them to continue their search for cures to many devastating diseases, and I think it is very important that we make that distinction. The chart that I have here illustrates my point. The research we're discussing today

involves taking the DNA out of a donated egg and replacing it with the DNA from someone who may have a disease like Alzheimer's or Parkinson's. That's called somatic cell nuclear transfer. Now my bill prohibits this process from ever leading to a human clone. But it does allow the creation of stem cells that could result in a cure; in other words, once you get the somatic cell nuclear transfer, you can go two ways: you can go to implantation in a woman's womb to try to get a cloned human, or you go in the other direction to get the stem cells that can go to cure someone who has an illness. What my proposed legislation would do would be to ban that one avenue, and to impose very strict criminal and civil penalties on anyone who would engage in that, thus leaving open the avenue that would go from somatic cell nuclear transfer down to stem cells and to possible cures.

This technology and science has enormous potential to ease human suffering, and I believe it would be a very serious mistake to ban it. My legislation would protect our values by banning human cloning, but protect our health by fostering research into stem cells.

We're very fortunate to have a distinguished panel of witnesses to testify about these issues this morning. Before we hear from them, I would turn now to my distinguished ranking member, Senator Specter, to make his opening remarks.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Well, thank you very much, Mr. Chairman, and thank you for promptly scheduling this hearing within just 10 days of the widely publicized disclosures regarding the cloning issue, which reached the covers of the national magazines. I think it is very unfortunate that the name "cloning" has been attached to what is called "therapeutic cloning," because it confuses the issue with reproductive cloning, and the appropriate scientific name, as you have already noted, Mr. Chairman, is somatic cell nuclear transfer. And there is no doubt about the abhorrence of reproductive cloning to create another human being. But simply stated, that is not what is involved here. What we have, essentially, is a technique which involves the taking of genetic material out of an unfertilized egg and inserting in its place the DNA of an adult cell, for example if somebody is suffering from Parkinson's or Alzheimer's or amyotrophic lateral sclerosis, so that when the stem cells are derived and injected into that individual, there is not a rejection. We have had some very heated debate on the floor of the U.S. Senate with all of the evils and all of the dangers of human cloning, which we all agree to. But I do believe it is plain at this juncture that we can have legislation which will ban human reproductive cloning without prohibiting so-called "therapeutic cloning." But I believe that it is indispensable that the scientific community come forward and take an aggressive role in educating the American people as to just what is involved here. The House of Representatives has passed legislation which prohibits somatic cell nuclear transfers, so-called "therapeutic cloning," and it is entirely possible that the Senate could take similar action. And we had the matter come to the floor of the Senate with our appropriations bill for the Department of Health and Human Services where this sub-

committee and the full committee inserted language which would codify the decision of President Bush to permit Federal funding on existing stem cell lines.

Now there is little doubt that President Bush does not intend to permit Federal funding on stem cell lines beyond the approximately 70 which he identified as of August 9. But the subcommittee wanted to codify that, and the full committee agreed, but concerns were raised on the Senate floor about that provision on the grounds that another president might permit further funding. Then amendments were offered which would raise a whole range of prohibitions against reproductive cloning and therapeutic cloning, and in order to avoid a lengthy debate we deferred the matter until February or March when the Senate majority leader has agreed to take this issue up as a free-standing bill. Then the publicity occurred 10 days ago when the matter was back on the Senate floor yesterday in a complex procedural issue where an effort was made to bring the matter back up, notwithstanding our agreement to defer it until February or March, and it came up on a so-called "cloture vote" and was defeated. That is interpreted in this morning's news media as saying that the Senate has rejected the effort on banning somatic cell nuclear transfers or therapeutic cloning. Well, that's not exactly right, but I don't think it's going to come back up this session.

This hearing has been called so that the scientific community can come forward. My own view is that the limiting of the Federal funding on stem cell research to the approximately 70 lines in existence as of August 9 is tying the hands of scientists. There hasn't been a groundswell on that issue because there has been insufficient time to find that those lines will not support all the research which is necessary. But prior to the President's announcement, we had some 64 senators who had signed on urging Federal funding on stem cell research, and another dozen had orally committed to me that they would support Federal funding, but didn't want to put it in writing.

So what we have are a group of issues where there is enormous potential for curing Parkinson's and Alzheimer's and heart disease and cancer and to have these matters inhibited on ideological grounds is, in my view, just unthinkable in the 21st century. There are people who feel very passionately on the other side, and in accordance with the way our democracy works, let's shed light on it. Let's bring it all out into the open. But to do that, the scientific community is going to have to be activated. Too often the scientific community is inert. And Senator Harkin and I have taken the lead in adding some $11 billion to the $12 billion in NIH funding, including our current appropriations bill, thereby providing the funding resource for enormous advances to cure many, many maladies.

So that's the challenge we have. So I hope the scientific community—I know quite a few will watch this on C-Span—understands that the time has come to move forward. Thank you very much, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter. Senator DeWine.

OPENING STATEMENT OF SENATOR MIKE DE WINE

Senator DEWINE. Mr. Chairman, I just thank you for this hearing. I'm a co-sponsor of Senator Brownback's bill. I'm looking forward to hearing his testimony and also hearing the other witnesses as well. Thank you.

Senator HARKIN. Thank you, Senator DeWine. I'll leave the record open for any other statements that any other members of the subcommittee might have. Now we'll turn to our first witness, our colleague Senator Brownback, who was elected to the Senate in 1996 and serves on the Commerce, Science and Transportation Committee, the Judiciary Committee, and the Foreign Relations Committee. He received his law degree from the University of Kansas and his BA from Kansas State University. Senator Brownback has testified before this subcommittee two times on the issue of stem cell research, and it is a pleasure to welcome him back again to discuss this important issue. Senator Brownback, welcome back.

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

Senator BROWNBACK. Thank you very much, Mr. Chairman, members of the committee and thank you for allowing me the opportunity to be here to testify in front of you today. My testimony will be more in the form of questions than in comments, as I really think that's the stage that we're at with the issue of human cloning, and that's why I've advocated on the floor a moratorium at this point in time before we go forward with further human cloning, under whoever's definition you want to put it, of human cloning, but that we just call a timeout now, while we really contemplate some deep questions.

I've supported and continue to support you and Senator Specter's efforts to increase funding at NIH for incredible breakthroughs that I think are potentially there as well in other areas, and in adult stem cell work, which I'm a strong advocate of us funding. And I continue to support that funding increases that you put forward at NIH and I think that's a wonderful place for us to invest. So we can find cures, so we can give hope. So we can give a better life to people that certainly deserve it. But at this point in time I have a lot of questions about human cloning and I think that's really where the public is, and that that's why the public in such an overwhelming fashion is opposed to human cloning. In any poll that you see it gets nearly 90 percent opposition to human cloning. And I want to pose some of those questions to you if I could this morning.

The issue of human cloning is an issue of vast historical significance, and one that should give us all considerable pause. It is, as I have stated before, a debate with a moral status of the young human. Succinctly put, is the cloned human a "who" or a "what?" A person or a thing? Does a cloned human embryo have any moral significance? Is there a difference between a human embryo created by man and one created by God? These are historical questions that the world is grappling with right now, as we hold hearings here, hearings are being held in the European Union, in capitals throughout the world some 28 countries have already wrestled with and passed laws to some degree or another dealing with the issue of human cloning. Yet it is occurring in our country, and I really,

Mr. Chairman, with all deference to my colleagues, think that this is a moment in history, the history of humanity, that we should pause. Just pause for a period of time and really hold a series of hearings over a period of months, while we hold up and say, now wait a minute, before we unleash this issue, and this question, let's pause, and let's really think this through and debate. Is this a person or not? Does this have any moral significance or not? And let's bring in a broad cross-section of people over a lengthy period of months, and then let's take this issue forward, rather than saying "We will let private companies decide this issue in the absence of any speaking of this by the congress and the president of the United States," which is currently the situation of what's taking place.

That's why I really think that this issue deserves considerable debate, and a moratorium at this period of time, for a period of 6 months, while we really sort through these historic questions about humanity.

Let me read to you some comments from other people that I want to share the broad-based nature of the concern over the issue of human cloning at this point in time. Because there's an interesting coalition of groups that are forming opposed to all human cloning, by all definitions, all human cloning. In fact, pro-choice feminist Judy Norsega, and biologist Stuart Norman recently commented in a Boston Globe column the following: Because embryo cloning will compromise women's health, turn their eggs and wombs into commodities, compromise the reproductive autonomy, and with virtual certainty lead to the production of experimental human beings, we are convinced that the line must be drawn here.

Now despite some similarities, this debate is not about abortion, and I don't think it should be confused with that debate. And perhaps this is why we have such a broad coalition forming of groups who are strongly opposed to abortion, groups also that are strongly supportive of abortion, environmentalists and others. The reason for the broad range of interests is that there is truly something about this issue that should concern us all, and should cause us to pause.

I'd like to read another statement, this from an environmentalist group. Dr. Brent Blackwelder, president of Friends of the Earth, stated at a recent news conference this:

"Environmentalists embrace an ethic of respect for nature and strive to demonstrate the interdependence of humans and our natural world. Proponents of cloning and inheritable modification, on the other hand, extol the virtues of 'remaking Eden,' of improving what nature has given us. For example: designer babies, or the cloning of pets that don't cause allergies, will lead us down a slippery slope toward the redesign of the rest of life. Indeed, if society allows the cloning of human beings today, inheritable genetic manipulation of humans and all other species cannot be far behind."

Now Mr. Chairman, I don't necessarily agree with what both of those individuals are saying. But what I want to demonstrate for you is the depth of conviction that some people have of the real historical questions that we're entering into right now, and that we're not even speaking on it. The Senate has not issued its rules that it is saying on this. There are no regulatory guidelines. These things are taking place basically at the review of ethical boards put

forward by private companies. At a monumental time. At a monumental time.

Therefore, Mr. Chairman, I would submit that the technology is now moving faster than expected, and our ability to consider a full and permanent ban on human cloning is moving slower than it should, and that it is time for us to pause and contemplate. I urge my colleagues, and in particular the Majority Leader, to call up H.R. 2505, that's the House-passed bill on a permanent ban on human cloning, or at a minimum—at a minimum—a 6-month moratorium so that we can restore the status quo in our country, until such time as the Senate can debate and really hear the issue.

The President has asked for us to pass the 2505 bill that the House has passed by a bi-partisan majority, a hundred vote margin passed that House bill overall. And I really think that—I do know how this debate—I do not know how this debate will be resolved, Mr. Chairman, but I do know that history is watching what we do today, and it will record our actions for the benefit of our ancestors. And I hope it's a history that we can be proud of at this point in time.

Mr. Chairman, I don't want to disparage anybody's work in the research community that they've done. I think all operate from a laudable set of objectives. But this is one that shouldn't be decided by private companies. The public bodies should speak, and should speak clearly on this issue, and we should have a moratorium at the present time, while we consider the full ramifications of what we're doing. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Brownback, for, as always, a very thoughtful and lucid presentation.

You were asking for a 6 month moratorium, is that correct?

Senator BROWNBACK. At this point in time, what I was bringing up on the floor yesterday was a moratorium for a period of 6 months, while we could fully contemplate, consider the issue, before really the technology gets out way in front of the contemplation.

Senator HARKIN. I just want to be clear. Since this is a private company that's doing this, I'm not certain if they're using any Federal monies at all—I don't know that. The answer to that question I'll find out soon, I guess. But how do you stop a private company?

Senator BROWNBACK. We put a moratorium on human cloning of all types for a period of 6 months.

Senator HARKIN. But how is it enforced against a private company?

Senator BROWNBACK. You could do the 2505 bill and sunset it in 6 months.

Senator HARKIN. No, but I'm saying——

Senator BROWNBACK. And that is a total ban.

Senator HARKIN. I mean, do you have criminal penalties or civil penalties in place?

Senator BROWNBACK. Criminal and civil penalties that would be in place for 6 months—period of 6 months and you would sunset it after that period of time so that they would have to act.

Senator HARKIN. What happened to my chart? You've taken an egg and removed the DNA, and you've taken the DNA out from this individual that may have Alzheimer's and you've placed this

DNA in this egg. What I'm saying is, you could put an iron curtain right here [motioning to chart], and say you can't go that path, but you could go this path. You still want to put a moratorium on that?

Senator BROWNBACK. If I could answer your question with the recommendations of the National Bioethics Advisory Commission—this is 1997—they stated this about the creation of that middle are, the somatic cell nuclear transfer. "The Commission began its discussions fully recognizing that any efforts in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term." In other words, that creation of the entity right there is a creation of the embryo by definition of the—President Clinton's National Bioethics Board, with the potential of implantation. I don't see how you stop the implantation from then taking place.

Senator HARKIN. Well, you pass a law that says if you do this, this has criminal and civil penalties attached to it.

Senator BROWNBACK. But what effect are—let's say you do implant at that point in time. Are you going to require that she abort the child in the law? I wouldn't anticipate we would do that. There might be some penalty that you put on a person, but you will have a cloned human born at that point in time.

Senator HARKIN. All right, I'll ask you the question. You say that you want to put the ban right here [motioning to chart]——

Senator BROWNBACK. From the creation of the somatic cell——

Senator HARKIN. Stop it right here [motioning to chart]——

Senator BROWNBACK. That's where an embryo is created by the definition of the National Bioethics Board.

Senator HARKIN. Let's say that someone went ahead and did it, and implanted it, then what would you do? Would you say that that woman would have to abort it or not?

Senator BROWNBACK. No.

Senator HARKIN. What would you do?

Senator BROWNBACK. I think you're going to—you're going to see the civil penalties put in place, but the child is going to be born.

Senator HARKIN. Well then, the penalties that my bill would put in place would be the same as yours if this happens. Right? If——

Senator BROWNBACK. I don't know what penalties you'd put—what would there be penalties——

Senator HARKIN. Well, let's say I have civil and criminal penalties, you would put these starting here [motioning to chart.] It would cover both of these.

Senator BROWNBACK. From the creation of the embryo, yes.

Senator HARKIN. What my legislation would do is say, okay, you would stop it here, you put the criminal and civil penalties here. Your question to me was, well what if someone went ahead and did this, what are you going to do? I mean, you're not going to abort it or anything but I asked you the same question. What if you draw the iron curtain here [motioning to chart] and someone goes ahead in a private company, does this, then implants it, you face the same problem with your legislation.

Senator BROWNBACK. You have that problem, but I also—as I posed at the outset the question of is there any moral significance at all to the creation of an embryo? Is there any? And what I'm

submitting to you at this point in time is that we should err on the side of caution and say there is some moral significance here, and that we shouldn't be allowing that to take place. I think you try to do the best you can to keep that from occurring.

Senator HARKIN. I just want to be clear on that, where you'd draw it here [motioning to chart,] some of us would draw it here and permit this. Now——

Senator BROWNBACK. The House drew it there as well.

Senator HARKIN. Pardon?

Senator BROWNBACK. The House, in their passed bill, drew it there, and that is what the President is seeking as well.

Senator HARKIN. You mentioned in your comments, Sam, that these ethical guidelines were put forward by private companies. In fact you pointed out that there was a national bioethics commission set up—at NIH it has just gone out of commission in October of this year, by the way, it sunsetted. They came up with a number of recommendations and ethical guidelines for stem cell research. And quite frankly, if you match their guidelines with the guidelines proposed by President Bush on August 9 of this year, they are exactly the same, except for one thing, one thing. I've got the list, I compared them side by side, they're exactly the same but for the fact that the President said you could only utilize stem cell lines that were derived prior to 9 p.m. on August 9. The bioethics commission did not draw that kind of arbitrary line. But the other thing—you know, you can't buy them, there cannot be any monetary consideration, they cannot be used for reproductive cloning—all those were in that bioethics commission. So this was not a private company. This was a separate bioethics commission you just quoted from.

Senator BROWNBACK. Yes, but—we know about the issue of stem cells, but I think that issue's been resolved pretty much by the President's order. What we're talking about here is the creation of a human clone, and I consider this a different set of issues that you're talking about on creating an actual—into which—as I recall in front of this entity before, this body before—most of the Members were advocating then we shouldn't be creating embryos for research purposes. I think the Members here have stated that to me previously. We're talking about, these are leftover embryos at in vitro fertilization clinics, going to be thrown away, so why not? Which, I have some questions about that, but that's not the stage we're at now. Now we're talking about the actual creation of embryos for research purposes, which Members of this body had talked previously we should not be doing that, and we should not be going there.

Senator HARKIN. That will be coming up here later about the definition really of an embryo and if something reaches just the blastocyst stage, it is—I'm not a scientist, but from what I have been told by scientists is that, at that stage of the blastocyst, where you have the requisite number of cells that you could extract for stem cell purposes, that at that stage the embryo really cannot be implanted in the womb. So it's still something prior to, or pre-embryonic at that point. It becomes embryonic at some point after that. Now I will ask the scientists to further elaborate on that. But you

are saying that as soon as you take DNA of any nature and put it in an egg, you have an embryo. That's what you're saying.

Senator BROWNBACK. I'm quoting from the National Bioethics Commission, that they're saying that's the creation of an embryo at that point in time. And the DNA structure of that embryo is the same DNA structure that, if you let it fully grow through to term, to full physical status, its DNA structure will not be any different. It will be—that will be its DNA.

Senator HARKIN. Let me ask you this question, Senator. Are you in favor or opposed to in vitro fertilization?

Senator BROWNBACK. I have no opposition to in vitro fertilization. And the issue here is about the creation of clones. I've had a number of friends and family members—not family members—friends who've gone through that procedure and they have children—beautiful children.

Senator HARKIN. So in vitro fertilization is fine?

Senator BROWNBACK. It is fine by me.

Senator HARKIN. But as you know, when you have in vitro fertilization you have leftover embryos.

Senator BROWNBACK. As it's practiced here in the United States, we do, yes.

Senator HARKIN. So what do you do with them?

Senator BROWNBACK. Well, we've been through this discussion before as well, there are adoption procedures that people can go through—what I'm discussing here today is the creation of an embryo just for that research purposes, which is the issue that we're on on human cloning. And that's the one I think we should pause on.

Senator HARKIN. I'm not so certain that—and I will ask scientists further to elaborate on this, and I'm not certain the bioethics commission was correct in that I haven't read that exactly. But I've been told, and I will ask further scientists to give me the exact reading on this is, if you implant DNA in an egg in which other DNA's been extracted, and that develops only to the blastocyst stage, is it really embryonic or is it not embryonic at that point? Again, I don't know, I'm not a scientist. But I've heard that it may not be, and I want to find that out. I don't know if that bioethics commission was correct in that, I just don't know.

Well, I appreciate the give-and-take with you, Senator, thank you very much. Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman. Senator Brownback, what we have here so far is research not to have human cloning, not to make babies, so to speak, but to develop tissues for treating disease. You raise a question about the moral significance of creating an embryo, and I can certainly understand that, where you raise a concern about having a man-made creation of an embryo result in reproductive cloning or the creation of another person. But it is quite another matter where this is done for therapy. For example if someone has Parkinson's you can have the curative stem cells derived from an embryo that has been created in part with the DNA of the potential recipient, someone illustratively who has Parkinson's, so that they will not reject the stem cells, but can, in fact, be cured. So taking away the possibility of creating another human being, and having as a sole purpose ther-

apy to cure someone with Parkinson's or amyotrophic lateral sclerosis, Lou Gehrig's Disease or many other ailments, what's wrong with that? The embryo has significance morally if it leads to the creation of a person. But if it's sole purpose is for therapy, and it works, why not?

Senator BROWNBACK. I would submit there's another route we can go, that we are going presently that's being quite successful, as we've discussed many times in the area of the adult stem cell work, where the genetic match-up is identical, where the donating person is also the person that needs the help. And that research is moving beautifully, it's being well-funded by the Federal Government and I support that. And I think we should be doing that as rapidly and as aggressively as possible.

The issue that you raise is about, well, why not just go ahead and create this human embryo, is the very question I put in front of you, and one I think we need to contemplate and that is, is there any moral significance at all to that human embryo that's being created? There is no difference physically between it and one created naturally by God.

Senator SPECTER. Well, Senator Brownback, that's by no means certain. There is considerable scientific speculation. At the time you have this entity, there's no person involved. There is only a procedure for curing a disease. If you strike out the possibility of creating a person, how does that differ from any other scientific research?

Senator BROWNBACK. What have you created then? I mean, have we created a human embryo or not? I guess there's dispute as to whether we've created a human embryo or not, and you'll hear from other testimony. I'm just reading from our own National Bioethics Advisory Board which says that we've created a human embryo. If that is the case, then this is a human egg that's fertilized that in other species we protect. We protect bald eagle eggs because we look at them, we say, well, if we don't protect them we're not going to get any bald eagles. So these or other endangered species we say we're going to protect these because they lead ultimately to a full grown bald eagle. DNA-wise, they are identical to what this bald eagle will be. We have contemplated that as a body, and we've enacted that in laws. What I'm saying here is that we should really contemplate as a body, is does what we're creating here have any moral significance? If it doesn't, if it's a piece of property, we move on forward with it. If it does have some moral significance, then we should grant it whatever protections that we deem appropriate, and that this is the point for us to stop and really chew through those, for a moratorium for 6 months, is why I asked for that.

Senator SPECTER. Senator Brownback, when you talk about adult stem cells, I'm for doing the research there. This is our 12th hearing on this subject. In the 3 years since stem cells came forward, we've invited you to testify on a number of occasions. But there's been a lot of scientific evidence at that table that the adult stem cells don't have the potential which embryonic stem cells do. But in any event, why should these decisions be made in room 192 of the Dirksen Senate Office Building as opposed to a laboratory? What business do we have, as long as we don't allow reproductive human cloning, to tell the scientists what to do?

Senator BROWNBACK. Because this body has generally considered issues regarding protection of rights and life, if that is a life. And that's what this body has generally considered. And we don't let just anybody take somebody's else's life or, for that matter, property without consequences in this society. We put boundaries. And what I'm simply asking here is let's contemplate that question first, before that's taking place in private laboratories in this country. This is the appropriate place for it to occur. This is where the people's business is discussed. The House has passed it and contemplated it. The President's asking for it. This is the appropriate place, Senator Specter.

Senator SPECTER. Senator Brownback, when we propose that we could ban reproductive cloning at implantation, and you say, how do you know that that's going to be carried out. Whenever you have a criminal law, you don't know that it's going to be carried out. We may pass your legislation, and someone may totally disregard it and move right through to reproductive cloning. Now they may run the risk of not being detected or run the risk of penalty. So if you prohibit part of it, if you prohibit only the second phase of implantation, you have precisely the same chance of having an effective criminal deterrent.

Where we have generalized agreement is on no reproductive cloning. Why not end it there and allow science to have free rein to try to cure Parkinson's, Alzheimer's, etc?

Senator BROWNBACK. I am for curing Parkinson's and Alzheimer's. I want that to be clear. I think that there is a way that we can go about this, and I think you'll look at the adult stem cell work today, because we've been in this debate now for a year, it has improved marvelously—that that has grown and that that has moved forward. But we have to contemplate, and a number of people in this country hold very significant, moral significance to the embryo. There's a large cross-section of Americans that do hold that there is moral significance to what you are laboring here, somatic cell nuclear transfer, what our bioethics board is calling the creation of an embryo. So I just think that the really sensible approach here is just to pause for a while. Just pause.

Senator SPECTER. Senator Brownback, is there any realistic likelihood that something's going to happen between now and February, March, when you and I have agreed to set in motion the mechanism where the bill will come up as a free-standing bill? These embryos didn't even succeed by the company which made them. Do you think there's any chance at all that something's going to happen between December 3 and March?

Senator BROWNBACK. Absolutely. Absolutely. I didn't know this was being contemplated—this work was being—was going on by this Massachusetts-based company. And I think that now that they've started and gotten this far, I think it's very clear that the road map has been made and that we're going to, going to see this moving on forward quite easily, quite quickly. Even though it may take, I think in Dolly there was 257 attempts before you finally got to Dolly, that was there, 257 aberrations or changes, you're going to see a lot taking place here as well. But I think that's a very high probability.

Senator SPECTER. Well, that is another area for disagreement. I think the chances in the few months are just nonexistent. Final question: when President Bush agreed to use Federal funding on stem cells, it drew a lot of opposition—I think opposition from you, among others—and the President has pretty much held the line. There was an overwhelming sentiment, as I said earlier, in the Senate to have Federal funding on stem cells. Don't you think that, in a sense, President Bush's recognition of the propriety of useing Federal funds on stem cell research has moved beyond some of the moral issues which had been raised earlier about the propriety of using these embryos and extracting the stem cells and working for the cure of diseases.

Senator BROWNBACK. Absolutely not, Senator, and I want to say as well, I generally was overall supportive, and I stated that at the time, supportive of what President Bush put forward. I had some questions and some concerns about certain key areas of it, but overall—and I stated that at the time—I thought he generally found a route where we weren't incentivizing further destruction of what a number of people believe is the starts of life. But now you have the President last week himself saying: "We shouldn't create life to destroy it." It's a quote from the President. We haven't resolved the moral issues here about the creation of life or its destruction. Indeed the President's saying we shouldn't do that. The House is saying we shouldn't do that. Should we have embryo farms, as being contemplated by a company in the state of Virginia? Where we get naturally created embryos, but that are more vigorous and vital, is what this company is saying, taking place. That's another issue that we really should wrestle with. But no, I think you're just—we're wading into—and then what about the issue when you start bringing genetic material from outside the human species into the human species, as some companies are contemplating? You know, clearly we ought to be taking that up, before that's actually a reality.

Senator SPECTER. Well, I quite agree with you about outside the human species and inside the human species, but your legislation doesn't do that. And I agree with President Bush's statement that we shouldn't create life to destroy life. But I hardly think that we're talking about the creation of life here. Well, Senator Brownback, I have deep respect for your convictions, and you and I have crossed swords on this here and in others forums, and I suspect we may well again even before March or—when we debate it on the Senate floor. So thank you.

Senator BROWNBACK. Thank you.

Senator SPECTER. Thank you, Mr. Chairman.

Senator BROWNBACK. Thank you, Mr. Chairman.

Senator HARKIN. Senator Brownback, we've talked about birth purposes versus therapeutic purposes. I wonder if, in your opinion, does the ultimate purpose for which a particular act takes place affect its morality or affect its propriety? In other words, does the intent of the person who is starting this act or doing these things ultimately affect how we as a society should view this particular act? It seems to me that distinction is being made here, and we're going to hear in a moment from further witnesses who are going to try

to shed some light on that. But I just wondered, in your opinion does that, does the intent matter?

Senator BROWNBACK. I don't know how you effectively draw clear differences if you're basing it upon intent. Is there an intent to implant or not? And yet you've still created the same entity. I don't think you can draw effective differences based upon the intent of the creator of the entity. So I—no, I don't think that's an effective line to draw, and indeed, basically that's what's taking place—here you're saying there's no intent to implant, therefore it's not a clone. Well, then you're making your distinction based upon what's in somebody's thinking process, and I don't think you can effectively do that and I don't think that's the right way for us to consider it. Thank you, Mr. Chairman.

Senator HARKIN. Thank you. Sam, before you leave, I pulled off the Scientific American web site an article that was by Ron Green—Mr. Green will be testifying later—and he said: "What is the moral status of the organisms created by cloning?" And basically—I'll let him read it when he comes up, but I ask—you ought to take a look at it and read it, it's from the November 24 issue, 2001 of Scientific American.

Senator BROWNBACK. I'm glad those issues are being contemplated——

Senator HARKIN. And Ron Green, who wrote it, is going to come up and testify, and I'm going to ask him—because he has a different view of it. He said:

> "We pointed out that, unlike an embryo, a cloned organism is not the result of fertilization of an egg by a sperm. It is a new type of biological entity never before seen in nature. Although it possesses some potential for developing into a full human being, this capacity is very limited. At the blastocyst stage, when the organism is typically disaggregated to create an embryonic stem cell line, it is a ball of cells no bigger than the period at the end of this sentence. Embryos normally do not attach to the wall of the uterus and begin development until after the blastocyst stage. It has no organs, it cannot possibly think or feel, and it has none of the attributes thought of as human. Although Board members understood that some people would liken this organism to an embryo, we prefer the term 'activated egg,' and we concluded that its characteristics did not preclude its use in work that might save the lives of children and adults."

So there's a difference of opinion about what the bioethics advisory commission had termed an embryo. I think these are the things we've got to be thinking about and looking at and getting the scientists and others to talk about and the ethicists and others to talk about.

Senator BROWNBACK. Well, as I stated at the outset, I have far more questions than I have comments at this point, but that's exactly why we should hold up here. Plus I would point out a number of people are saying the embryo is an embryo if it's implanted. Well that's a distinction based upon location. And do we make that distinction anywhere else—that it's an embryo if it's implanted, but it's not if it's not. I think you've got to really question if you draw lines based upon intent, which I don't think you effectively can do, or location as well. And I'm pleased that you're, and others, are considering these very historic type of questions and comments. Mr. Chairman, thank you very much for allowing me to come and discuss the issue and I have a great deal of respect for the charge that you have here.

Senator HARKIN. Thank you very much, Senator Brownback——

Senator BROWNBACK. Thank you.

Senator HARKIN [continuing]. I appreciate it.

Next we'd like to ask our panel to come up—that would be Dr. West, Michael West, Dr. Ronald Green, Dr. Bert Vogelstein and Ms. Phyllis Greenberger. All of your statements will be made a part of the record in their entirety. I'd like to ask if you could sort of summarize them in a short span of time. We'll put the clock on for 5 minutes. But we'll be very lenient there and—maybe 7 minutes or something like that—but if you could summarize it so we could get into a discussion I would appreciate that.

Dr. Michael West, we'll start with you, then we'll just go down the line. Dr. West is the president and CEO of Advanced Cell Technology in Worcester, Massachusetts. He received his bachelor's degree in psychology from Rensselaer Polytechnic Institute, his master's in biology from Andrews University and a Ph.D. in cell biology from Baylor College of Medicine. This is Dr. West's fourth appearance before this subcommittee. So we welcome you back, Dr. West. As I said your statement will be made a part of the record, so please proceed.

STATEMENT OF DR. MICHAEL D. WEST, PRESIDENT AND CEO, ADVANCED CELL TECHNOLOGY, WORCESTER, MA

Dr. WEST. Mr. Chairman and members of the committee, thank you very much for inviting me today. I would like to speak to you both about the opportunities and the challenges we have this year and moving into the coming years. I think we've been seeing three major developments in the history of biology and medicine that will impact our lives and the lives of our children and subsequent generations in, I think, a significant way. The first of course, which is, I think well known now, is the sequencing of the human genome. We have a fundamental new understanding of the blueprint of life, DNA, which will have a profound impact on all of our lives.

I would argue a second major development is the discovery or the isolation of the human embryonic stem cell. These cells are, to use an analogy, the building materials of life. If you imagine the building being constructed, and a truck driving up full of lumber, these cells are completely undifferentiated cells that can branch out and make any cell in the body. And of course their importance in medicine is exemplified by the recent report by the National Institute of Health. There's much discussion about their relative merit compared to the adult stem cell, but just as one simple example of their relative benefit: the embryonic stem cell can self-assemble into a complex tissue given the right circumstances. It can actually form intestine and other kidney tissue, and other important tissues—we've never seen this before in the history of medicine. So these cells are unique and have, I think, an important role in medicine in the future.

A third area where I think we've seen a dramatic advancement that could be used for the benefit of humanity is the discovery of nuclear transfer. What attracted cell biologists and medical researchers such as myself to the discovery of what we call cloning is not, I think, what's popularly perceived. It's not that we could clone our favorite race horse or hunting dog. What excites us about nuclear transfer is that it is a means of taking a person's cell back

in developmental time, to make embryonic stem cells identical to the patient. And of course, what this could mean is—you know, the dream of research scientists—is that we might finally solve this age-old problem of transplantation.

Our automobile, if the carburetor breaks, we can go to the store and get a new one. But, as amazing as it sounds, for our loved ones when we have a heart attack and our heart muscle dies, until now we've never had a means of giving people back all the cells and tissues of their own DNA type so they would not be rejected. And this is one of the greatest promises of the medical uses of nuclear transfer. Of course we're not talking about cloning of humans, as has been pointed out. We're talking about the cloning of cells.

Now it's been—the concept has been introduced, and the concern has been introduced, what is it that we're talking about making here? We're talking about cloned embryos. What are these, and what should be their moral significance? I think this is—and I share with Senator Brownback the concern over—this is a very serious issue. I personally hold a deep respect for the sanctity of human life. And let me say, if the proposition was that we would clone a developing human being, I would argue, with Senator Brownback, we shouldn't cross that line. We have a line here. It's the primitive streak. Early in development—what we call pre-implantation embryos—prior to forming a pregnancy—we're talking about a little clump of cells that has no body cells of any kind, and no cells on their way to becoming yet a body cell of any kind. Purely the raw material of cellular life.

The bright line, I would argue, would be a wise one for us to draw, is primitive streak. At about the time of implantation, this pre-implantation embryo begins the first steps toward becoming human being, or indeed it may form two human beings, identical twins. Primitive streak, I think, is an effective line to draw and say that is the beginning of a human being. And prior to primitive streak we should use some other terminology, a pre-implantation embryo or some other such terminology, because this is not an individualized human being.

I would like to summarize by saying and sharing the sense of gravity on this issue. Millions of human lives hang in the balance on these important decisions. One of the reasons I would not recommend a moratorium is, as I calculate, in 6 months, a 6 month delay in medical research we would estimate would cost potentially 541,800 lives that could potentially be treated someday with these technologies.

PREPARED STATEMENT

And so I would argue rather than slowing medical research, that we take the time to carefully understand these issues, as we did IVF. We had the same, I think, knee-jerk reaction to IVF. Isn't this Brave New World? Isn't this the kind of world we don't want to make? But with time we came to realize that the proposition of making in vitro fertilized embryos and making pregnancies was a gift to mankind. It built families, and it had in it positive benefit.

So what I would ask is, let's take the time and get this right. Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. MICHAEL D. WEST

Mr. Chairman and members of the Subcommittee, my name is Michael D. West and I am the President and Chief Executive Officer of Advanced Cell Technology, Inc., a biotechnology company based in Worcester, Massachusetts. A copy of my curriculum vitae is presented in Appendix A.

INTRODUCTION

I am pleased to testify today regarding human embryonic stem cell and nuclear transfer technology and their applications in medicine. I would like to first speak to the potential benefits of this emerging science, and then speak to some of the questions and concerns that have been voiced.

THE POTENTIAL BENEFITS OF ES AND NT TECHNOLOGY

Human Embryonic Stem (ES) cells are unique in the history of medical research for at least two reasons. First, they alone are totipotent stem cells. By stem cells, we mean cells that can branch out like the stems of a tree, becoming other cell types. By "totipotent" we mean to say that they stand near the base or "trunk" of the developmental tree and so are capable of forming any cell or tissue type needed in medicine. In addition to forming any cell type, they are unique in their ability to self-assemble into complex multicellular tissues such as intestine, full thickness skin, kidney tissue, and so on. They differ in this respect from adult stem cells that are "pluripotent"—that is, capable of forming several, but only a limited number, of cell types. One can think of adult stem cells as limbs further out on the branches of a tree. While able to branch out in several different directions, only the trunk of the tree branches out into every leaf and limb. An example of adult pluripotent adult stem cells are the bone marrow stem cells now widely used in the treatment of cancer and other life-threatening diseases.

The second distinguishing feature of ES cells is the ease with which they can be purposefully modified in a precise manner. This precise genetic modification is designated "gene targeting". The enhanced ability of ES cells to be modified with precision likely opens the door to many hundreds of clinical applications making human cells of any kind, genetically modified in any way to "heal" mutations in genes, something never before possible in medicine.

These two unique characteristics of human ES cells open the door to manifold novel therapeutic strategies. It may not be an exaggeration to state that the combination of the ability to precisely genetically modify these cells by targeted modifications and the ability to make any cell type may have as profound an application in medicine as the ability to arrange electrical components has made in the electronics industry.

To attempt to name every disease that potentially could be treated using this technology would require a larger report. Here are just a few examples. Neurons could be manufactured to treat degenerative diseases such as Parkinson's and spinal cord injury. Gene targeting to find and "heal" mutations could be used to manufacture neuronal stem cells for childhood retardation from diseases like Rett syndrome. Heart and skeletal muscle cells could be used for heart failure and age-related skeletal muscle wasting, and targeted genetic modification could be useful in muscular dystrophy. Blood forming cells would be useful in bone marrow grafting after cancer treatments, and anemias. Precision genetic modification could lead to better therapies for inherited blood cell disorders such as sickle cell anemia and infectious diseases such as AIDS.

I would argue that the debate over the number of human ES stem cell lines approved for Federal funding largely misses the point. Human ES cells obtained from IVF preimplantation embryos are not identical to the patient, that is they are "allogeneic". We should expect that such cells derived from the 20–60 approved lines would be rejected by the patient's immune system. The primary purpose in funding human ES cell research is not just the pure pursuit of human knowledge, but rather to accelerate the delivery of novel therapeutics to afflicted people. We must address from the beginning how we are going to make these cells useful in transplantation.

THE USE OF NUCLEAR TRANSFER IN MEDICINE

The recent success in the cloning of animals from body cells demonstrates that the transfer of a body cell into the environment of an egg cell can "reprogram" it back to an embryonic developmental state. We have recently demonstrated that such technology actually rebuilds the replicative lifespan as well, suggesting that "young" cells can be derived from "old" cells. This is a profound development and perhaps the ideal solution for making real the longstanding dream of transplan-

tation medicine; namely, to be able to offer any patient, even an aged patient, young healthy embryonic stem cells of from which any kind of cell could be make all of which would be their own cells, not expected to be rejected by their immune system.

Nuclear transfer offers an important solution of the problem of tissue rejection. Every year many thousands of people die for the inability to liver, kidney, or other tissue with the right constellation of markers to allow it to accepted by the body as self. It is estimated that three thousand people a day die from degenerative disease potential addressed by therapeutic cloning. This new procedure would begin with the patient donating living cells to a physician, who would then reprogram them back to a totipotent state using the cloning procedure. This is called therapeutic cloning, to distinguish it from reproductive cloning which is designed to clone an entire human being. Therapeutic cloning does not involve the cloning of a human being, it involves the medical use of cloning to make living cells. The cells and tissues made from these cloned stem cells would be expected to be grafted stably for the life of the patient without immunosuppression.

RESPONSES TO CONCERNS AND OBJECTIONS

(1) The preimplantation embryo is a human life and to use therapeutic cloning is to "clone and kill".

Answer. In the first few days following the fertilization of an egg cell by a sperm cell, there develops a microscopic ball of cells called a preimplatation embryo. This embryo is destined to die unless it implants in the uterus to form a pregnancy. Indeed, it is estimated that 50–80 percent of these preimplantation embryos naturally formed in a woman's body never implant and therefore die, naturally. Prior to day 14, the preimplantation embryo has no body cells of any kind, and, in fact, has no cells even committed to somatic cell lineages. Indeed, the embryo has not individualized. Once this ball of cells attaches to a uterus, one or even two or more individuals can form from it. It is therefore proper to say that it is not yet an individual. At ACT, we neither allow cell development beyond day 14, nor do we implant the cells in a uterus.

(2) Therapeutic cloning is merely theoretical; there is no reason to suggest it will work.

Answer. There are published reports of success of therapeutic cloning research in at least two mammalian species; namely mice (1–2). While never performed in a human, the animal data suggests that therapeutic cloning has great promise. The National Academy of Sciences has formally recommended in a report titled "Stem Cells and the Future of Regenerative Medicine" as follows:

"Recommendation: In conjunction with research on stem cell biology and the development of potential stem cell therapies, research on approaches that prevent immune rejection of stem cells and stem cell-derived tissues should be actively pursued. These scientific efforts include the use of a number of techniques to manipulate the genetic makeup of stem cells, including somatic cell nuclear transfer."

(3) Allowing therapeutic cloning would cause a "slippery slope" effect, whereby regulating human reproductive cloning would not be possible.

Answer. In reality the procedures to clone a human being are well known in the scientific literature. The widespread use of therapeutic cloning would not significantly increase the likelihood of the success of an effort to clone a human being. In addition, laws can easily be written to allow one and prohibit the other as reproductive cloning requires the transfer of a cloned preimplantation embryo into a uterus.

(4) Therapeutic Cloning will lead to "embryo farms".

Answer. Therapeutic cloning guidelines could easily be constructed to limit development to less than 14 days as is the current practice with in vitro fertilization.

SUMMARY

In conclusion, nuclear transfer and human embryonic stem cell technology offer novel pathways to develop lifesaving therapies that will impact the lives of millions suffering from such diseases as Parkinson's disease, diabetes, arthritis, heart disease, kidney failure, spinal cord injury, liver failure, skin burns, blood cell cancers, to name only a few. The gravity of this issue calls for a compassionate, reasoned, and dispassionate debate. History will judge us harshly if we as a society fail to recognize and deliberate carefully upon a medical technology that could so powerfully alleviate the suffering of our fellow human being.

SOMATIC CELL NUCLEAR TRANSFER TECHNOLOGY IS JUSTIFIED AND ESSENTIAL FOR PRODUCING EMBRYONIC STEM CELLS FOR BASIC RESEARCH AND THERAPEUTIC APPLICATIONS

Since 1997 The American Society for Cell Biology has stated and stood by its strong opposition to the reproductive cloning of human beings. Media claims notwithstanding, current scientific information suggests that the technology now available will not be able to lead to the creation of a cloned human being or to an embryo capable of being born as a cloned normal human. Equally important, no responsible scientist favors reproductive cloning.

It is unlikely that current biomedical technology can be used to clone adult human beings. But there is substantial justification to believe that somatic cell nuclear transfer (SCNT), or what many have referred to as therapeutic cloning, will energize scientific progress in the fight against the most debilitating illnesses known to man. New embryonic stem cell lines, potentially capable of avoiding the rejection complications of stem cell therapies for cancer, diabetes, spinal cord injury, kidney disease, and Parkinson's disease, may be produced by using the genetic material of the prospective transplant recipient to generate recipient-matched stem cells. These procedures could be vital in solving the persistent problem of a lack of genetically matched, qualified donors of organs and tissues that we face today. Stem cell research is an essential first step if we are ever to be able to achieve the promise of regenerative medicine, a wholly new approach for repairing cells and tissues in the treatment of currently intractable human diseases. Beside the therapeutic promise, the SCNT procedure permits entirely new approaches to the study of the earliest phases of human development, of how a single cell is transformed into the trillions of different cells and tissues with myriad fates and capabilities during embryonic development. By deriving embryonic stem cells with defined mutations scientists gain a new approach to understanding how such inherited predispositions lead to serious disease in adulthood.

Unfortunately, an onerous cloud has been cast on the term cloning because it has been used in the public discourse both to refer to attempts to create genetically identical adult humans and to describe other procedures that are less controversial. However, cloning is a scientific term that describes the preparation of an "infinite" number of copies of, for example a single molecule, cell, virus or bacterium. For example, cloning DNA molecules was essential for solving the human genome sequence. Similarly, cloning DNA is critical to fight against bioterrorism and has already been used in the determination of the entire genome sequences of several organisms identified as bioweapons. Furthermore, cloning is integral to modern forensic procedures, medical diagnostics, vaccine development, and the discovery and production of many of the most promising drugs. Cloning is also used to make genetically identical plants and livestock enabling continued agricultural breakthroughs necessary to feed a rapidly growing and undernourished world population.

Conflating the term cloning as it is used for the creation of genetically identical humans with the valuable and appropriate uses of cloning embryonic stem cell lines for basic research and therapeutic purposes is inappropriate. The two issues need to be considered separately; otherwise we run the serious risk of sacrificing certain great benefits to prevent a perceived undesirable practice.

Senator HARKIN. Thank you, Dr. West. Senator Specter has to go to another committee, but wanted to ask a question or two before he left. Normally I'd go through the whole panel, but I'm going to interrupt right here and let Senator Specter——

Senator SPECTER. Well, thank you very much, Mr. Chairman. The Judiciary Committee is meeting on the military tribunals and I'm going to have to excuse myself for a few minutes and I'll come back as soon as I can. But I wanted to question you a bit here, Dr. West. Picking up on the number of lives which you said could be saved in the intervening 6 months, what is the basis for you conclusion on that?

Dr. WEST. That's based on the number that approximately 3,000 people die a day, every day, from degenerative diseases that could potentially be treated with these technologies.

Senator SPECTER. So you think you could save a total of how many lives? And it will be—the delay would cost how many lives?

Dr. WEST. It's a large number, because——

Senator SPECTER. What figure had you just said?

Dr. WEST. 3,000 a day.

Senator SPECTER. So you made a calculation of 541,000, more than a half million lives would be lost by a 6 month delay?

Dr. WEST. Obviously we're not talking about therapies that would be available next week, next month, next year, but a delay would have that impact someday on——

Senator SPECTER. On the results that you reported, the embryos did not live. Is there any chance at all of human reproductive cloning in a 6 month period? Any chance at all?

Dr. WEST. Reproductive cloning? I don't think so.

Senator SPECTER. Creation of a human being.

Dr. WEST. Well, I mean, there's always some measurable chance. But the cloning of a human being, in my own professional opinion, I don't believe that that's at all a likely outcome.

Senator SPECTER. Dr. West, where the example has been used about taking the genetic material out of an unfertilized egg and illustratively taking some skin tissue from somebody who has Parkinson's, and placing that in the egg and then implanting it—could that result in having a human being created? If so, what if the donor of the DNA is a woman, is that possible, scientifically?

Dr. WEST. If the donor of the DNA is a woman?

Senator SPECTER. Yes.

Dr. WEST. Could a woman clone herself, you mean, or through——

Senator SPECTER. Well, the donated egg comes from woman, obviously. Then you have a woman who has Parkinson's, and you get a DNA specimen from that woman who has Parkinson's, and you put that in the donated egg—can that then be implanted in a woman and create a baby?

Dr. WEST. I think your diagram is very accurate. As far as we know today, both branches of that diagram are possible. So we believe, indeed, it would be—as best as we know today, possible.

Senator SPECTER. Even if the DNA from the Parkinson's patient comes from a woman?

Dr. WEST. If I understand your example correctly, once you've made a pre-implantation embryo by nuclear transfer, if that embryo was transferred into a uterus in an attempt to establish a pregnancy, which obviously it is not at that point, pregnancy would be possible.

Senator SPECTER. Even though you have a woman who has donated the egg, and you have a woman whose DNA is transplanted to the donated egg, you can create a baby?

Dr. WEST. As I understand your question, yes.

Senator SPECTER. The answer then is yes?

Dr. WEST. If the cell, the DNA from the sick patient is, you know, healthy DNA, then you would expect that you could create a healthy baby by transferring——

Senator SPECTER. And it doesn't matter that the DNA comes from a woman?

Dr. WEST. No. No, indeed Dolly the sheep was cloned from a female.

Senator SPECTER. Thank you very much. I'll come back as soon as I can.

Senator HARKIN. Okay, thank you very much, Senator Specter. Now we turn to Dr. Ronald Green. Dr. Green's been a member of Dartmouth University Faculty for 20 years. He is now the director of the Ethics Institute and Chair of the Religion Department. Dr. Green graduated from Brown University and received his Ph.D. in religious ethics from Harvard University. Now Dr. Green, I didn't mean to quote you earlier, but I had read that article in Scientific American, so I decided to go ahead and quote it, but—again, welcome, and please proceed.

STATEMENT OF DR. RONALD M. GREEN, PROFESSOR, DARTMOUTH COLLEGE

Dr. GREEN. Thank you for doing so, Senator Harkin. Good morning to Senator Harkin and the other members of the committee. As has been indicated, I am a professor of religion at Dartmouth College, where I also chair the Ethics Institute. As a matter of public service, I serve as head of the Ethics Advisory Board, or EAB as we call it, of Advanced Cell Technology in Worcester, Massachusetts. ACT's scientists recently announced that they had successfully produced the first cloned human organism. I want to report to you on some of the ethical reflections that led the members of ACT's EAB to endorse this research. Above all, I want to signal a crucial difference between what has been called reproductive cloning and the kind of so-called therapeutic cloning research in which ACT is engaged.

Reproductive cloning, as has been said today, aims at the birth of a child. ACT has never pursued this goal. All the members of ACT's EAB believe that at this time reproductive cloning in human beings is too risky to be responsibly pursued. In addition, most EAB members believe that many other difficult ethical questions would have to be answered before reproductive cloning could ever be justified. Therapeutic cloning is an entirely different matter. This is the kind of research ACT is conducting. Therapeutic cloning involves the use of nuclear transfer or cloning technology to produce immunologically compatible human stem cell lines. If therapeutic cloning research is successful it will mark the beginning of a new era in medical science.

You have all heard about the promise of human stem cells, the basic building blocks from which almost any tissue in the human body could be fashioned. This summer, President Bush authorized Federal funding for research using a limited number of human stem cell lines. However, the problem with these and any other stem cells is that the patient's body would see them as foreign tissue. The result could be rejection. Therapeutic cloning offers a way around this problem. In the future, the mother of a child suffering from juvenile diabetes could donate an egg from one of her ovaries. A cell could be scraped from the inside of the child's cheek. Using a cloning procedure it might then be possible to produce a stem cell line that could be coaxed to differentiate into new insulin-producing cells. These could be injected back into the child's body, where they would not likely be rejected. The child would be spared a life-threatening disease.

The members of ACT's EAB came to the conclusion that this research direction is important and ethically sound. On the one hand, we believe that the life-saving promise of this research constitutes an important ethical consideration in its favor. On the other hand, as we reviewed the biological qualities of these cloned organisms, we concluded that they could not be equated morally with the children or adults whose lives could be saved by therapeutic cloning research. We noted that these clusters of cells lack most of the qualities we normally equate with a human life. They are not the result of the union of sperm and egg. They represent an entirely new kind of biological organism, never before seen in nature. They have no differentiated cells, and cannot think or feel. Because spontaneous twinning is still a possibility at this very early stage of development, they are not yet human individuals.

We acknowledge that others may come to different conclusions about the moral status of this very early form of human life. We doubt, however, that there is a moral consensus in our society about this matter or likely to be one soon. In view of this, we concluded that privately funded researchers and scientists should be free to continue with this research on the basis of their own conscientious beliefs.

The primary message I have tried to communicate today is that therapeutic cloning and reproductive cloning are two different things. Some will object, however, that there is a slippery slope here, that therapeutic cloning could lead to reproductive cloning. For two reasons, the members of the ACT EAB did not share this fear. First, we believe that open and publicly discussed research like this may actually reduce the chances that unscrupulous researchers will pursue reproductive cloning. It could do so by highlighting the physiological dangers of reproductive cloning. ACT's research shows that cloned human organisms are extraordinarily fragile. Second, we do not agree that shutting down therapeutic cloning research is an effective way of blocking reproductive cloning. The best way to do that now is by imposing and enforcing a strict ban on reproductive cloning. Adding therapeutic cloning to the prohibition will only result in the loss of the medical benefits that therapeutic cloning research can bring. If I may use an analogy, banning therapeutic cloning in order to stop reproductive cloning is a little bit like halting all air travel in order to prevent hijacking.

PREPARED STATEMENT

The members of ACT's EAB stand ready to share our ethical debates and conclusions with you and the members of the public. Thank you very much for inviting me here today.

[The statement follows:]

PREPARED STATEMENT OF DR. RONALD M. GREEN

Good morning. I am Ronald M. Green, a professor at Dartmouth College in Hanover, New Hampshire, where I head the Department of Religion and direct the Ethics Institute. As a matter of public service, I also serve as chair of the Ethics Advisory Board (or EAB) of Advanced Cell Technology in Worcester, Massachusetts. The EAB is an independent body of ethicists and health care professionals brought together by ACT to provide guidance and oversight for the company's research.

ACT's scientists recently announced that they had successfully produced the first cloned human embryo. This accomplishment is the first step in the company's effort to use nuclear transfer (cloning) technology to produce replacement cells or tissues that would not be subject to rejection by a patient's body. The ACT EAB provided oversight for this research. I am here to report briefly to you on some of the ethical reflections that led us to endorse, with careful consideration, the research in question.

Above all, I want to signal a crucial difference between what is called "reproductive cloning" and the kind of "therapeutic cloning" research in which ACT is engaged.

Reproductive cloning aims at the birth of a child. ACT has never pursued this goal. All the members of ACT's EAB agree that at this time reproductive cloning in human beings is too risky to be responsibly pursued. Cloned animals in many species have evidenced problems during gestation or following birth. Until further research establishes the likely safety of cloning in human beings it would be irresponsible to try to bring a human child into the world in this way. In addition, most EAB members believe that many other difficult ethical questions would have to be answered before reproductive cloning could ever be justified.

Therapeutic cloning is an entirely different matter. It involves the use of nuclear transfer (cloning) technology to produce human stem cell lines. To accomplish this, a cloning procedure is used to produce a small cluster of early dividing cells similar to but not the same as a normal human embryo. Because these cells are produced by nuclear transfer, they are not the product of fertilization. They represent an entirely new kind of biological organism never before seen in nature. Following international guidelines, ACT's EAB laid down strict rules for the handling of these organisms, including the requirement that none be allowed to develop beyond fourteen days. We also insisted upon intensive security and monitoring procedures to insure that no cloned organisms could be diverted to reproductive purposes.

If ACT's research on therapeutic cloning proves successful, it will mark the beginning of a new era in medical science. You have all heard about the promise of stem cells, the basic building block cells from which almost any tissue in the human body can be fashioned. This summer, President Bush authorized Federal funding for research using a limited number of stem cell lines already in existence. However, the problem with these and any other stem cells is that the patient's body would see them as foreign tissue. The result would be rejection, or, worse, a very serious toxic crisis. To minimize these problems, patients could be given immunosuppressive drugs. But these drugs carry their own risks because they expose the patient to infections or the risk of developing cancer.

Therapeutic cloning promises a dramatic way to avoid all of these problems. In the not-too-distant future, the mother of a child suffering from severe Type I juvenile diabetes could donate an egg from her own ovaries. A cell could be scraped from the inside of the child's cheek. Using the kind of nuclear transfer procedure being researched now by ACT, it might then be possible to produce a stem cell line that could be coaxed to differentiate into new insulin-producing cells. These cells could be injected back into the child's body, where they would provide an entirely new pancreatic system. Because these cells are made from the child's own genetic material, they would not be rejected. The child would be spared a life-threatening disease often accompanied by amputations or blindness.

I should note that therapeutic cloning is only a transitional technology toward the long-term goal is direct cell reprogramming. We know that in the nuclear transfer procedure something almost magical happens when a differentiated cell nucleus is placed inside an egg. Substances in that egg return the nuclear DNA to its embryonic state and prepare it to become any cell type in the body. If cloning research helps scientists to understand these processes, the cloning step might be skipped. A cell could be taken from any of our bodies and directly induced to become primordial nerve, blood, muscle or skin tissue. By means of both therapeutic cloning and eventually direct cell reprogramming, we might realize the Biblical vision of the lame walking and the blind seeing.

ACT's EAB came to the conclusion that this research direction is important and ethically sound. On the one hand, we believe that the lifesaving promise of this research constitutes an important ethical consideration in its favor. On the other hand, as we reviewed the biological qualities of these cloned organisms, we concluded that they could not be equated morally with the children or adults whose lives could be saved or health restored by therapeutic cloning research.We noted that these clusters of cells, while arguably worthy of some respect, lack most of the qualities we normally equate with a human life. They are not the result of the union of sperm and egg. They lack differentiated cells and cannot think or feel. Since spontaneous twinning is still a possibility at this very early stage of development, they

even lack individuality. It is true that they could potentially go on to full development if placed in a womb. But in an era of cloning technology, this statement is true of every cell in our body. Surely we would not want to declare every human cell or tissue off limits to research.

We acknowledge that others may come to different conclusions about the moral status of this very early and novel form of human life. We doubt, however, that a consensus now exists in our society about this matter. In view of this dissension, we concluded that privately funded researchers and scientists should be free to proceed with this research on the basis of their own conscientious beliefs. We hope that the Senate will agree.

The primary message I have tried to communicate today is that therapeutic cloning and reproductive cloning are two different endeavors. Some will object, however, that there is a slippery slope here, that therapeutic cloning will lead inevitably to reproductive cloning and the birth of a human clone. Again, after considering this matter carefully, the members of the ACT EAB did not agree. Two considerations moved us.

First, we believe that open and publicly discussed research like this may actually reduce the chances that unscrupulous researchers will pursue reproductive cloning. It could do so by highlighting the physiological dangers of reproductive cloning. Most of the cloned human embryos produced at ACT died within hours of the nuclear transfer procedure. They are extraordinarily fragile and vulnerable organisms. Even if it is possible eventually to produce a stem cell line from these entities, as ACT researchers hope to do, it will be years before we understand all the genetic factors that are necessary for a healthy pregnancy and birth. Irresponsible researchers will certainly try to beguile women or couples into cooperating with reproductive cloning research by promising them a healthy child. ACT's published research on therapeutic cloning can help to better inform such couples of the gravity of the risks.

Second, we do not agree that shutting down therapeutic cloning research is an effective way of blocking reproductive cloning. The best way to do that now is by imposing and enforcing a strict ban on reproductive cloning. Adding therapeutic cloning to the prohibition will add little force to it and will additionally result in the loss of the medical benefits that therapeutic cloning research can bring. If I may use a readily understandable analogy, I believe that trying to stop reproductive cloning by banning therapeutic cloning is a little bit like trying to prevent hijacking by halting all air travel. The members of ACT's EAB stand ready to share our extensive ethical debates and conclusions with you and other members of the public. Thank you very much for inviting me here today.

Senator HARKIN. Thank you very much, Dr. Green. Now we'll turn to Dr. Bert Vogelstein. Dr. Bert Vogelstein is a professor of oncology and pathology at Johns Hopkins University, a leader and international expert and pioneer in the field of molecular genetics. He received his medical degree in 1974 from Johns Hopkins, where he's also completed his internship and residency. He joined the Johns Hopkins faculty in 1978. Dr. Vogelstein.

STATEMENT OF DR. BERT VOGELSTEIN, PROFESSOR OF ONCOLOGY AND PATHOLOGY, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD

Dr. VOGELSTEIN. Thank you, Mr. Chairman, all the members of the committee. I take to heart Senator Specter's directive to scientists to help clarify the issues in this debate. I think it is our responsibility to do so. In particular, my goal today is to try and clarify the differences between these very different procedures: one-cloning and second, regenerative medicine. And towards that goal I'd like to today propose a different name for the second procedure, the name nuclear transplantation. I think that has significant advantages over other names that have been used to describe parts of this procedure, such as therapeutic cloning, which is really not accurate, is a misnomer, or somatic cell nuclear transfer, although scientifically accurate, it's a mouthful.

In contrast, nuclear transplantation is both perfectly accurate and, in addition, has the connotation of transplantation. That's

what this scientific procedure is used for, much like bone marrow transplantation, heart transplantation, liver transplantation. The sole purpose of this procedure is to produce cells for transplantation.

Now I'd like to explain some of the scientific differences between these two procedures. What is a clone? A clone is an exact copy of an organism. The organism could be a fruit fly, it could be a mouse, it could even, perhaps, be a human. In the movie "Multiplicity" clones were created. Those were real clones, at least on the movie screen. There's a difference between clones and cells. Let me illustrate those differences by comparing what we could do with cells taken from me. I could take a—skin cells from a little biopsy or cheek cells, or I could even take a hair. Now, is that hair a clone of me? It's not such a trivial question, because each cell in the hair is genetically identical to me, to every other cell in my body, and moreover, the cells in that hair have the potential to be me. It used to be, just a few years ago, thought that there was a strict line between the potential to form human life and human life, and that potential was only in embryos. But we now know that every living cell in an animal's body could at least potentially be used to create human life. And it's very important to discriminate the potential for human life from real human life.

Let me give you some more examples that will emphasize these distinctions. This hair—is it a clone of me? Well, it can't walk, it can't talk, it can't be educated, it can't marry my wife, it can't father my children—it can do none of the things that we equate with human beings, and it would be clearly wrong to look or consider the cells in this hair as a clone—they are not.

Now, what else could we do with the cells from this hair? I could put them in a culture dish. I could grow millions of cells that were genetically identical to that hair or the cells from the hair. And, interestingly enough, I could use nuclear transplantation to create a variety of other cell types different from the hair that I could do even more interesting things with. Why would I do that? If I had Alzheimer's Disease or Parkinson's Disease or a variety of other degenerative diseases for which there was no other cure I might want to make such cells from that hair cell in a test tube. But these other cells are no more a clone of me than were the cells in the hair. There's a huge difference between the cells derived from me and a clone of me.

And furthermore, it's important to point out that one of the reasons I might wish to do this is that other forms of stem cells, such as those approved by President Bush on August 9th, could not do the same thing. Any of those other 64 lines, if I used them for transplantation purposes to try to correct a degenerative disease would not do the trick, they would be rejected, because they are not derived from me, they are not genetically identical to me.

PREPARED STATEMENT

I urge you then to deeply consider the differences between nuclear transplantation and human cloning, and to consider the enormous impact on research and, indeed, patients' lives if a ban on nuclear transplantation were to be enacted. President Bush's announcement on August 9th to allow Federal funding for research

on existing stem cell lines was a giant step in the direction toward realizing the promise of stem cells in regenerative medicine. To ban nuclear transplantation would be a giant step backwards in this effort. Thank you, and I'd be glad to try to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF DR. BERT VOGELSTEIN

Good morning, Mr. Chairman, and members of the Committee. My name is Bert Vogelstein, and I am a Professor of Oncology and Pathology at the John Hopkins Oncology Center and a Howard Hughes Medical Institute Investigator. I am here today as the chairman of a National Research Council and Institute of Medicine Committee on the Biological and Biomedical Applications of Stem Cell Research that recently released the report: "Stem Cells and the Future of Regenerative Medicine."

My goal today is to clarify some of the confusion surrounding two very different medical endeavors; the first is regenerative medicine, and the second is the cloning of a human being. Regenerative medicine, which as a field is in its infancy, involves growing cells and tissues for implantation in people with diseases or injuries to their organs, for example diabetes, Parkinson's disease, heart disease, and spinal chord injury. The most promising avenue of regenerative medicine is the use of embryonic stem cells for eveloping tissues of many different types for transplantation into patients with these diseases or injuries.

A substantial obstacle to the success of transplantation of any cells, including stem cells and their derivatives, is the immune reaction of a patient's body to cells that it perceives as foreign. Our report recommended that multiple approaches to reducing this problem be explored, including ways to manipulate the genetic makeup of the stem cell tissue to make it less likely to provoke an immune reaction, the creation of a large bank of diverse stem cell lines, and the development of embryonic stem cells using a technique known as somatic cell nuclear transfer. This involves taking the DNA from a cell of a patient in need of a transplant, inserting it into an egg cell that has had its nucleus removed, and triggering cell division. The resulting stem cells and tissue that can be obtained from this procedure would be genetically identical to the patient's cells, and would in theory not be rejected by the patient's immune system when transplanted into him or her.

This procedure for producing embryonic stem cells that are genetically identical to the donor's tissue should not be confused with human cloning, which has the goal of creating a human being. In that endeavor, the DNA from the cell of an individual would be inserted into an egg cell that has had its nucleus removed, and that embryo would be implanted into a woman's uterus so that it would grow into a child who is genetically identical to the individual whose DNA was inserted into the egg.

Unfortunately, the notion that genetically identical stem cells are the same as a genetically identical human being has obfuscated the important potential of developing transplant therapies with lower probabilities for rejection, and greater chance of helping improve the health of many sorts of patients.

There has been much confusion surrounding the terminology common to the causes of both regenerative medicine and those who wish to clone human beings. Because the term "therapeutic cloning" has been used by different sources to mean both the cloning of human beings and the production of embryonic stem cells genetically identical to their donor, it has become effectively useless. And because the term "somatic cell nuclear transfer" smells of scientific jargon, I propose the use of the term "nuclear transplantation" be entered into the debate over cloning legislation.

I urge lawmakers to deeply consider the differences between nuclear transplantation and human cloning, and to consider the enormous impact on clinical research, and indeed patients' lives, if a ban on nuclear transplantation were to be enacted. President Bush's announcement last August to allow Federal funding for research on existing embryonic stem cell lines was a great step in the direction toward realizing the promise of stem cells in regenerative medicine. To ban nuclear transplantation would be a step backwards in this effort.

Our committee is respectful of the wide array of social, political, legal, ethical, and economic issues that must be considered in policy-making in a democracy, and we have been impressed by the commitment of all parties in this debate to life and health, regardless of the different conclusions they draw. It should be recognized that a large number of citizens oppose human cloning at the same time they support embryonic stem cell research and regenerative medicine. We hope our report, by

clarifying what is known about stem cells and how best to realize their potential, will be a useful contribution to the discussion of this important issue.

Thank you for this opportunity to testify. I would like my statement to be put into the record, and I will be happy to answer any questions the Committee might have.

Senator HARKIN. Dr. Vogelstein, thank you very much for a very, I think, fairly presented concept. Now we turn to Ms. Phyllis Greenberger. Greenberger is the first president and CEO of the Society for Women's Health Research, a Washington, D.C.-based advocacy organization formed in 1990 to utilize medical research to improve the health of women. Ms. Greenberger received her bachelor's degree from Syracuse University and a master's from Catholic University here in Washington, D.C. Ms. Greenberger, welcome and please proceed.

STATEMENT OF PHYLLIS E. GREENBERGER, PRESIDENT AND CEO, THE SOCIETY FOR WOMEN'S HEALTH RESEARCH, WASHINGTON, DC

Ms. GREENBERGER. Good morning Mr. Chairman and members of the subcommittee. As you said, I'm Phyllis Greenberger, president of the Society for Women's Health Research, and I appreciate the opportunity to present this morning. And also, as you said, our mission is to improve the health of women through research.

For the last 10 years the Society has spoken out on important scientific issues that advance research on women's health, and have the potential to alleviate suffering and improve the quality and longevity of life. Today's discussion about therapeutic cloning is no exception. The Society is deeply concerned about any impediments that would slow research in regenerative medicine. This area of research has the potential to treat a range of confounding human diseases and health disorders, many of which are prevalent in or disproportionately affect women.

The specter of human reproductive cloning clouds the potentially enormous benefits of this new area of research. The future benefits are being overshadowed by a new cycle of ethical and political debate. We must carefully distinguish between creating an entire human being and therapeutic cloning, which, used in conjunction with new stem cell research, has the potential to produce new diagnostics, medicines and vaccines.

Research on human stem cells derived from both adults and embryos provides the most efficient and responsible means to fulfilling the promise of regenerative medical research for achieving medical breakthroughs. The Society for Women's Health Research believes that the potential of therapeutic cloning for treating and perhaps curing a variety of debilitating diseases demands that the scientific community be allowed to continue this promising work. Unfortunately, if the Senate were to pass the cloning prohibition act, HR 2505, this research would be prohibited.

Many of these research advances are critically important to women. We are on the cusp of putting into everyday medical practice many promising techniques. Investigators are evaluating the use of embryonic stem cells to treat incontinence. Stem cell tissue engineering has been used to restore urethral sphincter muscles in animal models. This lays the foundation for further investigative methods to use stem cells to treat urinary incontinence. Urinary incontinence affects 35 percent of American women over the age of

50. This kind of stem cell research is also being used to transplant or replace damaged cells in Parkinson's Disease. Studies in animal models have shown that embryonic stem cells derived from neural cells can be used successfully to treat nervous system disorders. Mouse embryonic stem cells which were stimulated to differentiate into neural cells, when transplanted into mice with neurological disorders helped to restore normal function. Heart muscle cells known as cardiomyocytes do not regenerate after being damaged by a heart attack and are replaced with non-functioning scar tissue. Each year more than 1 million Americans, more than half of them women, will have a heart attack, which is the primary cause of heart muscle damage. Therapeutically treated cardiomyocytes in animal tests have been shown to replace heart tissue and successfully reintegrate into the animal's heart.

We should also not overlook the fact that this field of research may also improve the way we develop and test new drugs. These drugs could be tested on liver cells or skin cells, and only those drugs that are safe and effective would be advanced for testing in humans.

Embryonic stem cell research is in its infancy and holds tremendous promise. An enormous amount of research must be done before it can be translated into medical treatments, but we should carefully weigh the implications of any roadblocks that might derail it. Any impediments would have serious implications for medical research. Pharmaceutical and biotechnology companies that have the resources to translate these breakthroughs into medical treatments would be reluctant to invest in this research if serious roadblocks were created.

We recognize that this research is controversial. But therapeutic cloning should not be confused with reproductive cloning. Never is there any intention of implanting the resulting embryo to produce a child. In therapeutic cloning the nucleus of an egg cell is removed and genetic materials are inserted from the transplant recipient, triggering cell division. This new technique goes a long way to overcoming tissue rejection, an important breakthrough in organ and tissue transplantation.

I believe it is important to point out that both the National Institutes of Health and the National Academy of Sciences recently noted that the use of this technique will lead to promising new techniques for patients. We understand the fundamental ethical dilemmas and scientific uncertainties raised by therapeutic cloning. The Society concurs with the National Academy of Sciences, which in late November created a national advisory committee made up of leading scientists, ethicists and other stakeholders to be established at the National Institutes of Health. This group is charged with ensuring that proposals for Federal funding to work on embryonic stem cells are justified on scientific grounds, and meet current and future federally mandated ethical guidelines.

The NIH in the past has set up similar watchdog panels including a recombinant DNA admonitory committee which oversees the once-controversial genetic engineering research. The Society agrees with a recent Washington Post editorial which said that barring all therapeutic cloning would likely drive research underground, and

guarantee that only the most unscrupulous would advance these technologies.

PREPARED STATEMENT

We urge you to take time and carefully weigh appropriate options for promoting public policy that best serves the nation. A rush to judgment would be premature, and has the potential for impeding much-needed and potentially beneficial research. Thank you very much, Senator.

[The statement follows:]

PREPARED STATEMENT OF PHYLLIS E. GREENBERGER

Good morning, Mr. Chairman and members of the subcommittee. I am Phyllis Greenberger, president of the Society of Women's Health Research. For over 10 years the Society has spoken out on important scientific issues that advance research on women's health and have the potential to alleviate suffering and improve the quality and longevity of life.

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This group is charged with ensuring that proposals for federal funding to work on embryonic stem cells are justified on scientific grounds and meet current and future federal mandated ethical guidelines. The NIH in the past has set up similar watch dog panels including the Recombinant DNA Admonitory Committee which oversees the once controversial genetic engineering research.

The Society agrees with a recent *Washington Post* editorial which said that barring all therapeutic cloning would likely drive research underground and guarantee that only the most unscrupulous would advance these technologies. We urge you to take time and carefully weigh appropriate options for promoting public policy that best serves the nation. A rush to judgment would be premature and has the potential for impeding much needed and potentially beneficial research.

Senator HARKIN. Thank you, Ms. Greenberger. Thank you all again for being here and for your statements. I'll start with my time of 5 minutes, then I'll recognize the senator, Senator DeWine.

Dr. West, let's start with you. Just a few weeks ago your company, ACT, indicated that you were able to take out the DNA from the donated egg, you took DNA from another donor—I don't know from what, where you derived that DNA—and you replaced it in the egg, but that it only developed into four or five cells. Could you elaborate on that? Now, the reason I'm asking is that—some have said that what you did was not all that significant, that this is not a big breakthrough, that the breakthrough will come when you actually are able to develop that into the blastocyst stage. Could you respond to that, please?

Dr. WEST. Right. What we reported on were the first steps towards demonstrating that this technique will work in humans. It's previously—us and others have demonstrated that this technique appears to work in mouse—where mouse skin cells were taken back to an embryonic state by nuclear transfer, making Parkinson's neurons and other types of cells. And we demonstrated this in a cow, as well—that you could reprogram a cell back in time using nuclear transfer.

On a human, we just reported that the first evidence is that we believe this will work. What were those evidences? One, what happens to the DNA of a body cell when you put it into an egg cell is, it is reprogrammed, like when you put a disk into a computer and you say "initialize," it takes it back to its blank state, this embryonic state. And when a somatic cell, body cell nucleus is put into an egg cell and reprogrammed, it takes on a certain kind of shape and appearance, called the pro-nucleus. And we reported——

Senator HARKIN. A pro or cro——

Dr. WEST. Pro-nucleus it's called. And we reported that, as evidence that—again, preliminary evidence, very preliminary, but—first steps that this is—the DNA is being reprogrammed, we reported that we saw pro-nuclear development.

No. two, we reported that we got the beginnings of cell divisions. Now obviously we would need to get these cells to divide to some one hundred cells, we think, to effectively take the step of making stem cells and then making medically useful cell types. We also reported on some related observations, what we call parthenogenesis, which is a whole separate discussion and a separate way of making stem cells directly from an egg cell.

The reason we reported on this without having taken the technology all the way through to showing that we could make stem cells and medically important stem cells, is in the spirit of transparency. We felt that it was important for us to publish often, every step, so we disclosed early on that we had arranged for egg cell donors to provide us with egg cells, and we decided that we would report each step of the way. Similar to the way in IVF, back some twenty years ago, Bob Edwards in publishing on the production of human embryo as an idea, first reported a paper that the sperm cell has penetrated the egg, and then another paper on -he'd gotten the embryo to divide once, and then another paper when he divided to make an embryo, and of course, finally, the production of the baby.

Senator HARKIN. Now let's get something secure and on the record. What you did is right now not against the law—there's no law against what you did.

Dr. WEST. That's correct.

Senator HARKIN. As I understand it there is no law against taking it the next step. In other words, if you were to take the DNA and put it into an egg from which the donor egg's DNA had been removed, and you were able to grow that into the blastocyst stage and to remove stem cells, there is no legal ban on that now, either?

Dr. WEST. As far as I understand.

Senator HARKIN. That's my understanding, I'm just wondering if any of you have any different understanding of that, Dr. Green, is that correct?

Dr. GREEN. I believe that is correct, there is no law that——

Senator HARKIN. Yes, I believe that's also correct, there's no Federal funding for it, but there's no law against it, for private entities to continue on down that course.

You told us two or three years ago you were doing this. I mean, it was not anything you didn't tell us, that ACT was going to be working on. I assume that you are proceeding to perfect the technique for the extraction of stem cells. My question is, what kind of timeline do you see for that, when you would actually have that kind of breakthrough where you could actually reach the blastocyst stage, remove the stem cells, and then regenerate them?

Dr. WEST. It's a difficult question to answer. We just reported yesterday in a meeting at the Society for Regenerative Medicine some now rather old research on nuclear transfer in non-human primates. When we move from one species to another like the recent effort to try to clone pigs, we saw obstacles in making this technology work, and then suddenly by altering the laboratory—

you know, the recipe, the media that these cells are grown in, so on, suddenly we get successful results. It's difficult to predict. And I would hesitate to——

Senator HARKIN. Could you do it in the next month or two?

Dr. WEST. You know, I would—let me say it this way: I would be disappointed if we could not publish another paper, scientific paper showing that we had successfully made heart muscle cells, neurons for Parkinson's and so on, using this technology, sometime in the next 6 months or so. I'd be disappointed if we couldn't do that in that timeframe.

Senator HARKIN. That's quite promising. Senator DeWine.

Senator DEWINE. Thank you, Mr. Chairman. Dr. Green you—let me quote from your written statement, and then I'll want to ask you a question if I could.

"We concluded that they could not be equated morally with the children or adults whose lives could be saved or health restored by therapeutic cloning research. We noted that these clusters of cells, while arguably worthy of some respect, lack most of the qualities we normally equate with a human life. They are not the result of the union of sperm and egg. They lack differentiated cells and cannot think or feel. Since spontaneous twinning is still a possibility at this very early stage of development, they even lack individuality."

And that's the end of the quote. During that period of time, are—this cluster that you refer to, is it distinguishable in any way from a cluster that would have been formed as a result of the conventional union of the sperm and egg? From a scientific point of view, not knowing how it started, is it distinguishable in any way? Or could that statement have been true about a cluster that was formed in the traditional way.

Dr. GREEN. Well, I think apart from the fact that the DNA is wholly from one individual, and there may be subtle differences at the DNA level, probably not. It might look like the result of fertilization.

Senator DEWINE. So my question, my point is, when you say, "they lack differentiated cells" that would be true.

Dr. GREEN. That's correct.

Senator DEWINE. They can't think. Or feel. And spontaneous twinning is still a possibility. So from a—however you come down on this issue—and obviously this is—I think we've had a very good discussion and debate here. There is no real distinction between what you have described and what we would see from the normal union of sperm and egg other than what you just said about the DNA. I just want to make sure I understand from a scientific point of view——

Dr. GREEN. I think that is correct, Senator——

Senator DEWINE. That's all, if anyone disagrees they can jump in, but just, from a scientific point of view I wanted to make sure I understood what we were——

Senator HARKIN. Will the Senator yield on that point, then? I do have a question.

Senator DEWINE. Well sure, Mr. Chairman, certainly.

Senator HARKIN. No, I was just wondering because I had to get cleared up in my head, too, then, because the Senator's asked a very pertinent question, very important question.

As I understand it, if you have an egg from a woman, it has her DNA in it, in the nucleus. If that is fertilized in the normal sexual

manner, by the sperm from the man, that has the DNA of the man, and those two combine.

Dr. GREEN. That's correct.

Senator HARKIN. If, however, you remove the DNA of the woman, and you replace only the DNA of a man or a woman, just one, then it is something different.

Senator DEWINE. Well, it's genetically different, right? Its DNA is different.

Dr. GREEN. The DNA is not the immediate result of the union of sperm and egg, it is the DNA from the individual who is the cell donor initially. And furthermore, I think, right down to the genetic level there may be subtle differences that we're not aware of, given the origin of that nuclear DNA. So I'm unprepared to say it is exactly identical, but my point in making this observation is that, traditionally we have thought of an embryo—if I were to ask you five years ago or two years ago "what is a human embryo?" you'd say, well, it is the product of human fertilization and it has these other qualities and characteristics. These cloned entities, these organisms, are not the product of fertilization. Their inception, their origin, is completely different. They are novel in nature in that regard.

Now they have some of the qualities that we liken to an embryo, although there are subtle differences as well. All of this, it seems to me, challenges the use of the term embryo in this case—I'm not clear that the term is an appropriate one. Beyond that I would say this, that the question of how embryos are to be treated, even embryos, is a very disputed one in our society, there is no consensus——

Senator DEWINE. Absolutely, Dr. Green, and I totally—I totally acknowledge that. My only point was, this debate is a debate that we have had before, and I suspect people that felt that there was great moral implication to be given to that cluster, as you referred to, before, will still feel, as I do, that there is great moral implication for this same cluster. I don't know that we have changed the—the debate's a little different, but I suspect that we have not changed the moral arguments, nor have we changed the ethical arguments that are involved here. What I was trying to do is, frankly, get beyond a label and get to a question of what, from a scientific point of view, are we dealing with. And what I take away from, Mr. Chairman, from your testimony, Dr. Green, is that we're dealing with a different origin of this cluster, but at least so far we can't see much difference in what we are looking at from a scientific point of view at that point. The DNA source is different, but your testimony as I hear it is that there is not really a fundamental difference.

Dr. GREEN. Well——

Senator DEWINE. So it doesn't seem to me—the conclusion I make—and everyone is going to have their different opinion—is that we're back—we're into the same moral dilemma and moral debate, where honest people can certainly disagree, about what moral weight to assign to that.

Dr. GREEN. But Senator——

Senator DEWINE. I'm afraid we have not escaped that debate.

Dr. GREEN. But if I may say so, the origin, I don't think, is morally insignificant. As Dr. Vogelstein has remarked, in era of cloning technology, every single cell in our body has the potential to be equated with these clusters of cells. Yes, it would, in that case be one cell, but it has a similar potentiality to go on to further development and so on.

So the problem here is that all of our terms, all of our ways of thinking, have been scrambled, really, by technological and scientific advances.

Senator DEWINE. They are changed—and I'm just trying to get the facts. And in fact, Dr. West, in a transcript from a recent NBC interview, actually—I'll quote him. You use the term embryo "talking about a cluster of cells far smaller than the head of a pin with no body cells of any kind, the embryo hasn't even decided if it's going to become one person or two." So it's understandable that we get into a question of labeling, and my questioning to you all was simply trying, Mr. Chairman, to get beyond that. And I see my red light's been on for a couple minutes, so I'll——

Senator HARKIN. I interrupted you, so——

Senator DEWINE. No, no that's fine. Thank you very much.

Senator HARKIN. This is an interesting pathway that Senator DeWine has opened up. Back to the question of, you know, when does life begin. It seems to me that the egg has life. Sperm has life. I mean, they're alive, they're not dead. I mean, if you look at them under a microscope they're very much alive.

Dr. WEST. May I speak to that? I think that's a very important point. We need to make a distinction between human cellular life and the beginnings of a human being. So a sperm cell is alive, and an egg cell is alive. The union of the egg and the sperm cell is alive, but the important point which we're trying to, I think, focus on is pre-implantation embryos, some—estimates are 50 to 80 percent of them may naturally, through sexual means, never find a home in a uterus, never attach, and therefore never begin to develop. So they begin to develop upon implantation, in the formation of a pregnancy. And if they never find a home in the uterus—in fact, the majority of such embryos never attach—they never begin to develop, and they stay in this, it's like a blank, you know, a blank sheet of paper.

And our point is, there is such a convenient line, a bright line that we could draw, which is drawn for us by nature itself. It's called primitive streak. So once this cluster of cells attaches and finds a home in the woman's uterus, to begin pregnancy, nature begins by drawing a line on those cells. It's called primitive streak, it's the first—it's sort of the spade in the ground, you know, the ceremonial spade to start the construction of a building. It's the first step toward the production, the beginnings of a human life. A human life, as opposed to what was cellular life.

And indeed, of course, our point is two lines can be drawn on that same cluster of cells making identical twins. I think this tells us something very significant. There is a line, it's a bright line that nature's given us for the beginnings of a human being, from what was just cellular life—the hairs that Dr. Vogelstein spoke of, the hair cells, living cells. And this line has been useful——

Senator HARKIN. Say again, what is that line?

Dr. WEST. Primitive streak. And it occurs at about fourteen days. It's about the time when the embryo implants. We don't say that that's an important line because of implantation, per se. It's just that, about the time of implantation this also occurs. So when the pre-implantation embryo finds a home and begins the pregnancy, then it starts to develop into a human, or two humans.

And so that's been an important distinction for IVF. It's been debated widely in medical ethics. And so the concept is, when we create pre-implantation embryos by IVF, the understanding is we would never take those embryos in culture beyond 14 days. Because that's when we would expect the beginning of the development of a human being out of what is just merely cellular life.

Senator HARKIN. Dr. Vogelstein.

Dr. VOGELSTEIN. Yes, I think you're right about two things. First of all, there's no clear line between cells that have the potential for life and those that don't any longer—any live cell has the potential for full human life at least in theory.

I think the most important line is the one you drew there. It's the legislative line. And the reason that's important is because it's easy—it legislatively, as apart from scientifically, to draw that line, and say "No implantation." That will totally preclude human cloning. You could say "No development of blastocysts past the 64 or 128 cell stage." You could say that every blastocyst should be destroyed after the inner cell mass has been removed to create stem cells. Any of those legislative mandates or dictates would totally preclude human cloning and still, as you said, help for patients.

Senator HARKIN. Is there a better one than just saying that it would be prohibited from being implanted? You mentioned a couple of others which I don't know that I understand——

Dr. VOGELSTEIN. I think yours is the best, because that's the easiest to monitor. In order for implantation you obviously need all kinds of people involved, including a woman. Not just a laboratory worker. So I think yours is excellent and the best.

Senator HARKIN. I just didn't know if there was maybe another approach on this. Now, Dr. Vogelstein, I just wanted to ask you, and perhaps others, too. You made a very good case when you took your hair out and you said this hair is a clone of me, it has all the cells in it that basically, that you have. And theoretically I assume you could take the cells from that hair and implant it into an egg and make a clone of you. It's theoretically possible, I guess.

Dr. VOGELSTEIN. Yes, and what I meant—I tried to ask the question, are those cells from the hair or from my skin really a clone of me. And the point I wanted to make is, even though they are genetically identical, and even though they have the theoretical potential to form me, with a lot of procedures, they are not a clone of me. As Dr. Green said, they have none of the characteristics of a human being.

It's essential to distinguish a human being from human cells. They are two very different beasts.

Senator HARKIN. My second 5 minutes is up.

Senator DEWINE. I have nothing further.

Senator HARKIN. Well, if you have anything, just interrupt me at any time. I have a couple more things I wanted to—one area I want to cover, Ms. Greenberger, with you is—in his testimony Sen-

ator Brownback quoted one woman as saying that this research would compromise women's health. That's one part. The other part was just that in a meeting I had last week with some individuals, we talked about how to get these eggs you have to pay women. How does that enter into the whole process here? Now again, the guidelines have been that you can't make money off of this, but obviously you still can pay for a woman to donate her eggs, I guess? I assume that's how ACT did it——

Dr. WEST. That's correct. That's right.

Senator HARKIN. I just wonder, from your standpoint—how do you see this in terms of affecting women's health, and sort of the status of women as it pertains to the donors of these eggs.

Ms. GREENBERGER. Well, first of all, obviously I disagree with the quote from Senator Brownback about it compromising women's health, it—my testimony's been clear that we see great potential for many of the diseases that disproportionately affect women, that this would be a great stride forward. So I don't know, obviously, what was behind that quote, but we certainly disagree with that.

In terms of paying for embryos, I think, as you know, and have said, that women can do that. There are certain restrictions on you not—you can't donate for yourself, you have to know—you can't use—there are certain Federal regulations that protect a woman and protect the embryo. And I think that, you know, along with legislation that's going to be passed, if it is, concerning this, that those stipulations would be included also. And I think women can make their own decisions. They don't need to be told what to do and how to do it. That they're capable of making their own decisions, and if they feel that they want to donate their eggs to research, then they should be able to do that. And if they want to help their own child or someone in their family or themselves, that they should be able to do that.

So I think—and we know, certainly, in terms of IVF and surrogate mothers, I mean, there are a lot of things that we accept now that, when we first discussed them years ago, people found sort of abhorrent and strange to imagine. But now it's accepted, and we seem to have been able to work with it.

Senator HARKIN. All of you have mentioned in vitro fertilization and I asked Senator Brownback whether or not he was in favor of in vitro fertilization, and I think his answer was he saw nothing wrong with in vitro fertilization.

I came across this article, it was in the paper here on November 30. It's an op-ed piece, so it's an editorial about this, in which the writer, Michael Kinsley, quoted the President saying: "We should not as a society grow life to destroy it. It is morally wrong, in my opinion." End quote. And yet, the President also earlier, in August supported in vitro fertilization, on his August 9 television address. The President praised IVF as "a process which helps so many couples conceive children."

And the article went on to say that there's a web called Healthfinder.gov. Didn't know it existed. But it's under the Department of Health and Human Services. And evidently, according to this article, that the first item on Healthfinder's list of references about IVF is a brisk discussion, published in the New England Journal of Medicine, of how many eggs should be fertilized to

produce an embryo. How many should be implanted in order to maximize the chance of producing one baby and no more? Or put it another way, how many embryos should you create and kill outside the many embryos—how many should you implant and hope all but one die? Seems to me if you're in favor of in vitro fertilization, then you're going to create more embryos than obviously can be implanted in the woman. There's going to be some left over. What do you do with those? I think I asked the Senator about that, he said something about adoption and things, but I have a feeling that most of those will be destroyed, I think a lot of them are frozen now, but are they going to be frozen for 50,000 years or 5,000 years or what?

Seems to me here a decision is made that the benefits to humankind, that is, the happiness and wellbeing of a couple to have a child far outweigh any of the other perceived, real, moral obligations or moral dilemmas regarding the destruction of the embryos that are left over.

And so, when we get to nuclear transplantation, then it seems that that same argument might just carry over, I would think. I mean, you're developing it into stem cells to help save lives and make peoples' lives better. And in the process destroying—whether it's even an embryo or a pre-embryo, I'm still not clear on that in my own mind, exactly what it is. But it seems like you almost have the same kind of balancing act there as you do with in vitro fertilization. I don't know, I just say that, and open it for any kind of discussion that you might want to——

Mr. VOGELSTEIN. The problem perhaps lies in the phrase—it sounds like a catchy phrase, create life to destroy it, which no one would be in favor of. But the real purpose of nuclear transplantation is to create life to save lives. It's to save the lives of sick people. That to me is a much more accurate and reasonable way to look at it.

Senator HARKIN. It's an interesting twist to put on it, yes. Dr. Green?

Dr. GREEN. Senator, I think your observation is a correct one. Apparently many thousands and thousands of couples routinely create what they know are spare embryos that will not be transferred to a womb, and they freeze them, and eventually they discard them—thousands have been discarded. They make the decision that the opportunity to have a child for their family outweighs those claims of those very early entities. Others may not agree with that, and not engage in that. Others may feel that contributing an embryo, a frozen embryo for example—ACT has received inquiries from individuals who have frozen embryos who—which they wish to donate for human stem cell research, and they say that the saving of a life of a child suffering from diabetes or whatever actually weighs far more in their thinking than simply having a child.

So I think there is a range of views about this. That's the reality. I don't think we're going to change anybody's opinion on that in 3 months, 6 months. Our society permits individuals to make those decisions right now. Whether to make more embryos than they need to have a pregnancy, whether to make an embryo for the purpose of assisting research—and we had many egg donors, inciden-

tally, this is one of the more interesting findings of the work of the Ethics Advisory Board.

We found that there were many women out there who were perfectly willing to donate an egg for lifesaving research, because they had family members who suffered from these diseases, but who would never donate an egg for reproductive purposes, because they didn't want to create a child with that egg, they wanted primarily to help save lives.

Those differences exist, they are not going to change, and I think that we can permit that kind of research going forward on the basis of what we all—the differences we all share now, without going the other route toward reproductive cloning. We can stop that and draw that line.

Senator HARKIN. Dr. Vogelstein, one last question, I'll recognize Senator Specter. Go ahead.

Senator SPECTER. Thank you. George Annas, who is a very well-known bioethicist who participated in our workshop addressed exactly the point you raise, and he gave what I thought was a very interesting example. He said, suppose you were in a room that on one side of the room had a dish of stem cells derived from a human blastocyst, say from in vitro fertilization, clearly have the potential for life. And on the other side of the room, there was a 30-year-old individual in a wheelchair, a policeman who was injured on the job and had a spinal cord injury. And suppose there was a fire in the room, and you could save one. Which would you save? I thought that was an interesting question.

Senator HARKIN. I think that kind of puts it really in perspective. I'm going to pursue that, that's a good thought.

I just want to say before I close down my questions, I know Senator Specter wants to engage in some dialogue with you.

Dr. West, I just want to make sure I heard correctly earlier, that you would be disappointed if there were not some derivations of cell lines that already had been differentiated into different types, differentiated into different types of cells, muscle cells, neuron cells—you would be disappointed if that had not been done within the next 6 months.

Dr. WEST. That's correct.

Senator HARKIN. Is that correct?

Dr. WEST. Yes——

Senator HARKIN. I would have thought you'd have said that you'd have been disappointed if within the next 6 months you were not able to reach the blastocyst stage——

Dr. WEST. Yeah, well——

Senator HARKIN. Now I find that you said 6 months not only to reach that, but the extraction of stem cells and the differentiation of those cells.

Dr. WEST. Yes. The——

Senator HARKIN. I just wanted to make sure I heard it correctly.

Dr. WEST. You heard it absolutely correctly.

Senator HARKIN. Well, I don't know about the press here, but I think that's about the most important thing that I've heard this morning. I mean, that really does push the envelope.

Dr. WEST. You're asking a question that scientists always hesitate to answer, you know, it's so hard to predict the future of

science and how fast things will develop, because they aren't all within our control. So the only way I've found that I can effectively answer that is to tell you my own anticipation as measured by—I would be disappointed, and that's based on, you know, the work that was done on both the mouse system and the cow, is to related mammals where we—based on those kinds of timeframes, we could generate successful results. That's my hope, and anticipation, but science moves at an unpredictable rate.

Senator HARKIN. Sometimes you have these serendipitous-type happenings that things happen and moves everything ahead light years——

Dr. WEST. That's right.

Senator HARKIN. And other times you go along for a long time. I understand that. But I find that exhilarating, quite frankly, that it's moving that rapidly. That gives even more hope to people who are suffering from Parkinson's Disease and spinal cord injuries that, in fact, this is not too far beyond the horizon.

Dr. WEST. Its been said that, you know, we should remember that many ideas fail. So going from the blackboard into the hospital—we can't take every step and successfully deliver a therapy. But given the breadth of this technology, I think it would be unwise for us not to recognize that there are likely going to be some applications that will prove lifesaving.

Senator HARKIN. Well, just for my own part, I just, I would just say that, rather than a moratorium, I feel very strongly what we ought to do is to speak very clearly and simply, as Dr. Vogelstein said, to absolutely ban the implantation, put severe restrictions, penalties on that. But I think we ought to promote and support as much as we can the nuclear transplantation, the somatic cell nuclear transfer, to derive those stem cells. To me that would be the proper course for us to take, and to move ahead aggressively in that manner.

Senator Specter welcome back.

Senator SPECTER. Well, thank you, Mr. Chairman, I regret the necessity to leave as this hearing is in process. As I said earlier, we're hearing testimony on military tribunals, and on the floor, I had an issue of importance to Pennsylvania on the Transportation appropriations bill. The Department of Defense is also being marked up on subcommittee, so although this is a matter of great importance, we have to balance it with a lot of other concerns.

I want to come back to the issue about how many people are likely to die as a result of a 6 month delay. I have not heard a quantification of what the stem cell research means and the benefits of nuclear transfers. Dr. West, I had asked you about that very briefly before I had to leave. Could you amplify your thinking on the calculation of three thousand people die a day? How did you come to that figure?

Dr. WEST. The estimates are that 3,000 people die a day of degenerative diseases that could be potentially treated by cell or tissue transplantation.

Senator SPECTER. When you say degenerative diseases, does that include heart disease?

Dr. WEST. Yes, heart attacks, myocardial infarction, congestive heart failure——

Senator SPECTER. Include cancer?

Dr. WEST. Renal failure, liver failure——

Senator SPECTER. Includes cancer?

Dr. WEST. That's a good question. I frankly don't know. I wouldn't think so, but I couldn't speak to that for sure. I don't know. Dr. Vogelstein knows.

Senator SPECTER. Dr. Vogelstein, what do you think about that estimate?

Dr. GREEN. I think that—without being able to say that this 500,000 identifiable people's lives will be saved—I think that would be mistaken. I think it would be wrong to say that there are people out there now whose lives certainly will be saved—say that we could point to. But I think the understanding that every day of delay puts off for young children, for example, a cure to diabetes, so that in the period of, say, 3 or 4 years a child may die who might have reached the point that that therapy was available.

And therefore I think it's not unreasonable to say that every day here is a lifesaving day if it can be gained. Even if it was one person.

Senator SPECTER. Ms. Greenberger, do you concur that each day has very substantial risks of many, many people dying?

Ms. GREENBERGER. Well, obviously I don't know as much about this as the other testifiers do, but certainly every day that's a delay in terms of finding the cures or the treatments for people suffering from these diseases, obviously makes a difference. I think for young children it's certainly, especially for them, but also—and I have a good friend that has Parkinson's, my mother has Parkinson's, I think the sooner we can find a cure or successful treatments—you know, every day, every day, every day that it takes is another day of agony for these people.

Senator SPECTER. Dr. Vogelstein I appreciated the comment in your statement that the term somatic cell nuclear transfer is excessive scientific jargon. Actually you said it smells of scientific jargon. And you suggest the term nuclear transplantation, maybe even simpler nuclear transfer. To eliminate the word cloning in therapeutic cloning might be enormously helpful in having the people understand that.

You also made a comment about the advances where the President had authorized the use of Federal funding on stem cell research. Do you have an opinion as to the adequacy of the so-called 64 lines? We've had a good bit of information which we had a hearing on here, but in the popular media, in the news media, about some of those cells being insufficient. Do you think that stopping as of 9 p.m. on August 9 of this year will be sufficient to provide the stem cell lines for all the productive research?

Dr. VOGELSTEIN. Yes, in our report we made a strong statement about that. The statement was that the President's remarks certainly opened the way to do research, which was an excellent first step. But there were many reasons to feel that other types of research to produce new stem cell lines would be needed to take this area from strictly the research arena to a clinical arena. And one of those areas in particular involved nuclear transplantation.

Perhaps a good way to put this is, our job as scientific advisors was simply to try and predict what would be the best way to win

this war against these diseases. And if military advisors were to say that one couldn't use jet planes against an adversary, or couldn't develop the technology to manufacture jet planes against the adversary, they wouldn't be very good military advisors. And we looked at our job in the same way. As scientific advisors we felt that the best way to make this research practicable in the clinic would be to approach several avenues including nuclear transplantation.

Senator SPECTER. And that would require additional stem cell lines beyond the so-called 64 available——

Dr. VOGELSTEIN. Yes. Yes, it would require lines derived from nuclear transplantation as well as perhaps other lines derived by more conventional techniques for a variety of reasons.

Senator SPECTER. Well, quantification would be enormously helpful in our public deliberation, in our Senate debates, so until Dr. West had advanced the figure of 541,800 lives lost over a 6 month delay or moratorium on nuclear transfer, I hadn't heard a quantification. I think it would be very helpful if we could have some judgment as to what is being lost by the failure to use Federal funding on stem cell research. Senator Harkin and I have taken the lead for many years on increasing the NIH budget, as you all know. And concluding this year's appropriation we'll have $11 billion dollars added to $12 billion. And if we could have some idea as to quantifying what that means in saving human lives, and what it means in the therapeutic process, it could be a very powerful tool in our debate. Because that really boils it down. I would very much appreciate it if you would give thought to that. I'm not going to ask you for judgment at all here today, but that would be enormously helpful, if these additional funds were put to use on stem cell research and therapy. Dr. West, you have your hand up?

Dr. WEST. Yeah, I was just going to say, this is one example of why it might be wise for us to consider using other lines and having Federal funding apply to them. We now know that it's possible to make embryonic stem cells or embryonic stem-like cells from egg cells that are activated, as we say, parthenogenetically, where the egg cell, without removing its DNA, is turned into a pre-implantation embryo, making embryonic stem cells that come from just an egg cell on its own. It's a new technique that we're working on. And those cells, because they are derived entirely from a female source, whereas you and I are made from DNA from a male and female source, they have a unique difference, a change in what's called "imprinting," which is sort of like when you highlight text in a book with a magic marker. The genes are marked as being whether they're coming from male or female sources. Those cells would be important for medical research, and would not—under the current guidelines you could not have Federal monies apply.

Also there are congenital or inherited genetic disorders that are now—we're beginning to be able to take a cell from a pre-implantation embryo and determine that that embryo has the gene for muscular dystrophy, you know, both bad genes. So that embryo then is not implanted into the uterus to prevent a pregnancy with that particular problem. Well, those could be used to generate embryonic stem cell lines. And then those neurons and other cells made

from that source would display, before the laboratory researcher, that particular genetic problem in the laboratory dish.

And so all these could be very important tools for medical research in the future. And unfortunately, because they would be made from future embryos, no Federal funding could apply.

Senator SPECTER. Dr. West, there's an article which appears by Dr. Harold Varmus in today's New York Times captioned "The Weakness of Science for Profit." Have you had a chance to see that?

Dr. WEST. No, I have not.

Senator SPECTER. Well, the article by Dr. Varmus, who used to be head of NIH, raises a number of points. I'd like to ask you about two of them.

Dr. WEST. Sure.

Senator SPECTER. He raises a question about the public disclosures which your firm made, suggesting that, while entirely appropriate within our free enterprise system, that the disclosures were early in terms—or premature in terms of where you were, and that he understands that that kind of publication, or that kind of attention is very helpful in getting additional investors so you can pursue your work, but—what would your comment be as to the consideration that you jumped the gun a little, with all that publicity—why the number of counter-attacks and whether it was really right for public disclosure.

Dr. WEST. Well, what we decided is that the application of nuclear transplantation or nuclear transfer in medicine—we knew that there's a considerable amount of public concern as to where these technologies go. And so we went back and took a lesson from history in the development of in vitro fertilization. There were the same concerns. Brave New World concerns, you know, where are we going with this technology. And the researchers who developed in vitro fertilization decided to publish in a very transparent manner, and to publish frequently. And indeed were criticized for similar reasons.

So when the first egg cell was successfully combined with a sperm cell and the sperm cell entered the egg cell, they published that data. They hadn't created an embryo, they hadn't created a pregnancy, but they wanted to frequently show what work was being done in their laboratory, and that's the policy we've decided to take. We recognize that our fellow scientists who like to see data published in a more complete form after certain milestones are met may find fault with us and the way we did this. But we felt it was important to be transparent and publish our data as frequently as we possibly could. And so that's why we published.

Senator SPECTER. And Dr. Varmus makes one more point, that understanding what you did, that it is not desirable to have the private sector solely conduct the research, and notes that in vitro fertilization has not been financed by any Federal funding. Dr. Varmus emphasizes the point that there really at least ought to be public financing. And with the tremendous sums which NIH now has as a result of the increase in funding, that rings loud and clear. Anybody disagree with the conclusion of the Federal Government ought to use the resources which the congress has appropriated to try to move ahead with stem cell research. May the record show

that people are just nodding in the negative. Thank you very much, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Specter. Senator DeWine.

Senator DEWINE. Nothing further, Mr. Chairman.

Senator HARKIN. Well again, thank you all very much for your attention to this matter. It's one of the most important issues I think confronting the American people—all humankind, I believe, in the broadest context. And I just hope that we can find our way clear through this, and to continue to try to develop those cures and therapies that will help so many people that suffer from these diseases. So I compliment you for the work you're doing. I encourage you and I urge you on, and I hope that we can perhaps at least approach it from this standpoint so that we can continue to develop the nuclear transplantation stem cell derivations that hold so much promise for people, at the same time preventing the implantation and the cloning of a human being. Thank you.

CONCLUSION OF HEARING

The subcommittee will stand in recess until the call of the Chair.

[Whereupon, at 11:15 a.m., Tuesday, December 4, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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