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RECENT CONTROVERSIES IN STEM CELL RESEARCH

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

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RECENT CONTROVERSIES IN STEM CELL RESEARCH

WEDNESDAY, SEPTEMBER 6, 2006

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

The subcommittee met at 9:30 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter and Harkin.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health, Human Services, and Education will now proceed. This morning we are going to have a hearing on stem cell research. This is the 19th hearing that the subcommittee will have held. In November 1998 stem cells burst upon the scene and this subcommittee held a hearing in early December, and we have had continuous hearings as we have followed the development of stem cell research.

This morning's hearing is going to take a look at recent claims that stem cells could be developed without destroying the embryo and then a series of retractions which appear to say that the original information was false. We want to find out exactly what the facts are, what is the status on stem cell research, and how there could be this kind of a serious misrepresentation, if in fact that is what happened.

In dealing with stem cells, as we all know, we have an extraordinary development to deal with the maladies which confront the human race, stem cell potential, embryonic stem cell potential, having been represented to have the potential to cure Parkinson's, Alzheimer's, cancer, heart disease, spinal cord, with the flexibility of these cells, virtually every known ailment. So, a lot of people are watching stem cells. A lot of people have hopes riding on stem cells. A lot of people have their hopes up on stem cells if they can be developed without killing the embryo to enable us to move Federal funding into this important field.

So it is a matter of great concern and, candidly, some distress to see the events of the past couple of weeks. Let me welcome my distinguished colleague, Senator Harkin.

The Advanced Cell Technology used 16 donated human embryos, which they took apart, therefore destroying them, as I understand the facts, and obtained 91 individual cells, and from these 91 cells

they derived two embryonic stem cell lines. Dr. Lanza's team showed proof of the principle that a stem cell line can be derived from only one cell, but they did not show that that could be done without destroying the embryo. This may yet be possible. I hope that it is. But it has not been shown.

Several respected scientists are quoted in the September 5 Wall Street Journal saying that the conclusion drawn in the press release requires a leap of faith, "a little too big to leap."

Advanced Cell Technologies published a press release saying, "Company scientists have successfully generated human embryonic cells using an approach that does not harm embryos." The publication Nature released a similar press release. The research article does make it clear that the embryos were destroyed, but neither the press release nor the Nature press release makes that clear.

Dr. Lanza is quoted in the press release, "We have demonstrated for the first time that human embryonic stem cells can be generated without interfering with embryonic potential for life." That will be a key question here today, Dr. Lanza.

The chief executive officer, William Caldwell, sent a letter to Congress stating, "We have demonstrated for the very first time that human embryonic stem cells can be derived from a single cell without interfering with the embryo's potential for full development." We are going to want to know what happened on that.

Dr. Green is quoted in the Washington Post as saying, "You can honestly say this stem cell line is from an embryo that was in no way harmed or destroyed." We are going to be asking you, Dr. Green, how you can honestly say that or if that was an honest statement.

Candidly, there is special concern from this subcommittee because of the fact that this is not the first time that Advanced Cell Technologies has overrepresented what they have done. In November 2001 Advanced Cell Technologies made a representation that they had achieved the first cloned embryo. The subcommittee held a hearing on December 4 and found that not to be the case.

The inspector general of Health and Human Services conducted an investigation because ACT was receiving research funds and Advanced Cell Technologies, according to the facts presented to me, was compelled to reimburse NIH $147,000 and no longer receives NIH funding.

Well, this is pretty serious stuff, dealing with a life and death matter, and we have representations which create a lot of hopes, a lot of hopes, and now they appear to be dashed. We want to find out what the facts are, and if it is true that these false and fraudulent representations were made, why.

Let me yield to my distinguished colleague, who has been a partner in this. There has been no, I think, no activity in the Congress since December 1998—we are on 8 years now and 19 hearings, a lot of energy and a lot of time and a lot of effort and a lot of fights, a lot of fights all the way to the White House, all the controversy and all the contentions and all the advocacy to the President himself, the President himself, eyeball to eyeball on this issue.

Senator Harkin and I have led the way for research funding to go from $12 to $29 billion. It is a big black eye if scientists are making false and fraudulent representations. We passed the bill in

the House and passed the bill in the Senate, ready to go again to try to build up enough support to override a veto. With 110 million people affected by maladies that could be cured by stem cells, themselves and their families, we are in a big, big arena.

Senator Harkin, your partnership is greatly appreciated. Our joint accomplishments I think are very significant. Nothing like health. Senator Harkin.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Well, Mr. Chairman, thank you very much. After that eloquent opening statement of yours and pointing out all the facts in this, I ought to just yield back my time. But I just want to add a couple things. First of all, I want to thank you, Mr. Chairman. Senator Specter had the first hearing right after the first stem cell lines were derived by Gerhart at the University of Wisconsin—Thompson at the University of Wisconsin, and Johns Hopkins. And he has been the leader in this issue since December 1998.

I just echo what he said earlier about the fact that we just cannot permit irresponsibility and irresponsible actions to dash a lot of cold water on what is one of the most promising lines of biomedical research in our lifetimes.

So I want to thank you again, Mr. Chairman, for your leadership and for calling this hearing today. A lot of confusion out there about this announcement that scientists can derive stem cell lines from individual blastomeres. Hopefully, this hearing will set some things straight, and I am glad to see that the press is here to help straighten this mess out. The confusion is regrettable and it could have been avoided if people had acted more responsibly, responsibly.

First, I guess I could commend ACT for breaking new ground on the derivation of stem cells. The company showed for the first time that a stem cell line could be derived from a single human blastomere. That is an interesting development. However, ACT should have made it more clear from the beginning that none of the embryos discussed in the Nature paper survived the experiment. ACT created the impression that it had done something that may be possible in theory, but has not actually accomplished.

Second, the journal Nature made things worse by putting out a press release that promoted this false impression.

Third, the media overhyped this announcement, portraying it as a silver bullet that will solve everyone's ethical questions about stem cell research. That is just wishful thinking.

What we need to do now is step back, examine what it was that ACT really accomplished, and discuss what it means to the future of stem cell research. But I think one thing is clear. This new technique, even if it proves successful, does not in any way diminish the need to pass H.R. 810, the Stem Cell Research Enhancement Act, which the President vetoed in July and about which Chairman Specter just said, just talked about, which passed in the House, passed overwhelmingly in the Senate.

The reason it is necessary is because the NIH estimates that there are about 400 stem cell lines worldwide. Right now, because of the President's decision on August 9, 2001, Federal funding can

be used to study just 21 of those lines, everyone of those being contaminated by mouse cells. So even if the method described by ACT actually works, it will take years for it to produce a substantial number of new lines. Those will be years in which people continue to die of Parkinson's and ALS and diabetes and cancers and dozens of other diseases that could one day be treated or cured by stem cell research.

We should not make the mistake of holding out all our hope for one new unproven method of deriving stem cells when we have hundreds of lines that already exist. Scientists need access to these lines now, not years from now.

Another thing. I think this incident, just like the incident that happened in Korea earlier this year, once again, as I said on the floor of the Senate before and I will say it again here, proves the need to pass the Stem Cell Enhancement Act that we worked so hard on, to open up these lines so that NIH, with its years, with its years of ability to conduct good peer review, to be able to oversee this, is so important.

This again points out why if we do not do this you are going to have—I want to be careful with my words, but you will have, I do not want to say "rogue," but you will have individual companies out there trying to hype things up. Now, I do not know whether this company did it to enhance their stock sales or not. That is what I read in the paper. Right after this announcement, the stock went up. Now the stock is back down again. Who made money during that period of time I do not know.

But that is why it is so necessary for NIH to have jurisdiction over this, and that is why I am glad to see Dr. Battey here again this morning, who is the leader of the stem cell research endeavor at NIH, and our other panelists who are here.

But to close, Mr. Chairman, I want to thank you again for your strong leadership on this issue from the very beginning. I am just proud to be a partner with you and to support you in this effort.

Senator SPECTER. Thank you, Senator Harkin.

Would you gentlemen stand for the administration of the oath.

Senator SPECTER. Raise your right hand, Dr. Green.

Does each of you solemnly swear that the testimony you will give before this subcommittee of the Appropriations Committee of the U.S. Senate will be the truth, the whole truth, and nothing but the truth, so help you God?

Dr. BATTEY. I do.

Dr. LANZA. I do.

Dr. GREEN. I do.

Dr. EGGAN. I do.

Senator SPECTER. You may be seated.

Dr. Lanza, the floor is yours for 5 minutes.

TESTIMONY OF ROBERT LANZA, Ph.D., VICE PRESIDENT, ADVANCED CELL TECHNOLOGIES

Dr. LANZA. Thank you. Before I even start, I want to make it very clear: Our paper is 100 percent correct. I have always been absolutely——

Senator SPECTER. How about your press release?

Dr. LANZA. The press release, okay, first of all, refers to a procedure that has been used for over a decade and does not appear, to the knowledge base that we have at this point, to interfere with the development or potential of that embryo.

Senator SPECTER. Does your press release represent that you can do embryo stem cell research without destroying the embryo?

Dr. LANZA. Using a technique——

Senator SPECTER. Are you accurately quoted as saying that?

Dr. LANZA. No. What the paper was about, the title of the paper, the reason Nature published this paper——

Senator SPECTER. We're not on the title of the paper. I'm on the statement in your press release that you can do embryo stem cell research without destroying the embryo.

Dr. LANZA. We have developed a technique that allows us to be able to generate embryonic stem cells without harming an embryo, yes, that is correct, using that technique.

Senator SPECTER. Without destroying the embryo?

Dr. LANZA. Yes, a technique that we have shown allows us to remove a cell, each and every cell, exactly the way it's done in PGC, and we can use that cell that was removed in exactly that same way to generate embryonic stem cells. Yes——

Senator SPECTER. You are quoted as saying, or I have your press release, "Until now embryonic stem cell research has been synonymous with the destruction of human embryos," stated Robert Lanza, M.D., Vice President of Research and Scientific Development at Act and the study's senior author. "We have demonstrated for the first time human embryonic stem cells can be generated without interfering with the embryo's potential for life."

Is that an accurate statement by you? Did you make that statement?

Dr. LANZA. Yes.

Senator SPECTER. Is the statement true?

Dr. LANZA. Yes, it is.

Should I give my testimony and explain?

Senator SPECTER. You're under oath, Dr. Lanza. You may proceed.

Dr. LANZA. Okay. Well, I would like to thank you for the opportunity today to describe our technique for human embryonic stem cells that we have isolated from single blastomeres. As you know, stem cell lines are conventionally isolated, as you have indicated, from left-over embryos created from couples seeking in vitro fertilization, and I join with the sponsors of S. 810 in my belief that scientific——

Senator SPECTER. The timekeeper will go back to 5 minutes for your full 5 minutes. You may now proceed again.

Dr. LANZA. So conventionally embryos are isolated from left-over embryos created by couples seeking in vitro fertilization, and I commend both of you for your support of S. 810. My belief is that scientists should have continued access to stem cells derived from the hundreds of thousands of such surplus embryos that otherwise will be destroyed. I know you share my frustration that this important legislation was vetoed by the President.

Therefore, at the outset I want to make it absolutely clear that the single-cell derivation technique that we have developed is not

a replacement for existing methods of generating embryonic stem cell lines. In fact, our intention is quite to the contrary. We think it would be tragic not to pursue all the options and methods currently available to us to get this technology to the bedside as soon as possible.

That being said, our hope is that this new method that we described in Nature can be used to increase the number of stem cell lines that qualify for Federal funding within the framework of the current existing U.S. laws and regulations and thus give this field a badly needed jump start.

Current U.S. law prohibits the use of Federal funds for research in which human embryos are harmed or destroyed. As a result of this policy, the field of stem cell research has been crippled by the lack of accessible quality stem cell lines. At present there are only, as you know, a handful of NIH-approved lines, all of which are potentially contaminated with animal pathogens and could lead to serious health risks, whereas others are difficult to grow and have started to display genetic abnormalities.

The approach we have developed does not involve the destruction of embryos. The procedure is commonly known as PGD and it's a well-established technique that has been used for a decade to generate thousands of healthy babies worldwide. In PGD, a single cell, known as a blastomere, is removed from an eight-cell stage embryo for genetic testing. By growing this cell overnight, the resulting cells can be used for both PGD and generation of stem cells without affecting the clinical outcome of the procedure or the subsequent chances of the couple having a child.

Numerous reports show that the success rate—the survival rate is unaffected by the biopsy procedure and that the subsequent development and chances of implantation are the same for both normal and biopsied embryos. In our study, multiple individual cells were removed from the embryos in the same way as would be employed in the clinical setting with PGD. Although these particular embryos were not allowed to develop further, we also carried out studies which confirmed that the biopsy procedure we use could be used without destroying an embryo, the embryo.

I want to be entirely, entirely clear on this point. The embryos used to create stem cell lines in our study were destroyed. However, in control experiments single cell biopsied embryos were allowed to continue development and they did not—they did indeed develop to a more advanced blastocyst stage. They were all frozen and remain alive. In fact, they continued developing at the same rate as non-biopsied embryos.

We also showed that individual biopsied cells have the capacity to create stem cells. Ninteen stem cell outgrowths in two stable embryonic stem cell lines were derived from 91 blastomeres. These stem cell lines have been growing for more than 8 months and are genetically normal and able to create cells from all germ layers of the body, including nerve cells, blood cells, and even retinal cells that could be used to prevent blindness.

Of course, embryonic stem cells derived this way could be of great benefit, not only for the medical research community but for the children born from transferred PGD embryos as well. The cells would be genetically identical to the child and they could be frozen

down and used throughout the lifetime of the person, for instance if they develop diabetes or heart disease.

First I would like to address several objections to the use of this procedure. First is that the technique may not be entirely without risk to the embryo, however minimal. We totally agree and until remaining doubts are satisfied and doubts about safety are resolved we do not recommend the procedure be applied to healthy embryos outside the context of PGD. However, in PGD a cell is already removed and could therefore be used to create stem cells without any added risk to the embryo.

Second, concerns have been raised as to whether individual cells, such as those used in our study, are totipotent and could themselves potentially generate a human being. It is our opinion that this is not true. Recent reports show that the cell fate is already being determined at the two to four-cell stage. Importantly, individual cells from an eight-cell stage embryo, such as those used in our study, have never been shown to have the capacity to create a complete organism in any mammalian species, not even a mouse or a rat.

Finally, questions have been raised as to whether the technique is completely applicable in the clinical setting. We believe it is and are working on procedures that could be utilized by clinicians in the IVF clinic environment. Thus, we believe it is now possible to create new stem cell lines without destroying human embryos. With the support of Federal funding, the single cell derivation technique could provide new, robust, and animal product-free cell lines for medical research and human clinical trials.

Since I testified here a year ago, we have managed to move the single cell derivation technique from the mouse to the human. But in the meantime, another million people have died of diseases that could potentially be treated and possibly cured using future stem cell therapies. How long are we going to allow this intolerable situation to continue? Stem cell scientists sorely need more lines to qualify for Federal funding.

Make no mistake about it, there are many promising alternatives out there, but the conventional methods and the single cell derivation techniques are a reality. They are here and now.

There are those who would want to set this research back, but there is a very real human tragedy out there and it would be a shame not to use this opportunity to try to lessen the misery of so many Americans with disorders and disabilities. This is my hope and it could start here with this committee. Now is the time to move, while the United States is still in the forefront of this research and while there is still time enough to develop therapies that could be used to alleviate the suffering of those we know and love.

Thank you for the opportunity to address this committee. I hope you find these comments helpful to you in your work.

Senator SPECTER. Thank you, Dr. Lanza.

We're going to turn now to Dr. Ronald Green, who is Director of Dartmouth's Institute for the Study of Applied Professional Ethics and currently heads the Ethics Advisory Board of Advanced Cell Technologies.

Dr. Green, the floor is yours for 5 minutes. I would like you in your opening statement to address the quotation in the Washington Post, "You can honestly say this cell line is from an embryo that was in no way harmed or destroyed". You may proceed.

TESTIMONY OF HON. RONALD GREEN, Ph.D., PROFESSOR, DARTMOUTH COLLEGE, AND CHAIR, ADVANCED CELL TECHNOLOGIES ETHICS ADVISORY BOARD

Dr. GREEN. Yes, thank you very much, Senator.

Let me address that initially immediately. That was an elliptical remark taken out of context. The journalist I believe is actually here today, and the question——

Senator SPECTER. What's an elliptical remark, doctor?

Dr. GREEN. Well, it was a part of my quotation, sir. It was a part of my quotation. The full quotation was something to the effect—and I don't have a recording of it—something to the effect, if a stem cell line were produced using this method, then you could honestly say that. That was the full quote.

Sir, I read the paper. I knew that 16 embryos were eviscerated and that's the reality. Five or six cells were taken from each embryo, which is incompatible with that embryo going on to full survival. I would never personally or as an ethicist have misrepresented that.

Senator SPECTER. Do you have the full quotation of which you say this is an elliptical extract?

Dr. GREEN. I'm willing under oath, sir, to say that I believe that the full quotation was something to the—was to the effect——

Senator SPECTER. Answer my question. Do you have the full quotation that you say this is an elliptical extraction?

Dr. GREEN. Sir, I was interviewed on the telephone. I was speaking to a journalist. He asked me a question.

Senator SPECTER. Interviewed on the telephone?

Dr. GREEN. That's correct. It was not a written interview.

Senator SPECTER. Okay, reset the clock to 5 minutes for Dr. Green.

Dr. GREEN. Thank you.

Good morning, Mr. Chairman and distinguished members of the committee. My name is Ronald M. Green. I am a professor of ethics at Dartmouth College and Director of Dartmouth's Ethics Institute. I also serve as chairman of Advanced Cell Technologies' Ethics Advisory Board. I would like to emphasize that I am a university-based bioethicist and that I have no financial interest whatsoever in ACT's technology.

I believe that the method of stem cell derivation announced by ACT researchers in their August 23 report in the journal Nature represents a real opportunity to move human embryonic stem cell research forward in this country in a way that respects the ethical sensitivities of the vast majority of our citizens.

Dr. Lanza has already touched on some of the key ethical issues. He has stressed how this research could be conducted in the context of pre-implantation genetic diagnosis, PGD, without any additional risk of harm to the embryos involved in this procedure. That's a key phrase: without any additional risk of harm.

Dr. Lanza has also shown that the extracted individual cells cannot reasonably be regarded as individual or independent human

beings. No cells extracted at this stage of development could go on to full term development.

There are two remaining ethical concerns that I would like to address. First, there is the connection between this new method and both in vitro fertilization, IVF, and pre-implantation genetic diagnosis, PGD. Some people in our society object to both of these technologies because they involve the manipulation of embryos and because parents using these procedures can elect not to implant some of the embryos produced in this way.

But this objection is made by only a very small minority. The overwhelming majority of Americans support both procedures. IVF helps infertile couples have children and PGD allows those who carry dread genetic diseases to have healthy children. Both procedures help people have children that otherwise would never have been conceived or born. In this respect, both procedures are profoundly pro-life.

Second, there is the concern that the embryos used in this research did not survive the experiment. Since the publication of the Nature report some critics have emphasized the fact that even though it remains true that the approach developed by ACT scientists requires no further destruction of any embryos—and that was the statement in the press report and that statement is accurate—even though this is the case, there was an initial destruction of embryos.

I would like to point out that because this research was privately funded, this experiment was fully legal. It was also approved by ACT's Ethics Advisory Board and by an additional institutional review board that is mandated under Massachusetts law. The embryos used were donated by people who had fully consented to this research and understood and even required that the embryos would not be allowed to go on to further development.

It is not unique that the initial research needed to develop morally acceptable methods or materials does not always meet everyone's approval. But this does not impugn the methods or materials produced as a result of this research. One example is the polio vaccines we use today. Some of the initial research back in the 1950s on these vaccines was conducted with a technique that required the use of tissues from aborted fetuses. Later this approach was replaced by other methods. Almost no one today refuses to vaccinate their children on the grounds that they object to the methods used in the initial experiments.

I would point out that even President Bush has been willing to use the harmless downstream results of research to which he objects. All of the cell lines being used today in federally funded research were produced by embryos that were destroyed for this purpose before the President's August 9, 2001, directive. The President could have said that none of these lines should be used because they were created in a way that he regarded as morally objectionable. But he did not. He concluded that so long as no future harm is done this valuable resource could be used.

Thanks to this surprising research breakthrough, we are in exactly the same position today. If Congress were to approve legislation that funded research on lines generated by this new method and if President Bush were to permit such legislation to pass into

law, both the Members of Congress and the President could honestly turn to the American people and say that no human embryo ever again needs to be harmed or destroyed to produce the stem cell lines that we need for federally funded research.

Many scientists believe that we will need several hundred new federally funded stem cell lines in order to have the genetic diversity we require. Well over 2,000 pre-implantation genetic diagnosis procedures are conducted in this country each year. If just one out of three of the couples using this procedure authorize the harmless derivation of a stem cell line from the extracted cell of each of the embryos they choose to implant, we could produce at least 50 new cell lines every year from now on, and I believe that is a conservative estimate.

The derivation of these cell lines would cause no added harm to any of the donor embryos, a fact of critical importance for both the ethical and legal authorization of this research.

Let me conclude by saying that I am not a scientist. Although I have been impressed by the quality and the integrity of ACT scientists, their work will have to be replicated by other researchers before we can say that it is ready for widespread use. But if Congress begins the legislative initiatives to test this method and fund research based on it, we can start today to move forward to the kinds of cures and therapies that stem cell research requires.

Thank you.

Senator SPECTER. Dr. Green, you talk about Congress moving forward to fund this research. Let me tell you, our job, the job of Senator Harkin and myself, is made a lot tougher, a lot tougher, by these claims, these statements, one of which you made, which have not been borne out. Talking about Congress to do something, you have made our job a lot tougher.

Dr. GREEN. May I reply to that, Senator?

Senator SPECTER. Go ahead.

Dr. GREEN. I have tried to explain what I regard as a misrepresentation of my telephone quote to a journalist. I hope I have made that clear.

Let me say this, sir. I believe that the controversy that we are seeing today is directly proportional to the importance of this breakthrough. I think that a controversy, an artificial controversy, has been generated by those who desperately do not want to see human embryonic stem cell research go forward. I hope that the Congress will be able to separate what I regard as an artificial and generated controversy from the significant scientific breakthrough that we're here talking about today.

Senator SPECTER. When you say you hope that Congress can separate it, Congress is worried about Guantanamo, worried about Iraq, worried about electronic surveillance, worried about social security. Very hard to get Congress to focus on stem cell research, and when you give Congress any reason not to, and you give them a lot of good reasons not to, they brush it off like lint off their jacket.

You're not very realistic. But then you aren't experienced with Congress. But we are.

We now turn to Dr. Kevin Eggan, assistant professor of Molecular and Cellular Biology at Harvard University, principal investi-

gator at the Harvard Stem Cell Institute and assistant investigator at the Stowers Medical Institute. Thank you for joining us, Dr. Eggan, and we look forward to your testimony.

TESTIMONY OF KEVIN EGGAN, Ph.D., ASSISTANT PROFESSOR, HARVARD UNIVERSITY

Dr. EGGAN. Thanks very much. Senator Specter, Senator Harkin, members of the Appropriations Committee, colleagues and fellow citizens: My name is Kevin Eggan and I'm an assistant investigator at the Stowers Medical Institute, a principal investigator of the Harvard Stem Cell Institute, and an assistant professor of Molecular and Cellular Biology at Harvard University.

I'm here today to provide testimony not only as a representative of these institutions and a scientist deeply involved in embryonic stem cell research, but also as a well-informed American citizen. I'm a citizen who believes, like a majority of Americans, that human embryonic stem cell research provides hope for the development of novel therapies for millions of people suffering from a wide variety of currently incurable diseases like diabetes, Parkinson's disease, heart disease, and amyotrophic lateral sclerosis.

I would in particular like to make several comments on the noteworthy work led by my colleague Dr. Robert Lanza that was recently published in the journal Nature. This paper describes the derivation of new human embryonic stem cell lines from individual cells, also called blastomeres, isolated from human pre-implantation embryos at the eight-cell stage. In this method the individual cells are removed from the pre-implantation embryo and co-cultured with clumps of previously derived stem cell lines. Under these appropriate conditions and currently at a low frequency, this method causes the blastomere cells to divide and eventually give rise to human embryonic stem cells of their own.

Although it seems reasonable to extrapolate these findings to the removal of a single blastomere from the pre-implantation embryo, this has not yet been demonstrated. In any case, it is my scientific opinion that these blastomere-derived embryonic stem cell lines differ in no significant way from embryonic stem cell lines derived by standard methods from pre-implantation blastocyst stage embryos, such as those donated by couples who have completed their assisted reproduction treatment.

This new method was not more efficient than currently published and widely used methods for deriving new embryonic stem cell lines and it does not directly enable the derivation of stem cell lines that carry patient genes which could be used as sources of transplantation tissue or serve as models of human disease. Additionally, it is unclear whether a single blastomere itself could be considered a pre-implantation embryo. Experiments in rabbits have shown that blastomeres isolated at this stage have the potential to develop into an entire animal, while experiments in mice suggest that this is not the case.

I know of no experiment that speaks to this issue in human pre-implantation development, although it is clear that the human pre-embryo is morphologically more similar to the rabbit than the mouse. As a result, professionally I can see no scientific rationale or advantage to deriving additional human embryonic stem cell

lines by this method. Personally, I can see no societal advantage to this approach either, as a majority of Americans approve of methods currently used for ESL line derivation.

I myself am not a physician involved in the treatment of infertile patients by IVF, nor do I provide pre-implantation genetic diagnosis with IVF for patients whose future children are at risk for genetic disease. However, as a stem cell scientist I have many colleagues that do practice these important forms of medicine. From my conversations with these individuals, I have come to understand that this proposed method for embryonic stem cell derivation is not really consistent with the commonly practiced standard of care that is administered by clinicians in the United States at this time, particularly this proposed method in which the cell is allowed to divide overnight before it's used for derivation and PGD.

The main problem in this regard is that the proposed approach, as has been articulated by Dr. Lanza, is that it might require a delay in the time of IVF embryo transfer into the woman's uterus, putting the treatment of the patient couple at risk. As a result, I feel that few if any patients would opt to consent to undergo this new procedure for deriving stem cell lines or, I think it's important to point out, any procedure which is perceived by them to possibly interfere with their treatment. Therefore it seems unlikely from a practical point of view that few if any embryonic stem cell lines would be generated by this new proposed procedure.

Thus, although these experiments provide interesting embryological findings concerning the biology of the human pre-implantation embryo, they do not in my opinion change the scientific landscape of human embryonic stem cell research in the United States today. At this time there is still a profound need for expanded Federal funding for research on new human embryonic stem cell lines that have been and will be derived, but that are not part of the presidential registry. This expanding funding which would have been provided by H.R. 810 and its Senate companion bill is still sorely needed.

Finally, I would like to highlight the continued need for experiments on a wide variety of approaches for generating stem cell lines that carry the genes of patients and those that cause human disease. These cell lines would not only serve as important models for the study of disease, but could also eventually provide a source of tissues for transplantation and cell replacement medicine.

In closing, thank you for your—thank you for the chance to testify today and thank you for your attention.

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

We now turn to the distinguished Chairman of the National Institutes Stem Cell Task Force and Director of the NIH Institute on Deafness and Other Communications Disorders, Dr. James Battey, bachelor of science from California Institute of Technology and M.D. and Ph.D. degrees from Stanford.

We thank you for your work in the field, Dr. Battey, and the floor is yours.

TESTIMONY OF JAMES BATTEY, M.D., Ph.D., CHAIRMAN, NATIONAL INSTITUTES OF HEALTH STEM CELL TASK FORCE

Dr. BATTEY. Thank you, Senator Specter, for the opportunity to address the subcommittee this morning, and thank you, Mr. Harkin, and thank both of you for the wonderful work you do in support of biomedical research.

I'm here today in my role as a scientist and Chair of the NIH Stem Cell Task Force to discuss with you a new technique for deriving human embryonic stem cell lines, one of several approaches that may some day make it possible to produce pluripotent human stem cells without the destruction of human embryos. Scientists at ACT have modified a technique pioneered by human fertility clinics called PGD, which we've heard discussed in great detail, so I won't go into any additional elaboration about PGD. The subcommittee I'm sure understands very clearly that it involves the removal of a single cell at the eight-cell stage.

In October 2005 Dr. Robert Lanza's research team at ACT reported that they had removed single cells from early mouse embryos in a process that they called single cell embryo biopsy. Rather than testing the single cells for inherited diseases, they used them to establish mouse embryonic stem cell lines, and the remaining cells of the embryo were implanted in surrogate mouse wombs and approximately half developed into seemingly normal mouse pups. In the control group of non-biopsied embryos, about half also developed to birth as normal pups.

This research was the first to demonstrate that single cell embryo biopsy can be used successfully to generate embryonic stem cell lines in a mouse model.

In August 2006, the ACT research team reported that they had successfully established human embryonic stem cell lines from single cells taken from pre-implantation human embryos. The human stem cell lines created using this technique behaved like pluripotent stem cells, including making proteins critical for stemness and being able to produce cells from all three germ layers, which indicates their potential to produce most, if not all, types of cells in a normal human being.

It's important to note that the August 2006 publication does not describe an identical method to that demonstrated in mice the previous October. In the human experiment published last month, ACT researchers removed multiple cells, four to seven per embryo, from each of the embryos used and in the process destroyed the embryos. They also cultured multiple cells from the same embryo together, raising questions about whether continued cell singling in the culture medium may have influenced their ability to produce stem cell lines and therefore whether it can be said that they indeed produced stem cell lines from single cells in a way that could be reproduced without requiring the destruction of embryos in the future.

These questions would need to be resolved by additional experiments and so, although the experiments described provide some remarkable and interesting new insights, we are not now in the position to say that single blastomere biopsy has been proven as a source of human embryonic stem cell lines.

These points were not immediately obvious in the publicity surrounding last month's publication, but have since been made clear. Proponents of single cell embryo biopsy suggest that since it requires only one cell from the embryo, the remaining cells may yet implant in the womb and develop into a living being. And although the technique proposes to avoid embryo destruction, scientists do not yet know how much risk the procedure might confer to an otherwise healthy embryo. PGD is a relatively recent medical procedure and there are no systematic studies of long-term effects on children born following PGD. Moreover, PGD is used to avoid transferring embryos that carry an inherited disease into the womb of the woman undergoing IVF. The same potential benefit to the embryo does not apply in the case of a single cell embryo biopsy performed on a presumably healthy human embryo.

Additionally, it may be argued that the biopsied blastomere is itself capable of developing into a living being. In sheep and rabbits, this, for example, single cells are capable of developing into viable animals. However, the same does not appear to be true for mice, at least not at an efficiency that can be reliably measured in experiments. Testing such a prospect with a single human blastomere would raise serious ethical questions and as a result as a scientist I cannot tell you whether or not it is possible at some frequency for a single human blastomere to develop into a living being.

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

The subcommittee again invited Dr. Edmund Pellegrino, Chair of the President's Council on Bioethics, to appear before this subcommittee and he again declined. Doctor—executive director of the National Council of Catholic Bishops Richard Doerflinger will be heard by the subcommittee at a later day.

Dr. Lanza, going right to the core of the press release which quotes you, "We have demonstrated for the first time that human embryonic stem cells can be generated without interfering with the embryo's potential for life." Is that an accurate quotation of you?

Dr. LANZA. Yes. What the whole press release is about is the technique. I think 100 percent we have shown that that is correct, that we have developed a technique that we have indeed shown does work and would be applicable in the clinical setting.

Senator SPECTER. But you did not generate human embryonic stem cells without interfering with the embryo's potential for life.

Dr. LANZA. Can I sort of explain how this research operates? One is——

Senator SPECTER. Well, you can try.

Dr. LANZA. Okay. One is is that we actually initiated our studies first to see whether or not we could use the technique we employed in these studies to remove a cell without harming the embryo. We did that and we found that by removing one cell, exactly the way we employed in this study, that we could allow the remaining embryos to go on to become blastocyst. They are frozen. They remain alive.

Then what our next goal was was to say, if we use that procedure, which we confirmed works and that has been used throughout the world literally for years and years in hundreds of clinics,

the question is if you remove each cell exactly the same way as in that PGD procedure, can that cell, just like it would be removed in PGD, create stem cell lines.

Senator SPECTER. Dr. Lanza, we understand your point. You made it in your opening statement.

Dr. LANZA. Right.

Senator SPECTER. In your opening statement you say: "The biopsy procedure we used could be used without destroying the embryos." That's enormously different from the earlier quotation I read to you.

Is there any consideration at all on your company for the financial benefits which will come to your company as a result of such a dramatic, albeit false, representation?

Dr. LANZA. Let me tell you one thing, and this is honest—I'm under oath—is I wasn't in contact with the business end——

Senator SPECTER. You're not telling us one thing that's honest and under oath. You're telling us everything that's honest and under oath. You're telling us everything that's under oath.

Dr. LANZA. Right.

Senator SPECTER. So I hope it's all honest.

Dr. LANZA. Yes. I've been trying to be as straightforward as I know how.

I've always focused on what the—the technique we have developed, and this technique, everything I said is absolutely correct and accurate.

Senator SPECTER. You're talking about, you're talking about a technique which you hope, which you speculate, may lead you to develop stem cells without destroying the human embryo, but you haven't done it.

Dr. LANZA. We removed the cell exactly as it is done in PGD and showed they can create stem cell. We've done that.

Senator SPECTER. Dr. Green, you made quite a representation about not having any financial interest in ACT. Are you paid for your work by ACT?

Dr. GREEN. Each member of the ACT Ethics Advisory Board is paid the equivalent of the NIH per diem, the study section payment, for any meetings, annual meetings or quarterly meetings, depending upon the frequency.

Senator SPECTER. Dr. Green, is that a yes?

Dr. GREEN. Am I paid for? I am paid only for the meetings that we have, which extend—we have not had a meeting for over a year of the board, a formal meeting, sir, and as a consequence I have received no payment whatsoever in the last year at all.

Senator SPECTER. Dr. Battey, do you think that this so-called technique has advanced the scientific research effort to derive stem cell lines, embryonic stem cell lines, without killing the embryo?

Dr. BATTEY. I think the technique is scientifically very interesting. I think it will be very interesting to find out if the stem cell lines derived from single blastomeres have the same or different properties than stem cell lines derived by removing the inner cell mass from an embryo. But at a minimum it provides an alternative source for pluripotent cell lines.

Senator SPECTER. Thank you. It may have the potential to advance that research?

Dr. BATTEY. Correct.

Senator SPECTER. Dr. Eggan, would you agree with that?

Dr. EGGAN. Well, I guess I would draw into question whether or not there's any reason to believe that these cell lines would be different from normal embryonic stem cell lines. I don't think we have a high confidence that that's certainly the case. One could investigate that.

I guess I would say that it seems to me that there really is no scientific advantage to this approach and it really in my mind represents more of a potential patient solution, and I would stress that it's still a potential solution, rather than having any particular scientific benefit. I think that there have been already many stem cell lines derived from discarded IVF blastocysts which could be used for the research which scientists would like to pursue, and if it could be accomplished that a framework could be established for Federal funding on those stem cell lines then I think this would be very useful.

Senator SPECTER. The red light went on during the middle of your answer, Dr. Eggan. So I'll yield to Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

I think one of the problems we have is that we're lay people, we're not scientists, and we're trying to explain this in non-scientific terms. Sometimes when you get scientific terms and non-scientific terms meeting there is confusion. I think this is what we're kind of caught up in right now.

I wish I had a chart Mr. Fatemi here just had drawn me yesterday of what happened, and I think if you put it on a chart it really makes it clear that what ACT did was rather unique in terms of deriving a stem cell line from a blastomere, but in fact the rest of the cells were all destroyed. Is that correct, Dr. Lanza? The rest of the cells were all destroyed?

Dr. LANZA. We did not allow those embryos to continue, yes.

Senator HARKIN. So you derived a stem cell line from that. Now, what people thought happened was that one cell was taken from that eight-cell mass and it was allowed to grow overnight. Out of that, since it then divided, you took a cell for the PGD experiment and then another for the stem line cell. That did not happen. That's what people thought happened. That still has never been done. That's never been done.

Dr. LANZA. We never said that or claimed that. But that's how it would be done in the clinical setting.

Senator HARKIN. We all get misquoted all the time. We are experts in that field. I understand that. But it's all this confusion. So there's the thought out there that you have already done what maybe you can do in the future, maybe. We don't know, but maybe you can do this in the future. I think that's sort of—I hope I was interpreting Dr. Battey right on that—that ACT did not prove—you have not yet proved what you claimed you can do.

Dr. LANZA. You're 100 percent right. All those claims that you're making now I never made. No one that I'm aware ever made those claims. We were always discussing our scientific paper, which was that we developed this technique, and then explained to people how it would apply in the clinical setting. So we tried to explain that.

Now, how the news reports are spinning it and how this hearing is doing that, I can't control that. I can only tell you the facts.

Senator HARKIN. Dr. Battey, let me ask you this. The procedure that they would like to experiment on, that is taking a single cell from the blastomere stage, letting it grow overnight, extracting from that a cell for experimentation on genetic imperfections, let's say, or PGD, taking another cell, the other part of that cell, and then growing that, attempting to grow that into a stem cell line—am I saying it correctly now?

Dr. BATTEY. Yes, you are.

Senator SPECTER. Would that be permissible now under Federal guidelines?

Dr. BATTEY. There are two issues. There is the issue of the Human Embryonic Research Prohibition Amendment, that is language that is found on the Department of Health and Human Services Appropriations Act.

Senator HARKIN. The Dickey amendment.

Dr. BATTEY. Also known as the Dickey amendment, which says that none of the funds made available in this act may be used for the creation of a human embryo or embryos for research purposes.

Senator HARKIN. Well, but we're not creating an embryo. The embryos are gotten from IVF clinics.

Dr. BATTEY. Then the second part—I think we should just go through it in detail so we can be clear—the funds may also not be used for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero.

Senator HARKIN. Got it, got it.

Dr. BATTEY. So the core issue then is how sure are we that removing a single cell doesn't in any way harm the embryo.

Senator HARKIN. Well, I guess the response of the other side would be to say that we have we don't know how many—I've heard between 1,000 and 2,000 children have been born from IVF clinics where this PGD experimentation has taken place.

Dr. BATTEY. Correct. We don't know whether it's harmful. We don't know whether—at some level, we know that certainly normal children can be born, so it's not always harmful, that's for sure.

Senator HARKIN. We also know that this has only been done in the past 10 years, so none of these kids are over 10 years of age.

Dr. BATTEY. That is also true.

Senator HARKIN. Okay, so we don't know the long-term effects.

Dr. BATTEY. So I think to answer your question with regards to the Dickey amendment, we would probably need to get a legal opinion——

Senator HARKIN. I see.

Dr. BATTEY [continuing]. About whether or not indeed the work could, Federal funds could be used for that purpose.

Senator HARKIN. I think again we get back—we go around and we come back to sort of square one again here, where Senator Specter and I have been for a long time. I don't mean to speak for him, but I think we both have an equal mind on this. That is that this type of experimentation should go forward, but it shouldn't go forward at the exclusion of—and I think, Dr. Lanza, you said

that—at the exclusion of the kind of stem cell research that would be allowed under H.R. 810.

Dr. LANZA. Absolutely.

Senator HARKIN. You agree with that?

Dr. LANZA. Absolutely.

Senator HARKIN. That's because if we are looking at—you mentioned about 2,000 a year. I think that's a little high, by the way, for PGD, but it's somewhere between 1,000 and 2,000; can we agree on that, somewhere in that neighborhood? These are very expensive. I've heard the cost of this is $10,000 or something like that, to do one of these experimentations. So you get very few. You said maybe we get 50 a year.

Well, to get to where we are right now with the existing stem cell lines that could be used by Federal researchers or researchers under the Federal umbrella of NIH, 400, would take us another 8 years, even if we could do it. We still don't even know if you can do it or not. That may take another couple of years, just to see whether or not we can do it.

Dr. LANZA. Let me make one point. I'm a stem cell scientist and more so than you I want those conventional methods to proceed. I want H.R. 810 to proceed. This is in no way supposed to interfere with it. That is going to continue on and hopefully that legislation will pass.

What we're trying to do now is to get some more lines available into the hands of researchers who are very severely limited. The field has been crippled because these people only have a handful of these lines. Now, as we move into clinical trials we're going to need new lines that have not been exposed to animal pathogens. So we have an opportunity here now to create these lines, animal-free conditions, and also with new robust techniques. So even a few of those lines could help.

Senator HARKIN. Again, fine. But see, we still don't know if this is allowed, Federal funding would be allowed, for this type of research. Dr. Battey said we'd have to seek some type of legal opinion on it, I suppose. I'm not certain myself.

Dr. LANZA. That was the main reason for doing this research, was to try to move this field forward. That was my intent.

Senator HARKIN. I understand. But, as I said in my opening statement, fine, you derived a stem cell line from a blastomere, that's fine. But all the rest of the cells were destroyed, so we still haven't gotten to the point where you can extract a single cell from a blastomere, let it grow overnight, divide in two, take one of those for PGD, and take the other one and develop it into a stem cell line. That has not been done yet.

Dr. LANZA. Right, exactly. This was a scientific paper to address the issue whether biologically, if you remove a single cell as you do in PGD, can it create stem cells, and we didn't know that. And this is what this paper's about. This is what we're——

Senator HARKIN. My final point on this issue is that, even if we go down this line to the exclusion of H.R. 810, it will take several years before we ever get there, because we don't even know if it can be done yet. Maybe, maybe. So we've got to prove it, proof of concept first. Second, deriving stem cell lines from this methodology would take several years.

Then you have to worry about the diversity. I mean, let's face it. Who gets IVF done in this country, and how many of those have PGD done or would allow? As Dr. Eggan mentioned, we're dealing with couples who want to have a child and you're going to tell them, well, we're going to take this embryo and we're going to take a cell out? I mean, they're going to say: Hey, we just want to have a baby.

Dr. LANZA. We're exactly on the same page. This is not a replacement for conventional methods. I 100 percent agree with you.

Senator HARKIN. That's why I think, while this is an interesting area of experimentation and scientific research, it's been hyped up too much, way overhyped, and we ought to come back down to earth and say, okay, fine, we can go ahead with this, but I think if nothing else comes out of this hearing this morning, it does not replace in any way the efforts that we tried to do under H.R. 810, which is to open up hundreds of stem cell lines.

Dr. LANZA. Absolutely. It was never our intention, absolutely.

Dr. GREEN. Senator.

Senator HARKIN. Yes, Dr. Green.

Dr. GREEN. May I add a clarification——

Senator HARKIN. Yes.

Dr. GREEN [continuing]. To Dr. Eggan's remarks as well? I think it is a mistake to understand that this research would proceed using IVF embryos. That is not the issue. One is not going to infertile couples and saying to them, please let us take a cell from one of yours. You could not do that ethically at this time, given the harm, unknown harm.

This is directed at couples undergoing pre-implantation genetic diagnosis. At least 2,000 such couples undergo this procedure every year. The cell is already taken from the embryo for the purpose of the genetic diagnosis. They have consented to that. They have requested that. They have paid that, 2,000 people.

Now, it seems to me that many of these people would be more than willing to see if the technique could be developed a bit further to see those cells grown out, for two reasons. First, those cells, if they become a stem cell line, will be immunologically compatible to the child they bring into being. So the child will now have in a freezer compatible stem cells for its future health care needs. Remember, they have already agreed to the biopsy. There's no additional risk to their child.

Second, these are people who are suffering from dreaded diseases, the vast majority of whom will consent to support this research. Before coming here I spoke to one of the leading PGD researchers in the country, who does over 700 such procedures every year. When we discussed this matter his initial and enthusiastic comment to me was: How can I start doing this?

I am personally confident—I'm speaking only personally, not as a scientist—that we will have hundreds and hundreds of stem cell lines in the near future. As the efficiency of Dr. Lanza's procedure is increased, we will have more than enough.

Is this a replacement for current methods? No, that's not the issue here. It is a new method coming on line, which if you in Congress will advance the support for its development and perfection will alter the shape of the stem cell issue in our country.

Furthermore, and I want to add one further thing to this. The removal of a single cell in the context of PGD—and that is all I am speaking about—but if this technique in fact over time proves harmless to further research on the children already produced by this method, the thousands, the hundreds of children produced by this, if it proves harmless I would say this is going to become a routine adjunct to in vitro fertilization as couples put aside a stock of ESL lines for their IVF child in the future.

So I am—we're speaking here of an enormous breakthrough in American medicine, not undertaken solely for ethical reasons, as Dr. Eggan has suggested, but for biomedical and scientific reasons. I think the challenge before us is to separate a furor that's been created by some opponents of this research from the reality of the science and ethics that it involves.

Senator HARKIN. Dr. Green, one correction. There has been no big scientific breakthrough in this regard. It has never yet been done, what you are talking about, okay?

Dr. GREEN. I disagree with you on that, sir.

Senator HARKIN. Never been done.

Yes, Dr. Eggan.

Dr. EGGAN. Thank you for the opportunity to respond, and I apologize to Dr. Green if my testimony was not clear. But I was referring only to these cases in which the proposed method of obtaining blastomeres from PGD embryos was used and I was in no way referring to use this with standard IVF procedures, because I agree that that would be irresponsible at this time.

Again, I will not speak as a clinician who is involved in IVF or PGD research. However, I will speak as a stem cell scientist who is intimately involved with the process of consenting human subjects, the patients themselves who are involved in these IVF procedures to participate in stem cell research. In this regard I can relate my personal experience, and that is that couples are quite willing, it seems, to participate in research which in no way puts their current treatment at risk. For instance, they seem very willing to donate discarded IVF embryos or even embryos which have been subjected to PGD and have been determined to carry the affected disease genes and would be discarded.

However, in my experience they tend to be quite resistant to any sort of change in the medical procedure which would put their current treatment at risk. Although I recognize that it may not be always the case, my discussions with a variety of IVF personnel lead me to believe that currently one of the limiting factors in the PGD treatment is the time which it takes to actually perform the preimplantation genetic diagnosis.

Now, in some clinics this may not be the case. But in many clinics it is true that the blastomere is retrieved and essentially literally sent to the genotyping company by Federal Express to be genotyped and then the patient is often waiting for the genotype information for the embryo transfer to be performed. Now, again this is not always the case, but it is often the case.

So my sense is that for many of these patients they would be resistant to anything which would cause a delay in the time of the embryo transfer which might be sub-optimal for their treatment. So again, at least for some cases I think this is reason enough for pa-

tients to not want to participate, and if there is any perception on their part that it's going to hurt their chances of becoming pregnant, which it may or may not, then I think they'll be resistant to being involved in this research.

Senator SPECTER. Thank you, doctor.

Dr. LANZA. Can I reply to that?

Senator SPECTER. Thank you, gentlemen. I think the point has just come out, emphasized by Senator Harkin, that this in no way affects the research which is being undertaken at the present time. That's a very, very important point.

Dr. Green, I have to disagree with you about opponents of this method having undercut it. It's been undercut by the proponents of this method. I find Dr. Lanza's explanation totally unsatisfactory, totally unsatisfactory. The only way to read the press release and the affirmative representations made by your company is to the effect that you can have stem cell research without destroying the embryo.

You may have a hope and you may have a technique or you may not, but you certainly haven't accomplished that, and that's what you told the world.

Dr. Green, you have to—your explanation is similarly not acceptable, although if you talked about it on the telephone you have to be concerned with what you say on the telephone. You're a prominent ethics expert. You're connected with ACT and people look to you for accurate representations as to what's going on.

It is only my hope that this doesn't set back stem cell research generally, that the opponents of stem cell research don't paint with a broad brush and say, you see, you haven't done anything to prove you can deal with Parkinson's or Alzheimer's or heart disease or cancer, and here's another big fat representation, it's been blown to smithereens, not worth the paper it's written on.

We had a hearing on December 4, Dr. Lanza, where we had to call you to task for ACT's misrepresentations. I hope we don't have it in the future, so that we can proceed, as Dr. Battey has said, to try to develop research along stem cell lines which will get congressional approval and ultimately lead us to eliminate the prohibition against Federal funding.

CONCLUSION OF HEARING

Thank you all very much for being here. That concludes our hearing.

[Whereupon, at 10:10 a.m., Wednesday, September 6, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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