AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 107–812

HUMAN CLONING: MUST WE SACRIFICE MEDICAL RESEARCH IN THE NAME OF A TOTAL BAN?

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

FEBRUARY 5, 2002

Serial No. J–107–55

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

83–684 PDF WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON THE JUDICIARY

PATRICK J. LEAHY, Vermont, *Chairman*

EDWARD M. KENNEDY, Massachusetts
JOSEPH R. BIDEN, JR., Delaware
HERBERT KOHL, Wisconsin
DIANNE FEINSTEIN, California
RUSSELL D. FEINGOLD, Wisconsin
CHARLES E. SCHUMER, New York
RICHARD J. DURBIN, Illinois
MARIA CANTWELL, Washington
JOHN EDWARDS, North Carolina

ORRIN G. HATCH, Utah
STROM THURMOND, South Carolina
CHARLES E. GRASSLEY, Iowa
ARLEN SPECTER, Pennsylvania
JON KYL, Arizona
MIKE DEWINE, Ohio
JEFF SESSIONS, Alabama
SAM BROWNBACK, Kansas
MITCH MCCONNELL, Kentucky

BRUCE A. COHEN, *Majority Chief Counsel and Staff Director*
SHARON PROST, *Minority Chief Counsel*
MAKAN DELRAHIM, *Minority Staff Director*

CONTENTS

STATEMENTS OF COMMITTEE MEMBERS

	Page
Brownback, Hon. Sam, a U.S. Senator from the State of Kansas	76
Cantwell, Hon. Maria, a U.S. Senator from the State of Washington	77
Durbin, Hon. Richard J., a U.S. Senator from the State of Illinois	85
Feinstein, Hon. Dianne, a U.S. Senator from the State of California	1
Hatch, Hon. Orrin G., a U.S. Senator from the State of Utah	3
Kennedy, Hon. Edward M., a U.S. Senator from the State of Massachusetts	86
Leahy, Hon. Patrick J., a U.S. Senator from the State of Vermont	86
Specter, Hon. Arlen, a U.S. Senator from the State of Pennsylvania	15

WITNESSES

Charo, R. Alta, Professor of Law and Medical Ethics, University of Wisconsin Law School, Madison, Wisconsin	30
FitzGerald, Kevin, S.J., Georgetown University Medical Center, Washington, D.C.	44
Greely, Henry T., Professor of Law, and Director, Center for Law and the Biosciences, Stanford University, Stanford, California	25
Greenwood, Hon. James C., a Representative in Congress from the State of Pennsylvania	12
Gulden, Kris, Coalition for the Advancement of Medical Research, Washington, D.C.	34
Kimbrell, Andrew, Executive Director, International Center for Technology Assessment, Washington, D.C.	38
Weissman, Irving L., M.D., Chair, National Academies Panel on Scientific and Medical Aspects of Human Reproductive Cloning, and Professor, Stanford University School of Medicine, Stanford, California	20
Weldon, Hon. Dave, a Representative in Congress from the State of Florida	6

QUESTIONS AND ANSWERS

Questions submitted by Senator Feinstein to the witnesses	65
Responses of Dr. Weissman to questions submitted by Senator Feinstein	67
Responses of Mr. Greely to questions submitted by Senator Feinstein	70
Responses of Ms. Charo to questions submitted by Senator Feinstein	71

SUBMISSIONS FOR THE RECORD

American Society for Cell Biology, Bethesda, Maryland, statement	75
Citizens' supporting legislation to prohibit cloning, joint statement	79
CNN.com, article	83
Coalition for the Advancement of Medical Research, Washington, D.C., statement	84
NewScientist.com, article	87
New York Times:	
editorial, January 19, 2002	88
Jack M. Balkin, article, January 30, 2002	89
St. Louis Post-Dispatch, editorial, December 3, 2001	90
United Network for Organ Sharing, Richmond, Virginia, list	92
Verfaillie, Catherine, M.D., Professor of Medicine, and Director, Stem Cell Institute, University of Minnesota, Minneapolis, Minnesota	96
Washington Post, editorial, January 22, 2002	96

HUMAN CLONING: MUST WE SACRIFICE MEDICAL RESEARCH IN THE NAME OF A TOTAL BAN?

TUESDAY, FEBRUARY 5, 2002

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The committee met, pursuant to notice, at 2:10 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Dianne Feinstein presiding.

Present: Senators Feinstein, Kennedy, Durbin, Hatch, Specter, DeWine, and Brownback.

OPENING STATEMENT OF HON. DIANNE FEINSTEIN, A U.S. SENATOR FROM THE STATE OF CALIFORNIA

Chairperson FEINSTEIN. I would like to begin by calling the hearing together and welcoming the two distinguished Members of Congress.

I would like to begin by making a brief statement and then the Ranking Member, who will be for this hearing Senator Hatch, will be on his way over and he will make a brief statement.

Do you gentlemen have a time problem, because if you do, I will accommodate you now.

Mr. WELDON. I am fine.

Mr. GREENWOOD. I am not leaving until he leaves.

[Laughter.]

Chairperson FEINSTEIN. Cloning seems to be one of those words and concepts that seems to inspire a lot of dread in people, visions of an apocalyptic world marching lockstep. However, as is the case with many medical technologies, it is not cloning that is the problem, but some of its potential applications. For example, we are all concerned about the sale of human organs or the transplant of organs from executed prisoners, but few people argue that the solution to these potential problems is to ban organ transplantation.

The truth is that there is bad cloning and good cloning, I believe. Bad cloning is human cloning, the creation of carbon copies of whole human beings. Good cloning is nuclear transplantation to produce stem cells.

There is broad agreement across our society, in Congress and in the scientific, medical and religious communities, that we should ban human cloning. Such cloning is scientifically unsafe, morally unacceptable, and ethically flawed.

However, at least to me, it is also clear, and I think to the overwhelming majority of the scientific and medical community, that we should not ban nuclear transplantation to produce stem cells. Many doctors and scientists have argued that we must protect our ability to use cloning techniques to try to save and improve the lives of those ravaged by disease and other ailments.

In fact, nuclear transplantation offers enormous potential for providing cures to diseases such as cancer, diabetes, cystic fibrosis, and heart disease, as well as conditions such as spinal cord injuries, liver damage, arthritis, and burns.

This technique could allow the creation of bone marrow for transplants to leukemia victims, islet cells for the pancreas of a diabetic, heart or liver tissue to repair the damage caused by heart attacks or hepatitis, healthy skin for grafts for burn victims, and many other potential cures and treatments for a variety of diseases and ailments.

Let me make a few points. First, nuclear transplantation could be used to create embryonic stem cells which could be used to make tissues, and even organs, for transplant. This would help relieve the serious shortage of tissues and organs for transplant. Over 50,000 Americans today are waiting for organ transplants, while hundreds of thousands more need tissue transplants. Tragically, over 5,000 people die a year because they can't get the organs or the tissues they need to be donated, and many of these are very young children.

Second, the use of nuclear transplantation to produce a tissue or organ could virtually eliminate the danger that the patient's body would reject it. Nuclear transplantation techniques could allow the implantation of new cells or tissues that exactly match those of the person to whom they are implanted, greatly reducing the likelihood that the person's body would reject those cells or tissues. Such research has the potential to save thousands of lives and relieve the pain and misery of thousands more.

Third, nuclear transplantation has many other applications as well. It could be used to produce human proteins, such as blood-clotting factors that aid in healing wounds. It could yield information on stem cell differentiation, providing valuable information about the mechanism of aging and the causes of cancer. It could even be used to find a cure for cancer by teaching us how to reprogram cells.

Senator Brownback and I both co-chair the Senate Cancer Coalition. I am delighted he is here today. We are also both part of the National Cancer Dialogue.

So I believe strongly that it would be a disaster to ban this kind of valuable research. Thus, Senator Kennedy and I have introduced a bill, S. 1758, that takes a balanced approach, we believe, to the cloning issue. This legislation would make the cloning of a human being a crime, while allowing research involving nuclear transplantation to proceed.

This is the same approach recommended by a number of blue ribbon scientific and medical panels, including the National Bioethics Advisory Commission, the National Academies' Panel on Scientific and Medical Aspects of Human Cloning, and the California Advisory Committee on Human Cloning.

All of these commissions and panels delved deeply into the cloning issue and ended up coming to the same conclusion: ban human cloning, but don't interfere with important areas of scientific research using nuclear transplantation to produce stem cells.

So I am very pleased that two of the colleagues sponsoring this bill are on this committee, Senator Kennedy and Senator Durbin. In addition, Senators Boxer, Miller, Corzine, Clinton, and Mikulski are cosponsors. I am also happy that the Federation of American Societies for Experimental Biology, as well as 22 other scientific and medical organizations, have endorsed the bill.

In this letter, they note that S. 1758 is a carefully worded bill that should expedite the development of therapies for millions of Americans. I would now like to put this letter in the record.

I also want to acknowledge Senator Specter's leadership on the cloning issue, as well as on stem cell research generally. He and Senator Harkin have introduced legislation, S. 1893, that is very similar to our bill, S. 1758, and I look forward to working with them on this issue.

I very much look forward to hearing from the witnesses today.

I would now like to turn to the very distinguished ranking member of the full committee, the distinguished Senator from the Olympic State, Senator Hatch.

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

Senator HATCH. Thank you, Madam Chairman. First, I would like to inform the Chair that Senator Kyl is managing an important amendment on the floor and will unfortunately be unable to attend this hearing.

Today, the committee takes up an important set of issues as we explore how considerations of law and ethics affect, and should affect, the science of what is commonly and perhaps confusingly lumped together under the term "cloning."

In a general sense, cloning merely means making a xerox copy, an exact duplicate. There are, in fact, many types of entirely unobjectionable, non-controversial, common uses of cloning in science. For example, if researchers developed a new smallpox vaccine and needed to clone billions and billions of copies of a snippet of genetic material as part of this new therapy, no one would complain, or at least I believe nobody would.

In the context of this hearing, cloning does raise substantial questions. Today, we will examine cloning as a technique to produce cells, or even potentially whole individuals, with the identical genetic code of one parent cell.

Cloning stands in sharp contrast to normal reproduction, the proverbial birds and the bees, in which the father and the mother each contribute one-half of the genetic makeup, the DNA, of the offspring. While nature in some cases produces twins who share the same two parents and virtually identical genetic code, cloning technology could conceivably 1 day enable the birth of literally a new type of person who springs forth from solely the genetic contribution of a single parent.

The type of cloning we are discussing today revolves around the technology of somatic cell nuclear transfer. This consists of removing the nucleus of an egg and replacing it with the full complement of 46 chromosomes from an adult body cell.

This, of course, is very different from the time-immemorial case in which the egg and spermatozoa contribute 23 chromosomes each to the offspring. Theoretically, an embryo produced in the test tube through this somatic cell nuclear transfer technique could be implanted into a womb and result in a live birth.

No doubt somewhere, some, such as the Ralians, are trying to make a name for themselves and are busy trying to apply the techniques that gave us Dolly the sheep to human beings. Frankly, I am not sure that "human being" would even be the correct term for such an individual heretofore unknown in nature.

I am a conservative, and an unabashed pro-life conservative at that, or should I say, to be more politically correct, I am a faith-based conservative. In any event, I would be extremely hesitant to rewrite the Book of Genesis as the story of Adam or Eve.

We know that most everyone at this time opposes so-called reproductive cloning, the development and birth of a completely new type of individual through what would essentially amount to an elaborate form of asexual reproduction.

The fact is that, today, there is not a simple, straightforward Federal law that prohibits reproductive cloning. I believe, and I believe that the members of this committee and the entire Senate and House believe that it is long past time for reproductive cloning to be prohibited by Federal law.

Here is the rub: There is another branch of cloning, termed by its proponents as "therapeutic cloning," which I think is a lousy name for it, whose motivation is not birth, but the development of a broad range of new treatments and diagnostic tests for a host of diseases. Through cloning techniques, it is possible that the type of highly versatile pluripotent stem cells we heard so much about last year could be produced.

As some of the testimony today reveals, many scientists and advocates believe that this line of research is both ethically proper and appears extremely promising. Many believe that the problem of potential rejection of new stem cell-derived tissues could be minimized and perhaps avoided altogether by what I would call DNA regenerative therapy.

Other well-respected experts and groups will tell us that not only is the science being over-hyped, but there remain fundamental legal and ethical objections to this line of research because the very creation and subsequent destruction of these new types of cloned embryos is inherently immoral.

A question with which the Senate struggled in 1998 and with which we still struggle today is to see whether we can find a way to outlaw the offensive uses of cloning techniques but do so in a manner that does not bar potentially life-saving and ethically proper scientific research.

So I commend Senator Leahy and Senator Feinstein for holding this hearing today so that we may more fully explore these complex issues. The Senator from California, together with our colleague Senator Kennedy, has offered legislation on this topic. As well, Sen-

ator Specter, in partnership with Labor-HHS Appropriations Subcommittee Chairman Tom Harkin, has held over 12 hearings in this general area, and they have also offered both legislation and leadership in the biomedical research arena.

Frankly, I think we all need to take our hats off to President Bush and congressional leaders like Arlen Specter and Tom Harkin for the bipartisan achievement in doubling our Nation's investment in biomedical research at NIH over the past 5 years.

My pro-life colleague and good friend, Senator Brownback, takes a different view than Senators Feinstein, Kennedy, Specter and Harkin on some key aspects of cloning legislation. He, too, has offered a bill. It is similar to the measure sponsored by one of our most influential witnesses today, Representative Dave Weldon, that passed the House last year. We also welcome Representative Jim Greenwood here today and commend him for his efforts as well.

I am studying the issues and the proposed legislative responses. I have met with experts on all sides of this issue from all over the world, and I welcome the opportunity to learn more today.

This debate today will inevitably and ultimately involve questions regarding when and under what circumstances life begins. As we saw during the debate on the Federal funding of certain stem cell research last year, these are difficult issues and opinion is unlikely to be monolithic.

Public education and debate are essential in our pluralistic society if we are to reach acceptable compromises on contentious issues. Toward this end, I would repeat a thought I raised at a Judiciary Committee markup last August, when I wondered aloud whether the development of an egg incapable of implantation might alter the debate on these issues. I intend to ask this question of the witnesses today.

I hope that today's hearing will help the members of the committee gain a better understanding of the science, law, and ethics of cloning. It is my hope that this committee and the Congress will be able to arrive at a reasonable consensus on a policy that fully respects the dignity of humanity with respect to reproduction and research.

So I want to thank you, Madam Chairman. I appreciate being with you.

Chairperson FEINSTEIN. I thank you, Senator.

Now, we will turn to our two House Members, and I would like to introduce them both at one time, beginning with Congressman Weldon.

Congressman Dave Weldon, of Florida, was elected to Congress in 1994. He represents Florida's 15th Congressional District. He is a practicing physician and an Army veteran. I am very pleased to note that he served his internship and residency in San Francisco at the Lederman Army Medical Center, which is unfortunately no longer there today.

Mr. Weldon serves on the House Science Committee, the House Financial Services Committee, and the Government Oversight and Reform Committee. He is the sponsor of H.R. 2505, the House-passed legislation that would ban both human reproductive cloning and therapeutic cloning.

While I am doing it, I will also introduce, if I may, Congressman Jim Greenwood. He was elected to Congress in 1992. He represents Pennsylvania's 8th District. He serves on the House Commerce Committee and Education and Workforce Committee. He served as chairman of the task force charged with reforming the Food and Drug Administration, and he has also been active on many health care issues, including Medicare and Medicaid. Mr. Greenwood sponsored the House substitute to the Weldon anti-cloning bill. That legislation would prohibit human reproductive cloning, but permit therapeutic cloning.

So welcome, gentlemen. We are delighted to have you here.

Mr. Weldon, if we could begin with you, please.

STATEMENT OF HON. DAVE WELDON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Representative WELDON. Thank you, Madam Chairman. I want to thank you for the opportunity to be here to testify on this very important issue, and I certainly want to commend you and the ranking member for taking this issue up. I think the American public really would like the Senate to speak on this issue. It is very, very obvious that scientists are moving ahead and creating cloned human embryos in the lab.

Let me just start out by saying that I practiced medicine for 15 years. I still see patients once a month at the veteran's clinic in my district. I have taken care of patients with diabetes. My father had diabetes. I have taken care of patients with Alzheimer's disease, spinal cord injuries. So I do not approach any consideration that would preclude a particular avenue of research lightly.

I would just like to underscore—and I believe both of you touched on this issue in your opening statements—the belief is that by allowing embryo cloning in the lab, you will somehow be able to extract stem cells from this and would be able to treat somebody with some type of condition.

Right now, today, that is purely a theoretical construct. It does not exist, nor is there an animal model of such a therapy. You cannot take a mouse, for example, with a disease and extract stem cells from a cloned embryo of mouse and treat that disease.

It certainly is well worth saying that there are hundreds of millions of dollars being spent on all types of research modalities to treat these conditions—surgical modalities, pharmacologic modalities. I think the important point I would like to underscore about this is when we use the terms "enormous potential" and "tremendous breakthroughs," you can lead some people who are suffering from these diseases or their family members to develop false hopes.

I just want to underscore that the legislation that we passed out of the House and that is very similar to the legislation introduced by my friend, Sam Brownback, does not preclude animal research in this arena. It would allow it to go forward unfettered.

The real central debate here is are we now going to carry the stem cell debate to the place where we are now creating human embryos for this purpose. The debate 4 or 6 months ago, or a year, 2, 3, 4, years ago was on using excess embryos from fertility clinics, and I think many very, very thoughtful people believed that that was morally and ethically OK.

Indeed, it was viewed that these embryos were destined for destruction and that it would be inappropriate to just allow them to be destroyed without having any redeeming use, and therefore this type of embryo stem cell research should be allowed to proceed.

I would just like to point out that many people who put forward that argument in the past, including the Washington Post in an editorial they did in 1994, and including some letters to the President that actually came out of this body, underscored the fact that creating embryos for destructive research purposes was a direction that we did not want to go into. But that is exactly the direction we are heading into now.

Now, some may contend that these embryos are not human or that they are not really embryos. I can just tell you from a scientific basis there is absolutely no foundation to put forward such a claim. This is a human embryo that we would be essentially saying it is legal to create this, but only for the purpose of exploiting it for research purposes and then it has to be destroyed. We would be saying it is illegal to implant it into a woman.

I just want to underscore a couple of additional points. One important one is that some people have tried to portray this as a pro-life/pro-choice type of debate. While there may be some people who may view it in that context, if you actually look at what went on in the House, it pretty much transcended that, in that there were a lot of people who were very pro-choice in their outlook, some of whom had a 100-percent approval from various groups like NARAL, who voted for the ban.

Indeed, some pretty vocal feminist groups came out in support of banning human cloning, most notably Judy Norsigian, with the Boston women's health book group, the coauthor of Our Bodies, Ourselves for the New Century. She and Steward Newman of the Council for Genetic Responsibility wrote in a Boston Globe op ed, "Because embryo cloning will compromise women's health, turning their eggs and wombs into commodities, compromise their reproductive autonomy, and with virtual certainty lead to the production of experimental human beings, we are convinced that the line must be drawn here."

The point they are alluding there, of course, is that if we are going to allow research labs all over the country to start creating these embryos in large quantities for research purposes, they are going to have to get female eggs from somewhere. Where are they going to get these female eggs from? Well, the same place the group in Worcester, Massachusetts, got them from; they paid women to do it. So you will be, in my opinion—and they agree with me—you will be essentially exploiting women by—it will be women who need money who will come forward and donate their eggs.

Another very, very critical point about this relates to the recent National Academy of Sciences report that you cited in your opening statement, Madam Chairman, in support of embryo cloning. They in that report interestingly opposed reproductive cloning because they said it would involve the exploitation of women.

But in that report, as you mentioned, they support the so-called therapeutic cloning or research cloning that we have had. And I would have to assert that it involves the same type of exploitation of women and women donating their eggs in the fashion described.

Let me just point out several other groups on the left who have come out in opposition to this so-called therapeutic cloning or embryonic cloning: Friends of the Earth, Council for Responsible Genetics.

Importantly, the bill that passed the House with a strong bipartisan majority was not only supported by the Conference of Catholic Bishops, but it was supported by the General Board of Church and Society of the United Methodist Church, which is, of course, a group that has always stood in strong support of abortion rights.

I say all this to just emphasize that this is not an abortion debate. I think we have to ask a lot of questions as we go through the process of moving this legislation forward in the Senate. Do scientists have the moral authority to go wherever they wish to go? Should the Congress pass a law that would mandate for the first time that a certain class of human embryo, if created, must be used for experimental research purposes and then has to be destroyed?

Now, perhaps most importantly, if we have all of these research labs all over the country producing hundreds or thousands of cloned embryos, will it be possible to prevent a physician from implanting one of those embryos in a woman? The implantation of a cloned embryo into the womb of a woman would occur within the confines of the doctor-patient relationship, and it is for that reason, I think, more than any other that many people, such as myself, believe that you really cannot have both. You cannot have all of this research proceeding and prevent reproductive cloning.

Because the implantation of a clone in a woman would occur within the privacy of the doctor-patient relationship, and because research labs throughout the world, throughout the United States, would be producing large quantities of these embryos, it would only be a matter of time before a rogue physician, in defiance of the law, would implant one of these embryos in a woman.

Indeed, in the event of that, it would put the Government of the United States in a very, very awkward position because though it may have been made illegal, you would be getting into the issues of reproductive rights and autonomy of the woman, of the doctor-patient relationship.

It is for these reasons and many others that I felt the only way to properly prevent human reproductive cloning from proceeding was to ban it at the very beginning, at the creation of the embryo.

I would be very happy to field any questions. Thank you.

[The prepared statement of Mr. Weldon follows:]

STATEMENT OF HON. DAVE WELDON, A U.S. REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

INTRODUCTION

Thank you for your invitation to appear here before you today. I appreciate this opportunity to share with the Committee why I am concerned about this issue and what led me to introduce in the House, along with by good friend, Democrat Rep. Bart Stupak, a bill banning human cloning.

I assume the debate in the Senate will, most likely, follow along similar lines as to what occurred in The House. In that body there was an almost universal agreement that so called reproductive cloning (an attempt to create a live baby using cloning technology) should be illegal, but some people would like to allow scientists to be able to create human cloned embryos in the lab for research purposes. This latter position is defended by its advocate because of the claim that such research might lead to treatments for various diseases.

It also takes us beyond the position many people held by some during the debate in support of embryo stem cell research. Destroying human embryos was felt justified by some because these embryos in the fertility clinics were held to be excess and destined for destruction anyway. Now we are debating

> ". . .creating human embryos specifically to be used for research and then destroyed ". . . creating embryos for research purposes is entirely different from using spare embryos leftover from infertility treatments. . . " So wrote 13 Senators in a recent letter to the President Bush on July 20, 2001. Also adopting this ethical principle are 59 Senators who on July 20, 2001 wrote the following to the President regarding embryo stem cell research: ". . . for we must bear in mind that the embryos used in this research are produced in vitro fertilization clinics and if not used for humanitarian research may otherwise be discarded."
>
> A 1994 Washington Post editorial labeled as "unconscionable" the notion of allowing embryos to be created solely for research. These Senators, the Post and others saw clearly the great peril of allowing the creation of human embryos, cloned or not, specifically for research purposes. Regardless of the issue of personhood, nascent human life has some value, it's not bacteria, and as these statements suggest, the creation of human embryos for the sole purpose of research is a line which should not be crossed.

TERMINOLOGY

The term "therapeutic cloning" has suffered an image crisis and so there has been an effort to come up with a new label. Some call it "nuclear transplantation", others call it "therapeutic cell transplantation". Is it an embryo. Period. The simple test is, if you place the product of nuclear transplantation into a woman's womb could it grow into a human baby. The answer is "yes." It is an embryo regardless of what name it is given.

COMPLETE BAN HAS BROAD SUPPORT/NOT A PRO-LIFE VS. PRO-CHOICE ISSUE

Broad Support for Weldon/Stupak Cloning Ban

By more than a 100 vote majority (265–162) the House passed H.R. 2505, the Weldon/Stupak bill to ban human embryo cloning for both experimental research and human reproduction.

The House considered and rejected on a 175–251 vote, a bill offered by Rep. Greenwood. The Greenwood bill offered a simplistic solution to a very complex issue. It allowed for the cloned human embryos to be created for research purposes but attempted ban the use of these cloned embryos to initiate a pregnancy. This is the very thing that the Post called "unconscionable." It is the very thing countless witnesses before House Committees called "unworkable." Unfortunately, the bill offered by Senator Feinstein is very similar to the Greenwood bill and it faces the same problems that the Greenwood bill faced.

Voting for the full cloning ban which passed the House were pro-choice and pro-life Members. Some of the most liberal Members in the House voted for the complete ban. Why did these Members vote for a complete ban on human cloning? Why has such a large and diverse group of Americans across political ideologies and religions affiliations joined in support of the Weldon/Stupak/Brownback bill? I will shed some light on that.

Exploitation of Women

Judy Norsigian noted feminist of the Boston Women's Health Book Group and co-author of *Our Bodies, Ourselves for the New Century* testified in support of the bill that passed the House. She and Stuart Newman, Ph.D. of the Council for Genetic Responsibility wrote in a Boston Globe Op-ed, "Because embryo cloning will compromise women's health, turn their eggs and wombs into commodities, compromise their reproductive autonomy and, with virtual certainty, lead to the production of 'experimental' human beings, we are convinced that the line must be drawn here." Any bill that falls short of the complete ban enables this exploitation of women and experimentation would go forward.

The National Academy of Sciences (NAS) cited as a reason for opposing human reproductive cloning, the increased "risks to women donating eggs." The same principle should apply to selling eggs to biotech companies for highly speculative human cloning research. For every patient, at least one cloned embryo would be required, therefore to treat millions of diseased patients, millions of women's eggs will be required. Where will they come from?

Environmentalists

Friends of the Earth President, Dr. Brent Blackwelder, has urged the House and Senate to enact the House-passed bill.

The Council for Responsible Genetics,[1]

The Nation's oldest organization scrutinizing new genetic technologies opposes all human cloning.

Liberal and Conservative Religious Leaders

The pro-choice General Board of Church and Society of The United Methodist Church and the pro-life United States Conference of Catholic Bishops support the House passed bill.

HUMAN CLONING NOT THE MOST PROMISING FOR CURES

New Discovery

A significant blow was dealt to the advocates of cloning on January 23, 2002, when it was reported in the *New Scientists*, that "'A stem cell has been found in adults that can turn into every single tissue in the body. It might turn out to be the most important cell ever discovered,"

Irving Weissman, who is on the next panel, stated in that article, "It's very dramatic, the kinds of observations [Verfaillie] is reporting. . . .The findings, if reproducible, are remarkable."

that a new adult stem cell had been discovered that is can change into many other types of human cells. This morning that study is published in the peer reviewed scientific *Journal of Clinical Investigation* with an accompanying commentary praising the discoveries of Reys, Verfaillie et al.

These findings are remarkable, and I would urge that we immediately thoroughly review these findings and see them duplicated in independent studies.

I think everyone in this room hopes that this finding can be independently reproduced. This finding would be one of the most dramatic findings ever and would indeed lead us on the path seeking cures for diseases without raising the serious moral and ethical issues that would otherwise be raised. I would hope that this Committee would invite these researchers to appear before your Committee as you consider this legislation.

Autoimmune Concerns

Furthermore, while proponents of research cloning say that human embryo cloning is necessary to develop cures and produce "immunologically acceptable tissue" some stem cell researchers disagree. In the Journal *Science*, John Gearhart of Johns Hopkins University states that many scientists feel "there are ways of getting around [the rejection problem] without the nuclear transfer [cloning] paradigm."

One of the most respected members of the Senate, Dr. Bill Frist, stated in his November 27, 2001, floor statement urging the Senate to take up and pass the House bill that, "the idea of therapeutic cloning, intended to combat the danger of autoimmune rejection, something I as a transplant surgeon am very aware of, carries with it challenges of its own and does not necessarily solve the problem of autoimmune rejection."

Patients Hopes Raised and Dashed

As a physician who still sees patients on a regular basis, I find it deeply upsetting to see patients suffering from serious diseases intentionally used by some in the debate over human cloning. These patients' hopes were raised early in the 1 990s over the prospects of using tissue from aborted fetuses for curing diseases. Those experiments have been disastrous. We saw this again just a few years ago with the promises of gene therapy. Nothing could be more cruel than to see suffering patients used for the cause of the moment.

Even Biotech Says So. . .

Often omitted by the supporters of embryonic stem cell research and cloning, are the serious hurdles that must be overcome. The New York Times ran several articles on this issue, one on December 11, 2001 and another on December 18, 2001. The December 18 article stated "Though not often discussed in public forums, the obstacles are so serious that scientists say they foresee years, if not decades, of concerted work on basic science before they can even think of trying to treat a patient." The failure of researchers and biotech companies to filly disclose and openly discuss these very serious challenges is prone to mislead many of those who suffer from these diseases.

Most scientists, according to leading scientific journals, now regard research cloning as impractical for treating patients. In the December 2001 issue of *Nature*, Peter Aldous (chief editor of news and features of Nature) said, "The idea of 'therapeutic cloning' seems to be on the wane.. . most [scientists] now believe this will be too expensive and cumbersome for regular clinical use."

In *Stem Cells*, (the first to isolate human embryo stem cells in 1998), Jamie Thomson of Johns Hopkins University writes, "[T]he poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision this [therapeutic cloning] becoming a routine clinical procedure."

And a recent *New Scientist* editorial states, that "Ministers in Britain have too easily swallowed the line that cloning human embryos is essential to medical progress. It is not. Like stuck records, ministers and policy makers continue to enthuse about therapeutic cloning even though the majority of bench scientists no longer think it's possible or practicable to treat patients with cells derived from cloned embryos."

Specific Objections and Concerns Raised by Researchers

University of Colorado biologist Jonathan Van Blerkom said he supports a blanket ban on all human cloning until scientists thoroughly understand what causes the birth defects that have plagued efforts to clone other mammals, such as cows and sheep.

"Until you really understand the underlying biology of what you're dealing with in a very comprehensive way, it's crazy, it doesn't make any sense," said Van Blerkom, who works with human embryonic stem cells at his Boulder lab.

The New York Times reported on December 11, 2001, reported that Dr Tanja Dominko went to a lab in Oregon to attempt to clone monkeys. "She left a year ago, with a cloning portfolio that she calls her gallery of horrors."

The National Academy of Sciences recently released a report of scientists, no bioethicists were involved, in which they supported research cloning while calling for a temporary ban on human reproductive cloning. "The greatest benefit we see as scientists is to get [human] research models who have real diseases," said the panel's chairman, Irving Weissman. He continued, "We are stymied as scientists in trying to study these diseases on mouse models." In other words, the term "model" refers to living organisms used in research. It is important to realize that regardless of potential clinical applications, the panel's recommendation is based on the desire to do basic research.

Conclusion

In conclusion, I suggest that there are several questions before the Committee today. These are fundamental questions that deserve serious consideration.

Does science have the moral authority to go wherever it wishes?

Should Congress pass a law that would mandate for the first time ever that a certain class of human embryos if created, can only be mined for their cells and then destroyed?

Is it realistic to think that it is possible to allow the creation of cloned embryos and still provide 100% certainty that no rouge scientist will take one of these embryos and implant it?

What would law enforcement do if it is found that a woman is carrying a cloned human embryo? If nothing, then why even posit the notion that therapeutic and reproductive cloning can be separate? If intervention, then aren't we into a whole new realm of civil liberties and privacy issues?

Are federal law enforcement officials going to inject themselves into the physician-patient relationship?

Are women being exploited by biotech companies?

Are there more promising alternatives? If so, many scientists are raising questions about the practicality of research cloning actually being used in therapies.

Are patients' hopes being needless raised once again, only to be dashed by scientific reality?

These just a few of the questions about the Greenwood bill that were unresolved during the House debate. And, they remain unresolved in the Feinstein bill.

I appreciate this opportunity to address the members of the Committee and would invite any questions you might have either about my bill or any of the issues I have raised.

Chairperson FEINSTEIN. Thanks very much, Mr. Weldon.

Mr. Greenwood, welcome.

STATEMENT OF HON. JAMES C. GREENWOOD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Representative GREENWOOD. Thank you, Senator Feinstein, Senator Hatch, Senator DeWine, Senator Brownback, for the invitation to testify today on the subject of human cloning.

I am encouraged to see the Senate take up this difficult issue as it confronts some of our most basic questions about science, the use of technology in improving health care, and life itself. These are questions that, however politically charged, we must forthrightly address.

Eighty years ago, Aldous Huxley wrote his literary masterpiece *Brave New World*. In that book, he posited a future where genetic engineering is commonplace and human beings, aided by cloning, are mass-produced. Controllers and predestinators have replaced mothers and fathers as the new authors of human life.

For most of its 80 years, *Brave New World* was seen as a disturbing work of science fiction, but that is no longer the case. The cloning of human beings is no longer relegated to the world of fiction. On March 28th of last year, I held a hearing in the Energy and Commerce Oversight and Investigation Subcommittee that found that the science existed and that there were sufficiently funded fringe groups that sought to clone a human being.

These fringe groups, combined with the recent announcement by a Massachusetts company that it had actually succeeded in the effort to grow stem cells for therapeutic purposes, has forced each of us to ask what should we do with this science.

I believe that as policymakers we must not only address the problems that come about from the use of the technology, but the foregone opportunities, cures for diseases, ailments and illness, that well may be lost should we entirely ban every aspect of this technology.

Let me be clear. I oppose human cloning, both the implantation of an embryo in a uterus and the creation of these embryos for reproductive purposes. Cloning human beings must be outlawed, and it must be outlawed in this Congress. But I also reject the premise that we are unable to distinguish between the dangers of untrammeled scientific experiments, on the one hand, and new paradigms in biomedical research on the other.

Somatic cell nuclear transfer, the science in question, holds the very real promise to enable a new kind of therapy, known as regenerative medicine. This therapy is one of the goals of stem cell research. Stem cells have the potential to form any cell in the body, and it can replicate indefinitely.

Regenerative medicine, when perfected, will use the knowledge we will gain in stem cell research to ultimately replace damaged or dead cells with transplanted healthy and vigorous new cells. These cellular therapies also hold the potential to cause an individual's currently malfunctioning cells to begin to function properly again.

Research with these stem cells and regenerative medicine holds great promise in the noble struggle to cure and treat millions of Americans who suffer from Alzheimer's and Parkinson's disease, diabetes, stroke, and spinal cord injury.

To achieve the goals in regenerative medicine, somatic cell nuclear transfer research is essential. This technology will help us understand biological properties that enable a differentiated cell nucleus to act like an undifferentiated one in a pluripotent cell. Scientists are still not sure how this reprogramming process works, but research to date supports the argument that potentially we could use our own tissue to create pluripotent stem cells, reducing the need for immunosuppressive drugs as part of the cellular therapy.

Last year, the House faced a choice of two approaches on how to deal with this science. The first, sponsored by Congressman Weldon, seeks to provide a simple and straightforward solution to this very complex matter of science. It seeks to ban all forms of cloning, effectively banning the related science of therapeutic cloning, thus shutting the door to these potentially life-saving technologies. Unfortunately, science will not yield up its mysteries in such constricted space.

The measure that I introduced, which is similar to your bill, Senator Feinstein, and to Senator Kennedy's, provides a more sophisticated solution to this terribly complex issue. Like you both, I wish to outlaw reproductive human cloning, while permitting further and carefully circumscribed research.

Unfortunately, the House chose to yield to fear-mongering and voted for the Weldon bill. Now, the Senate asks, what should we do with this science? Human reproductive cloning is not fiction and we should ban it. At the same time, I urge the Senate to enact meaningful legislation that also recognizes and responds to the possibilities of therapeutic cloning.

If I may, I would like to respond to a point or two that my colleague has made.

Chairperson FEINSTEIN. Please.

Representative GREENWOOD. First, he referenced or referred to false hope, that this science is not yet proven and he hesitates to provide false hope to the millions of our fellow humans who suffer from these diseases.

I would hold that hope is at the core of our humanity and we should allow our brilliant researchers to tell those who suffer from heretofore incurable illnesses and injuries if the hope is false or not. We should not legislatively dash their hopes.

A second point that my colleague made was on the question of whether this science holds out the potential to exploit women, because somehow there has been this notion created of embryo farms, thousands of women lining up to donate their eggs for this science. This is an incredibly important point in this argument.

What we want to promote is the science that would enable us to understand how this transformation occurs between a differentiated cell placed in a nucleus, surrounded by the contents of the egg—how that becomes an undifferentiated cell, and then again specializes in differentiation.

That science will enable us to identify the chemicals that are present at that transformation. When we understand what those chemicals are and what those processes are, we no longer need a supply of eggs. This is not a process that has to be replicated in order to provide the therapy.

The promise that is held out is that once we understand the chemistry of this process at the cellular level, then in the relatively near future when the patient comes to the hospital with a spinal injury, with the incurable disease, the therapist, the doctor, only needs to take that individual's somatic cell and then, in combination with these other chemicals, allow it to become a pluripotent cell and then a specialized cell to repair that spinal cord damage, to repair the damaged cells in the other organs, including the brain.

This vision of embryo farms needs to be removed from the debate. There is no such thing. The only way you could create this scenario is to have women line up and ask to be put through the extraordinarily painful process of super-ovulating so that scientists could have these eggs.

In nature, millions of fertilized eggs are flushed from the female body daily. That is, if you will, God's process. In in vitro fertilization, we have a surplus of fertilized eggs that, in the name of providing couples around the world the opportunity to have children when they couldn't otherwise do it, are destroyed by the thousands.

The research that we are talking about, as Senator Hatch said, is not about bringing together sperm and egg, but allowing the division of a somatic cell, if you would, from the inside of a cheek to study the processes that occur when that somatic cell is in the environment of the egg, to learn from it and then to provide therapy. We are not talking about vast quantities of eggs necessary to do that. We are probably talking on the order of magnitude of scores.

Thank you for the opportunity to testify, and I would also be pleased to answer your questions.

[The prepared statement of Mr. Greenwood follows:]

STATEMENT OF HON. JAMES C. GREENWOOD, A U.S. REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Senator Feinstein, senator Hatch, thank you for your invitation to testify today on the subject of human cloning. I am encouraged to see the senate take up this difficult issue, as it confronts some of our most basic questions about science, the use of technology in improving heatlhcare, and life itself. These are questions that, however politically charged, we must forthrightly address.

Eighty years ago, Aldous Huxley wrote his literary masterpiece, *brave new world*. In that book, he posited a future where genetic engineering is commonplace and human beings, aided by cloning, are mass-produced. Controllers and predestinators have replaced mothers and fathers as the new authors of human life.

For most of its eighty years, brave new world was seen as a disturbing work of science fiction. That is no longer the case.

The cloning of human beings is no longer relegated to the world of fiction. On March 28 last year, I held a hearing in the energy & commerce oversight and investigations subcommittee that found that the science existed and that there were sufficiently funded fringe groups that sought to clone a human being.

These fringe groups, combined with the recent announcement by a Massachusetts company that it had actually succeeded in the effort to grow stem cells for therapeutic purposes has forced each of us to ask, "what should we do with the science?"

I believe that as policymakers, we must not only address the problems that come about from the use of the technology, but the forgone opportunities—cures for diseases, ailments, and illness—that may be lost should we entirely ban every aspect of this technology.

Let me be clear. I oppose human cloning both the implantation of an embryo in a uterus and the creation of these embryos for reproductive purposes. Cloning human beings must be outlawed. And in this congress. But I also reject the premise that we are unable to distinguish between the dangers of untrammeled scientific experiments on the one hand and new paradigms in biomedical research on the other.

Somatic cell nuclear transfer, the science in question, holds the very real promise to enable a new kind of therapy known as regenerative medicine. This therapy is one of the goals of stem cell research.

Stem cells have the potential to form any cell in the body and can replicate indefinitely.

Regenerative medicine, when perfected, will use the knowledge we will gain in stem cell research to ultimately replace damaged or dead cells with transplanted healthy and vigorous new cells. These cellular therapies also hold the potential to cause an individual's currently malfunctioning cells to begin to function properly again.

Research with these stem cells and regenerative medicine holds great promise in the noble struggle to cure and treat millions of Americans who suffer from Alzheimer's and Parkinson's diseases, Diabetes, Stroke, and Spinal cord injury.

To achieve the goals in regenerative medicine, somatic cell nuclear transfer research is essential. This technology will help us understand biological properties that enable a differentiated cell nucleus to act like an undifferentiated one in a pluripotent cell. Scientists are still not sure how this "reprogramming" process works. But, research to date supports the argument that potentially, we could use our own tissue to create pluripotent stem cells, reducing the need for immunosuppressive drugs as part of this cellular therapy.

Last year, the house faced a choice of two approaches on how to deal with this science. The first, sponsored by Congressman Weldon, seeks to provide a simple and straightforward solution to this very complex matter of science. It seeks to ban all forms of cloning, effectively banning the related science of therapeutic cloning, thus shutting the door to these potentially life-saving technologies. Unfortunately, science will not yeild up its mysteries in such constricted space. The measure that I introduced, which is similar to your bill, senators Feinstein and Kennedy, provides a more sophisticated solution to this terribly complex issue. Like you both, I wish to outlaw reproductive human cloning, while permitting further and carefully circumscribed research.

Unfortunately, the house chose to yield to fearmongering and voted for the Weldon bill.

Now the senate asks: what should we do with this science? Human reproductive cloning is not fiction—and we should ban it. At the same time, I urge the senate to enact meaningful legislation that also recognizes and responds to possibilities of therapeutic cloning.

There is a line from John Keats' work, the fall of hyperion, which the late Robert Kennedy once used to describe the burden of public service that applies here, where the poet wrote of those "who feel the weight of the world and more like slaves to poor humanity labour for mortal good."

We are now called upon to labor for the needs of those millions who suffer and whose greatest and best hope is in the benefits which can only be derived from advances in this remarkable science.

Thank you very much.

Chairperson FEINSTEIN. Thanks very much, Mr. Greenwood.

Do members have questions of this panel?

Senator SPECTER. Madam Chairman?

Chairperson FEINSTEIN. Senator Specter, welcome.

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

Senator SPECTER. A comment and a question of sorts. The subject matter today is human cloning, and the frequently used phrase has been "therapeutic cloning." In hearings which we had in the Appropriations Subcommittee for Health and Human Services, we called it a nuclear transplant, and I see that Senator Hatch today has called it DNA regenerative therapy.

The word "cloning" conjures up reproductive cloning, which is generally objected to and has a very, very unpalatable connotation. This, of course, is not cloning of another human being, but is a process to enable therapy to be applied so that the patient does not reject it.

So my question is, Congressman Greenwood, do you think it would be a good idea not to call it therapeutic cloning, but to call it something else?

Representative GREENWOOD. I do. I think "somatic cell nuclear transfer" is the appropriate scientific term. And I agree with you, Senator Specter, that everyone rejects the notion that we should reproduce humans by cloning. I think that every child deserves to be the unique process of reproduction between a mother and a father, and not someone's duplicate. That is the vision that is conjured by the word "cloning," and I think it is a misnomer to refer to this somatic cell nuclear transfer as cloning and it would be less confusing to the public if we dropped that terminology.

Senator SPECTER. Well, I thank you, Congressman Greenwood, and also Congressman Weldon, for your participation. This is a very, very important debate. As already noted, Senator Feinstein and Senator Kennedy have introduced legislation, as have Senator Harkin and myself. I think Senator Brownback is interested in this subject as well.

Chairperson FEINSTEIN. And Senator Durbin is a cosponsor of our bill, as well.

Senator SPECTER. And Senator Durbin.

It is very important to have a thorough debate and I compliment you, Madam Chairman, for convening the hearing.

Chairperson FEINSTEIN. Well, thank you.

Senator Durbin, any questions of these witnesses?

Senator DURBIN. No.

Chairperson FEINSTEIN. Any other questions?

Senator BROWNBACK. I do, Madam Chairman, if I could, briefly.

Chairperson FEINSTEIN. Senator Brownback?

Senator BROWNBACK. Thank you for holding the hearing. I appreciate your doing that and I appreciate looking at the topic carefully. I think it is an extremely important topic and one that hopefully we are going to take action on this spring. The Majority Leader has stated that we would have a vote on this sometime in February or March on the floor. So I think it is good that we lay the groundwork here.

I would ask either Congressman Weldon or Greenwood, why are we trying to get around this notion of calling the clone an embryo.

Congressman Greenwood, what you are describing in therapeutic cloning is, that someone would take the egg, de-nuclei it; then take a somatic cell from you, and then, put it in the egg and start it growing again. Is that correct?

Representative GREENWOOD. That is roughly the description of the process of somatic cell nuclear transfer, yes, sir.

Senator BROWNBACK. So we would have a genetic copy of you, then, if we did it the way I have just described. Is that correct?

Representative GREENWOOD. Well, we would have in that cell all 46 of my chromosomes, yes.

Senator BROWNBACK. And they would be identical to your genetic makeup. Is that correct?

Representative GREENWOOD. That is correct.

Senator BROWNBACK. And if we are able to perfect the system—and I think there is a way to go before we do, but if we are able to perfect it the way Dolly the sheep was created, at the end of that

process if we nurtured that clone, if it is able to follow on through, we would have a baby that would come forward that would be physically identical to you. Would that be correct?

Representative GREENWOOD. God forbid.

[Laughter.]

Senator BROWNBACK. Or me or anything else like that, but that is what would happen at the end of that process. Is that correct?

Representative GREENWOOD. Yes. Theoretically, if you planted that dividing cell into a woman's uterus and it took and it came to term, yes, it would be a genetic reproduction of the donor of the somatic cell. Of course, that is why we expressly prohibit that course of action in our legislation.

Senator BROWNBACK. You expressly prohibit the implantation, correct?

Representative GREENWOOD. Correct.

Senator BROWNBACK. It is not the creation, it is the implantation in the Feinstein bill and in your process.

Representative GREENWOOD. Correct.

Senator BROWNBACK. So you would allow the creation, but not the implantation of it?

Representative GREENWOOD. That is correct.

Senator BROWNBACK. I think here is, if I could engage Congressman Weldon, where the rub on the bill is, that you have then created a clone. Now, some may not deem it a clone until it reaches a certain age, but the genetic composition in this process doesn't change, does it, Congressman Weldon?

Representative WELDON. No, it doesn't.

Representative GREENWOOD. Pardon me. May I be excused? I promised to stay longer, but I have been reminded I have a television appearance at three.

Chairperson FEINSTEIN. Please, and thank you very much.

Senator BROWNBACK. Thank you for being here.

Representative WELDON. You have created a clone. It begins the process of differentiation and it goes through various phases. You have the blastocyst phase and then you have the embryonic phase, and then it goes into the fetal phase after that.

It is a genetic copy, and that is really why the researchers want to use it. The theoretical construct is that you develop leukemia, you go into the doctor, he creates a clone of you and then he extracts new bone marrow cells from the clone, or stem cells that would then become bone marrow cells. The clone is then destroyed and the cells that were extracted or harvested are then used to treat your condition. That is where the term "therapeutic cloning" was derived.

As Senator Specter said, it has very high negative connotations amongst the public. So an attempt is being made to give it a different name, but it is still the same thing that we are talking about.

Senator BROWNBACK. Madam Chairman, I don't want to belabor the discussion here, but I think it is a key part of what the discussion is because we are all saying we are opposed to cloning because of the repugnance and we don't think that seems quite right and a number of other factors that people might cite.

But one bill that several people have put forward bans the implantation, not the creation. The Weldon approach and the approach I have put forward would ban the creation of the clone, and that is, I think, a key distinction that we need to understand in the various approaches. Those are basically the two approaches that are involved here with the legislation and the legislative debate that we are involved in.

Chairperson FEINSTEIN. Thank you, Senator Brownback.

Senator Durbin?

Senator DURBIN. If I might ask Congressman Weldon for the record, do you suggest that we should prohibit in vitro fertilization?

Representative WELDON. Oh, no, absolutely not, absolutely not. That is a totally different issue.

Senator DURBIN. Well, help me with this because you are trained in the science and I am not. If I understand in vitro fertilization, at the end of the process, if you are successful, you may have one implanted embryo that leads to a healthy baby and many other fertilized eggs that are ultimately discarded.

If the core of your belief here is that once you have joined this sperm and ovum either in a Petri dish or through another process that you have a human being, can you explain why you would support that process?

Representative WELDON. Sure, I would be very happy to respond to your question. Actually, the technique that is used in in vitro fertilization is multiple eggs are usually harvested, though in some cases they only get one or two that are viable and then they have to do a procedure called twinning to get more eggs.

Then they go through the fertilization phase with the sperm and they try to get multiple embryos, and they usually implant multiple embryos because it usually requires implanting multiple embryos to get one to take. This is why you get the high multi-birth incidence in women who have undergone the in vitro fertilization.

The important distinctions in this whole process from a moral and ethical perspective, which is I believe what you are getting at, are really two- or three-fold. No. 1, it is sexual fertilization, so you are not creating a clone and you don't get into all the ethical and moral issues associated with creating clones. We really didn't get into that, either Mr. Greenwood nor I, in our testimony, but there are legal issues and there are moral issues associated with that.

Typically, what happens in the in vitro clinic is after the first attempt, there is a 25-percent success rate with the first attempt. So 75 percent of the time you get a failure, so then you use any of those additional embryos for the second attempt. What is true is that 25 percent of the time you get a success the first time around and then you will have these extra embryos in the freezer, and that is really the issue that you bring up.

How are they different from clones? Well, one of the things that makes them very different is they are owned by the mother and father, and frequently in a high percentage of cases the reason the fertility experts like to keep these in storage is the couples come back and they say they want a second child.

What we really didn't get into in the egg donation issue but which is worth mentioning and why I talk about it as being exploiting women is there are some hazards associated with the egg-har-

vesting process. You have to give the women a super-ovulatory drug. There is a certain complication rate. They can get ovarian cysts, and it requires an anesthesia to harvest the eggs.

Senator DURBIN. I hate to interrupt you, but I am really trying to get to the bottom-line question here, not the process, but the result. At the end of this process, you end up with surplus embryos.

Representative WELDON. Sometimes, sometimes.

Senator DURBIN. So you are drawing a distinction of ownership. If there is ownership of these embryos by a married man and woman, then it is morally acceptable to store them, to use them. But if they are created through a scientific process through cloning, that is where you draw the line? The ownership is different?

Representative WELDON. Well, no, it is not only the ownership; it is the purpose and the intent. The purpose and the intent when you go to an in vitro clinic is you want to have a baby. You are creating these embryos because you want it ultimately to result in a child.

During the natural process, they may insert five embryos and only one may take and four are lost. In the other case——

Senator DURBIN. Isn't that a slippery slope? If it is intent and I know that my wife and I want one child and we are going to end up with surplus embryos that we are never going to use, you still think that is morally acceptable to go forward. Yet, if there was a cloned embryo coming out of a laboratory for whatever purpose, you would say that is morally unacceptable?

Representative WELDON. Well, I think you are comparing apples and oranges. What I would object to is if you and your wife said we are going to go down to the clinic and she is going to donate eggs, and me my sperm, and we are going to create embryos and then we are going to give them to this research department at the university so that they can extract stem cells and then destroy them. I would say then you are comparing apples to apples.

But when you say we are doing this because we want to have a baby and, yes, during the process there may be embryos that are lost, I think that is an ethically and morally -it is a very, very different situation than when you are creating embryos for the express purpose of extracting stem cells and destroying them.

Senator DURBIN. Thank you.

Chairperson FEINSTEIN. Thanks very much, Senator.

Thank you very much, Congressmen, for taking so much time. We appreciate it.

We will move on with the next panel, if we may, and as the next panel comes up I am going to begin to introduce them to save time.

The first panelist is Professor Irving Weissman. He is Professor of Pathology and Developmental Biology at my alma mater, Stanford, School of Medicine. He serves as a member of numerous professional societies, institutions, and editorial boards. He has been elected to the National Academy of Sciences and to the American Association for the Advancement of Science. He has also received the Kaiser Award for excellence in pre-clinical teaching, the Passerow Award, and the Outstanding Investigator Award from the National Institutes of Health. Professor Weissman is also the Chair of the Panel on Scientific and Medical Aspects of Human

Cloning, of the National Academies. That Panel just issued its long-awaited report and recommendations about cloning.

Professor Weissman, welcome. I am going to observe the 5-minute rule and we will go right down the line so that we have an opportunity to ask questions. I hope that is all right.

STATEMENT OF IRVING L. WEISSMAN, M.D., CHAIR, PANEL ON SCIENTIFIC AND MEDICAL ASPECTS OF HUMAN REPRODUCTIVE CLONING, THE NATIONAL ACADEMIES, AND PROFESSOR, STANFORD UNIVERSITY SCHOOL OF MEDICINE, STANFORD, CALIFORNIA

Dr. WEISSMAN. Madam Chair and members of the committee, my name is Irv Weissman and I am an M.D. and professor at Stanford Medical School. My main research field for the past 20 years has been the biology and transplantation of adult cells in mice and in humans.

I am here as Chair of the National Academies' Panel on Scientific and Medical Aspects of Human Reproductive Cloning, which released its report on January 18 of this year.

The charge to the panel in June 2001 was to examine the scientific and medical issues relevant to human reproductive cloning, including the protection of human subjects, and to clarify how human reproductive cloning differs from stem cell research. Our charge did not extend to an examination of the ethical issues related to human reproductive cloning.

We needed to determine whether current methods for reproductive cloning are scientifically feasible and reproducible and are medically safe. In addition, we needed to examine whether human participants in the process could be adequately advised and protected. Society and its leaders will need such scientific and medical information if they are to address the relevant ethical and public policy issues.

In reproductive cloning, the nucleus of a body cell is transplanted into an egg whose nucleus has been removed, stimulating it to divide to produce a blastocyst embryo. The blastocyst is then placed into a uterus with the intent of creating a newborn.

In a related but different procedure, cells are isolated from a blastocyst derived by nuclear transplantation and the cells are used to produce stem cell lines. This is shown here in the figure where, from the inner cell mass of a blastocyst created by nuclear transplantation, you make an embryonic stem cell line. Such stem cells are unspecialized cells and develop into almost all kinds of body cells. That is here, all these different kinds of cells.

In what is sometimes called therapeutic cloning, the donor of a nucleus for transplantation to produce stem cells can be a person in whom the daughter cells of the stem cells are transplanted back to regenerate damaged tissue. But there is another medical use for nuclear transplantation equally or more important, to produce stem cells.

Stem cells derived from a body cell or a disease cell of a patient who has inherited the risk for that disease, and therefore whose body cells or whose disease cells have completed the process to make the disease and have the life history of that process, are

transplanted to make stem cell lines, and now you can study how this goes wrong in particular diseases.

For example, in breast cancer the body cell often has the predilection for the disease, but numerous mutations occur, ones that we don't understand, to take it through the rest of the process to become a cancer cell. We need to be able to study that in a test tube and when we transplant the cells in mice.

We studied the scientific and medical literature and held a workshop with world leaders in the relevant technologies. Among the participants were persons who planned to clone human beings. The data from animal studies of reproductive cloning demonstrate that only a small percentage of the attempts are successful; that many of the resulting clones die during all stages of gestation or pregnancy, late and early; that newborn clones often are abnormal or die; and that the procedures carry serious risks for the mother. However, the data on nuclear transplantation to produce stem cells shows that these cells are functional.

Given those findings, the panel unanimously approved the following recommendations.

Human reproductive cloning should not now be practiced. It is dangerous and likely to fail. The panel therefore unanimously supports the proposal that there should be a legally enforceable ban on the practice of human reproductive cloning.

The scientific and medical considerations that relate to this ban should be reviewed within 5 years. The ban itself should be reconsidered only if at least two conditions are met. The first is that a new scientific and medical review indicates that the procedures are likely to be safe and effective, and that information must lead to a broad national dialog on the societal, religious, and ethical issues to suggest whether a reconsideration of the ban is warranted.

Finally, the scientific and medical considerations that justify a ban on human reproductive cloning at this time are not applicable to nuclear transplantation to produce stem cells. Because of the considerable potential for developing new medical therapies for life-threatening diseases and advancing fundamental knowledge, the panel supports the conclusion of a recent National Academies report that recommended that biomedical research using nuclear transplantation to produce stem cells be permitted. A broad national dialog on the societal, religious, and ethical issues is encouraged in this matter.

Scientists place a high value on the freedom of inquiry, a freedom that underlies all forms of scientific and medical research. Recommending restrictions of research is a serious matter and the reasons for such a restriction must be compelling. In the case of human reproductive cloning, we are convinced that the potential dangers to the implanted fetus, to the newborn, and to the woman carrying the fetus constitutes just such compelling reasons. In contrast, there are no scientific or medical reasons to ban nuclear transplantation to produce stem cells, and such a ban would certainly close avenues of promising scientific and medical research.

The panel stressed that all concerned segments of society should examine and debate the broad societal and ethical issues associated with human reproductive cloning, as well as those associated with nuclear transplantation to produce stem cells. We hope that our re-

port will help this committee and President Bush's Council on Bioethics in this regard.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Weissman follows:]

STATEMENT OF IRVING L. WEISSMAN, CHAIR, PANEL ON SCIENTIFIC AND MEDICAL ASPECTS OF HUMAN REPRODUCTIVE CLONING, NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, NATIONAL RESEARCH COUNCIL AND KAREL AND AVICE BEEKHUIS PROFESSOR OF CANCER BIOLOGY, AND PROFESSOR OF PATHOLOGY AND DEVELOPMENTAL BIOLOGY, STANFORD UNIVERSITY, STANFORD, CALIF.

Madam Chair and members of the Committee. My name is Irv Weissman. I am a professor at Stanford Medical School, and my main research field for the last 20 years has been the biology and transplantation of adult stem cells in mice and humans. I am here as chair of the National Academies Panel on Scientific and Medical Aspects of Human Cloning, which released its report on January 18, 2002.

The charge to the panel in June 2001 was to examine the scientific and medical issues relevant to human reproductive cloning, including the protection of human subjects, and to clarify how human reproductive cloning differs from stem cell research. Our charge did not extend to an examination of the ethical issues related to human reproductive cloning.

We needed to determine whether current methods for reproductive cloning are scientifically feasible and reproducible and are medically safe. In addition, we needed to examine whether human participants in the process could be adequately advised and protected. Society and its leaders will need such scientific and medical information if they are to address the relevant ethical and public-policy issues.

In reproductive cloning, the nucleus of a body cell is transplanted into an egg whose nucleus had been removed, stimulating it to divide to produce a blastocyst embryo; the blastocyst is then placed into a uterus with the intent of creating a newborn.

In a related but different procedure, cells are isolated from a blastocyst derived by nuclear transplantation, and the cells are used to produce stem cell lines. This is shown in the figure. Such stem cells are unspecialized cells that can develop into almost all kinds of body cells. In what is sometimes called therapeutic cloning, the donor of a nucleus for transplantation to produce stem cells can be a person in whom stem cell daughter cells will be used to regenerate damaged tissues. There is another medical use for nuclear transplantation to produce stem cells; stem cells derived from a body cell or a disease cell of a patient who had inherited the risk for that disease could be powerful tools for medical research and lead to improved therapies.

We studied the scientific and medical literature and held a workshop with world leaders in the relevant technologies. Among the participants were persons who planned to clone human beings. The data from animal studies of reproductive cloning demonstrate that only a small percentage of the attempts are successful, that many of the resulting clones die during all stages of gestation, that newborn clones often are abnormal or die, and that the procedures carry serious risks for the mother. However, the data on nuclear transplantation to produce stem cells show that these cells are functional.

Given those findings, the panel unanimously approved the following recommendations Human reproductive cloning should not now be practiced. It is dangerous and likely to fail. The panel therefore unanimously supports the proposal that there should be a legally enforceable ban on the practice of human reproductive cloning.

The scientific and medical considerations related to this ban should be reviewed within five years. The ban itself should be reconsidered only if at least two conditions are met: (1) a new scientific and medical review indicates that the procedures are likely to be safe and effective, and (2) a broad national dialogue on the societal, religious, and ethical issues suggests that a reconsideration of the ban is warranted.

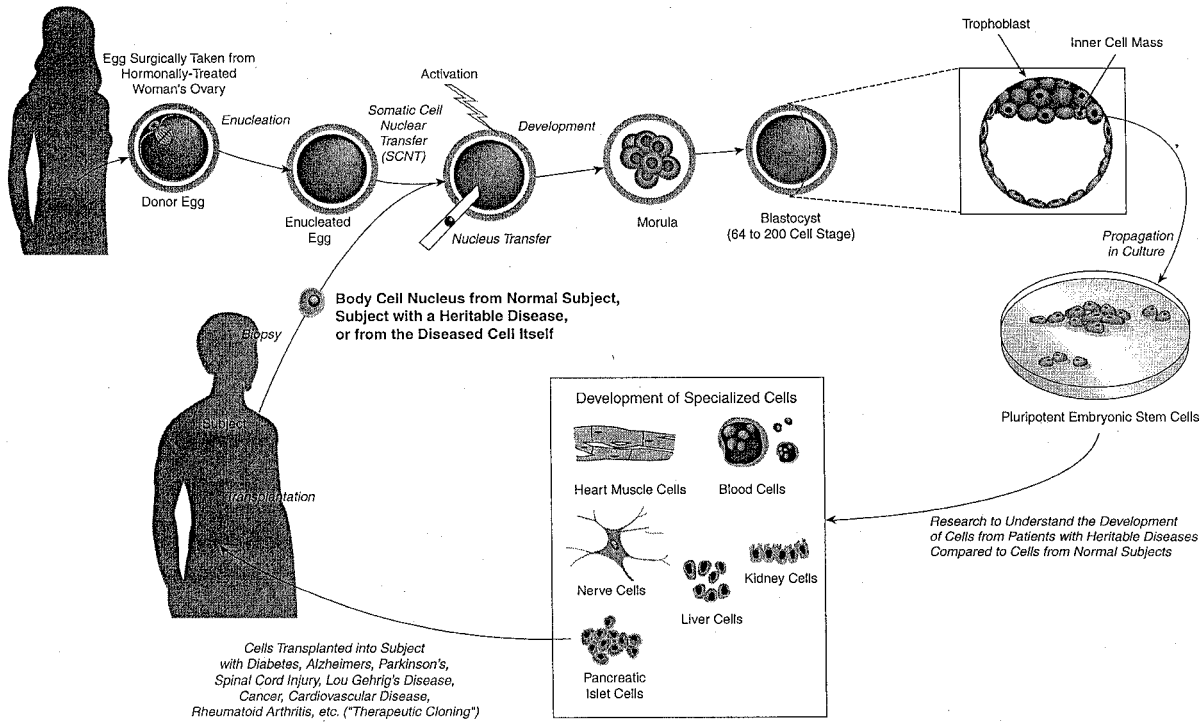
Finally, the scientific and medical considerations that justify a ban on human reproductive cloning at this time are not applicable to nuclear transplantation to produce stem cells. Because of the considerable potential for developing new medical therapies for life-threatening diseases and advancing fundamental knowledge, the panel supports the conclusion of a recent National Academies report that recommended that biomedical research using nuclear transplantation to produce stem cells be permitted. A broad national dialogue on the societal, religious, and ethical issues is encouraged on this matter.

Scientists place high value on the freedom of inquiry—a freedom that underlies all forms of scientific and medical research. Recommending restriction of research is a serious matter, and the reasons for such a restriction must be compelling. In the case of human reproductive cloning, we are convinced that the potential dangers to the implanted fetus, to the newborn, and to the woman carrying the fetus constitute just such compelling reasons. In contrast, there are no scientific or medical reasons to ban nuclear transplantation to produce stem cells, and such a ban would certainly close avenues of promising scientific and medical research.

The panel stressed that all concerned segments of society should examine and debate the broad societal and ethical issues associated with human reproductive cloning, as well as those associated with nuclear transplantation to produce stem cells. We hope our report will help this Committee and President Bush's Council on Bioethics in this regard.

Thank you for the opportunity to testify. I hope that my statement and the panel report can be put into the record. I will be happy to answer questions.

NUCLEAR TRANSPLANTATION TO PRODUCE STEM CELLS



Chairperson FEINSTEIN. Thank you very much, Dr. Weissman.

We will now turn to Professor Henry Greely, who also comes to us from Stanford University. He is the C. Wendell and Edith M. Carlsmith Professor of Law, and Professor, by courtesy, of Genetics. He is an expert in health law and health care policy and has written extensively on issues concerning genetic testing, human cloning, and the ethics of human genetics research.

He is the Chairman of the steering committee of the Stanford University Center for Biomedical Ethics. He co-directs the Stanford Program on Genomics, Ethics, and Society. He is also the Chairman of the Ethics Subcommittee of the North American Committee of the Human Genome Diversity Project, and serves on the California Advisory Committee on Human Cloning.

Welcome, Mr. Greely.

STATEMENT OF HENRY T. GREELY, PROFESSOR OF LAW, AND DIRECTOR, CENTER FOR LAW AND THE BIOSCIENCES, STANFORD UNIVERSITY, STANFORD, CALIFORNIA

Mr. GREELY. Thank you. Good afternoon, Madam Chairman and members of the committee. You have heard who I am. Let me just add that I am deeply honored to have the opportunity to speak to you today about this important issue.

I am here for two reasons. As a member of the California Advisory Committee on Human Cloning, I am here to report to you our committee's results, and then as an individual who has studied this area to give you my own views on some of these issues, not necessarily that committee's views.

I have submitted written testimony. I want to use my brief time here to highlight some of its more important points. My bottom-line conclusion is based on our report, and based on that view, I strongly support Senate bill 1758.

The California Advisory Committee on Human Cloning grew out of the fact that California was the first jurisdiction in the United States to ban human cloning. California did that in 1997, shortly after Dolly was announced. It is a 5-year ban on reproductive cloning.

The legislation also required the State to appoint an expert committee to advise the Governor and the legislature—before those 5 years were up—on how that bill should be revised. The committee was appointed in early 1999 and has spent the last 2½ years studying this issue, with public hearings, with testimony from experts, and with an incredible amount of argument.

We spent 8 months writing our report, debating over sentences, words, and the placement of commas. I imagine it would be like an 8-month conference committee, not something that you particularly want to go through. But I am happy to say that at the end, when we finished our negotiations 8 hours before we turned in our report, we had five unanimous recommendations. They are attached to the testimony as part of the executive summary of our report.

What is important about that is that we all, the 12 of us on the committee, came into this process with very different views. We left with different views, but not very different views. The more we studied it, the stronger our consensus grew.

Our most important recommendations are that reproductive cloning should be banned and that non-reproductive cloning should not be banned, but should be regulated. Coming from very different positions, we ended up in that same place.

At least in California, and I think in much of the country, there is a latent consensus on this point: ban cloning for making babies, allow cloning but regulate it more seriously for research purposes. In fact, Madam Chairman, I am authorized to say that your opponent in your last election, my law school comrade, Tom Campbell, supports your general approach to the cloning issue.

With respect to reproductive cloning, there is not much to say. I don't think policy issues get much easier. There are compelling safety concerns about the health of any infants produced. There are very serious non-safety concerns. There are no compelling reasons to produce a baby by cloning. California banned this 5 years ago. I agree with Senator Hatch that it is long past time for Congress to follow that lead and to ban human reproductive cloning.

Human non-reproductive cloning was a more difficult issue for our committee, and clearly is a more difficult issue today. Our position was two-fold: California shouldn't ban it, but California should impose new regulations on it. One of the things I particularly like about S. 1758 is that, mirroring one of the California recommendations, it proposes that IRB review be required for non-reproductive cloning research. We think that is a good idea as well.

In looking at non-reproductive cloning, it is very interesting to start with the arguments against such cloning. There seen to be some novel coalitions against such cloning research. I don't know whether it is ironic or appropriate that an asexual method of reproduction is producing strange bedfellows. But we are seeing an unusual, to say the least, political coalition opposing non-reproductive cloning.

Two points. First, most of the arguments about non-reproductive cloning are arguments about human embryo research in general. Those arguments have been around for 10 years. The related arguments about human fetal tissue research go back to at least 1988. Arguments about the moral status of the embryo or the fetus and the arguments about possible exploitation of women are not new.

Our society has not come up with a happy resolution of these, but we have come up with a compromise that everyone is unhappy with, but everyone lives with: no Federal funding for this kind of research, but no Federal ban on privately funded such research. I see no reason for it to be different with non-reproductive cloning.

The only argument about non-reproductive cloning that is not a general argument about human embryo cloning research is the argument that once there are cloned embryos for research, they will be implanted. Even though the law would criminalize such implantation—not require an abortion, but send the doctor who implanted the cloned embryo to jail.

The research institutions that are doing this research for developmental biology purposes aren't experts in implanting embryos. In vitro fertilization clinics are experts in manipulating eggs. It is very unlikely that someone who wanted to do this 1) couldn't make the embryo itself, 2) would be able to steal an embryo from a re-

search institution that is not an in vitro fertilization clinic and, then implant it successfully.

So, in summary, the dangers of human reproductive cloning compel responsible legislators to ban it. The promises, as well as the dangers, of non-reproductive cloning compel that it be permitted, but that it be more extensively regulated along the lines of S. 1758.

Thank you, Madam Chairman.

[The prepared statement of Mr. Greely follows:]

STATEMENT OF HENRY T. GREELY, C. WENDELL AND EDITH M. CARLSMITH PROFESSOR OF LAW, PROFESSOR, BY COURTESY, OF GENETICS, DIRECTOR, CENTER FOR LAW AND THE BIOSCIENCES, STANFORD UNIVERSITY

Madam Chairman and members of the Senate Judiciary Committee, my name is Hank Greely. I am a professor of law and a professor, by courtesy, of genetics at Stanford University.

Since early 1999, I have been a member of the California Advisory Committee on Human Cloning, which made its statutorily-mandated report, entitled Cloning Californians? Report of the California Advisory Committee on Human Cloning, to the California legislature on January 11, 2002. I have made copies of that report available to the Committee's staff; I am only attaching its Executive Summary to this testimony.

I am here today both to report the findings of that Committee and to provide my own insights into legislation now pending before this body concerning human cloning. Except as specifically noted, the views I express today are my own and not necessarily those of the California Committee or of Stanford University. Those views lead me to support, strongly, Senate Bill 1758.

I want to discuss four things in my testimony: The California report, reproductive cloning, non-reproductive cloning, and the implementation of any legislation related to human cloning.

THE CALIFORNIA REPORT

In 1997 California became the first U.S. jurisdiction to ban human reproductive cloning. The ban was to last for five years, until January 1, 2003. As part of this statute, the legislature required the executive branch to appoint a committee to make recommendations back to the legislature about appropriate policy on human cloning by December 31, 2001. The legislature and the governor would thus have a full year to consider the report before the existing ban on reproductive cloning expired.

The California Advisory Committee on Human Cloning was appointed in early 1999. Its twelve members, identified below, represented a variety of professional backgrounds and a wide range of political viewpoints.

Francine Coeytaux, MPH	Public
Prof. Theodore Friedmann, MD	Genetics
Dr. David Gollaher, PhD	Biotechnology
Prof. Henry T. Greely, JD	Law
Dr. Roger Hoag, MD	Medicine
Prof. Bernard Lo, MD	Ethics
Dr. Bert Lubin, MD	Medicine
Prof. Margaret R. McLean, MDiv, PhD	Religion
Francis C. Pizzulli, JD	Law
Prof. Radhika Rao, JD	Law
Prof. Larry Shapiro, MD	Medicine
Dr. Tracy Trotter, MD	Medicine

Under the leadership of Dr. George Cunningham, Chief of the Genetic Disease Branch, California Department of Health Services, the Committee held five public meetings, beginning in May 1999, and innumerable closed meetings. It discussed, debated, negotiated, and argued about the subject and about its report up until the day before it delivered that report to the State. But, remarkably, the report it delivered contained five unanimous recommendations, as the Committee achieved a consensus on these very difficult issues.

The exact recommendations are contained in the Executive Summary of the Committee report, attached at the end of this statement. The most important recommendations were the first that California should ban human reproductive cloning and the second that California should not ban, but should regulate, human non- reproductive cloning.

Those recommendations are not, in themselves, novel. Other groups, and other jurisdictions, including the United Kingdom, have reached similar conclusions. What was remarkable about the Committee's conclusions, I believe, is not what they were but how they were reached. The twelve members of this Committee started with very different positions on both reproductive and non-reproductive human cloning. As we heard more testimony and public comment, read more deeply in the literature, and began writing (and arguing about) our report, our views began to converge. They never converged completely. We have some different reasons for believing human reproductive cloning should be banned; although all of us agree more regulation of human non-reproductive cloning is needed, we have different ideas for the appropriate extent of such regulation. But, in 32 months of study and effort, we came much closer together. I believe our experience is evidence that, although the issues raised by human cloning are both profound and complex, a latent consensus exists, in California and, I believe, in the United States, on these issues. Government should not allow human cloning to be used to make people; it should allow with due care human cloning research to proceed to find ways to relieve diseases and conditions that cause suffering to existing people. Senate Bill 1758, introduced by Senator Feinstein and others, reflects that emerging consensus; Senate Bill 790, introduced by Senator Brownback and others, does not.

HUMAN REPRODUCTIVE CLONING

No responsible authority has supported the current use of human reproductive cloning. The California Committee was no exception. Every member of our Committee concluded that the issues of the physical health and safety of any children produced by such cloning compelled its prohibition. Every member also had concerns about human reproductive cloning even if it were proven safe. A large majority of the Committee concluded that other issues would justify a ban on reproductive cloning even if it were proven safe, although there was no agreement on just which non-safety issues were compelling.

The safety concerns are not a smoke-screen for the other worries; they are only too real. Many strong theoretical reasons cast doubt on the safety of this procedure. The empirical results to date with reproductive cloning in other mammals are a daunting record of miscarriages, still-births, birth defects at ten times the normal rate, and at least some possible indications of late onset illness. The almost total failure of efforts to clone non-human primates, in spite of substantial efforts, is yet another reason for concern. One should not demand perfect safety the usual way of making babies has its own serious risks for both mother and child but before we should consider seriously allowing human reproductive cloning, the procedure should have demonstrated, in non-human mammals (and preferably primates), that it is as safe or nearly as safe as normal reproduction or in vitro fertilization technologies.

Statutory prohibitions of reproductive cloning, such as exist in California and a few other states, would be useful. It is not clear that they are essential the unanimous condemnation of the procedure by professional groups; the potential for civil liability; the assertion by the Food and Drug Administration, no matter how questionable, of jurisdiction over cloning; and their own professional duty to "first do no harm" should stop all but the most reckless physicians. Adding a statutory prohibition, with clear and serious penalties, would, however, be another useful measure to limit such unjustified experiments.

HUMAN NON-REPRODUCTIVE CLONING

The California report's position on human non-reproductive cloning is more complicated. We believe that its medical promise meant that it should not be banned. At the same time, we do not believe that the existing regulation of this research is sufficient. Both parts of that recommendation were essential to our unanimous conclusion. Only Senate Bill 1758 combines those two crucial points.

Consideration of human non-reproductive cloning can usefully begin with analysis of the arguments against it. Almost every argument about human non-reproductive cloning is, in fact, an argument against any destructive research with the human embryos. Arguments about the moral status of the embryo, the possible commodification of human life, the risk of oppression to egg donors have been made for more than a decade about human embryo research, as well as human fetal re-

search. Our society has not reached a consensus about any of those arguments, but our governments have reached a compromise resolution. The federal government does not fund research that entails the destruction of human embryos; nor does it, under President Bush's August 9, 2001 position, fund research on embryonic stem cell lines derived from human embryos that were destroyed after that date. But neither the federal government nor most states forbid such research if it is privately funded. This resolution makes both sides unhappy, but it has proven, to date, an acceptable compromise. There is no reason to treat human embryonic research differently because the embryo involve was created through cloning.

Only one argument against non-reproductive human cloning is not just a recycled argument against human embryo research. Some have argued that human non-reproductive cloning must be banned to forestall human reproductive cloning. This "slippery slope" argument is largely silly. One could make the same argument for banning automobiles because they might be used for get-aways from bank robberies or banning electricity because it might be used to commit a murder. In the case of human cloning, the argument requires that someone who is willing to violate the law (and incur its penalties) by performing human reproductive cloning would not be able to make his own embryos, but would be able to beg, borrow, or steal a most likely anonymous cloned embryo from a research laboratory and, using an in vitro fertilization clinic, implant the transported cloned embryo into a willing woman. If the production of cloned human embryos proves possible, it is most likely that, as with other cloned mammals, the creation of the cloned embryo will be the easy part of the work bringing it successfully to term will be the hard part.

This slippery slope argument does have one good use. It highlights the value of increasing the regulation of human non-reproductive cloning. The California Committee concluded that the State should regulate non-reproductive cloning by at least a) forbidding all research with cloned human embryos after the appearance of the so-called "primitive streak" at about 14 days from its creation, b) requiring the informed consent of all those who donated cells to the process, and, last but most importantly, c) requiring the review and approval of any such work by an Institutional Review Board. Such IRB review will help ensure that the research is documented, that the researchers are accountable, and that the means and goals of the research are appropriate. This review is not now generally required for research that does not involve federal funding, Food and Drug Administration approval, or major research institutions. I am pleased that Senate Bill 1758 includes this extension of IRB review to human non-reproductive cloning.

Issues of Implementation

Finally, the California Committee discussed not just what policy the State should adopt, but how that policy should be implemented. We strongly recommended that the legislature delegate the details of regulation, including the detailed definition of the covered procedure, to an administrative agency. The same concerns clearly exist at the federal level.

It is difficult for a legislature to regulate science effectively, particularly in a fast-moving field. Drafters of the legislation, in spite of their best efforts, may not understand scientific terms in the same way the scientists do. Even if their understanding is correct at the time the legislation passes, the science can and will change much more quickly and easily than statutory language. I have studied the definition of human cloning in the numerous bills introduced and the few statutes passed in various jurisdictions after Dolly. See Henry T. Greely, Banning "Human Cloning": A Study in the Difficulties of Defining Science, So. Cal. Interdisc. Law Rev. 8:131–152 (1998).

Many of those bills would not have achieved their goals because their loose use of terms like "cloning", "somatic cell," or "diploid" left loopholes that could be exploited. Some used definitions that made no sense at all. Several bills would have banned "the replication of a human individual by cultivating a cell with genetic material through the egg, embryo, fetal and newborn stages into a new human individual." Unless the term "replication," itself undefined and ambiguous, has special meaning, this definition seems to describe the age-old method of human reproduction. A bill introduced in Florida would have banned human cloning, defined as "creating a new individual by using the complete nuclear genetic material of an existing human being to create a second genetic duplicate of that human being." Presumably the first duplicate would have been permitted. Even the California legislation, which, in my professional view, has the best definition of human reproductive cloning, could be read to exclude some advanced reproductive technologies that involve transfer of a nucleus into an egg but do not involve human cloning the resulting egg would later be fertilized with sperm.

Although the Congress is likely to avoid making some of these mistakes, it cannot avoid the unpredictability of the future course of this science. Any legislation passed, therefore, should define human reproductive cloning broadly probably as the intentional creation of a fetus or child that is substantially genetically identical to a previously existing human and delegate the power to define the subject matter more precisely to an administrative agency.

CONCLUSION

The explosion of our knowledge about biology confronts us all as legislators, as citizens, as moral actors with new challenges. It holds the promise of unprecedented reductions in human suffering; it also holds the threat of unprecedented changes. . .and dangers. . .to our humanity. The combination of a science that is both unclear and rapidly changing with a host of moral questions of great depth makes perfect solutions impossible. We cannot know what is right; we can only act, humbly, in ways that, after due consideration, seem right based on what we now know. The various dangers of human reproductive cloning, as we now understand them, demand that it be banned. The various promises of human non-reproductive cloning, with the benefits they now seem likely to offer, compel its continuation but with appropriate new regulation. This mixed verdict is not the perfect solution to the challenge of human cloning; it is merely the best solution we fallible humans can come up with today. As such, Congress should enact it into federal law through adopting Senate Bill 1758.

It has been an honor, and a pleasure, to appear before you. Thank you for the opportunity to discuss these fascinating and compelling issues.

Chairperson FEINSTEIN. Thanks very much, Professor Greely.

I will now turn to R. Alta Charo. She is a professor of law and medical ethics at the University of Wisconsin at Madison. She is on the faculty of both the university's law and medical schools. Since arriving at the University of Wisconsin in 1989, Professor Charo has served on the University of Wisconsin Hospital Clinic Ethics Committee and the university's Bioethics Advisory Committee. From 1996 to 2001, she was a member of the Presidential National Bioethics Advisory Commission where she participated in drafting numerous reports, including "Cloning Human Beings." Since 2001, she has been a member of the National Academy of Sciences Board on Life Sciences.

Welcome, Professor.

STATEMENT OF R. ALTA CHARO, PROFESSOR OF LAW AND MEDICAL ETHICS, UNIVERSITY OF WISCONSIN LAW SCHOOL, MADISON, WISCONSIN

Ms. CHARO. Thank you very much. Madam Chairman, members of the committee, first I would like to thank you for the opportunity to address you.

Debates over reproductive cloning, stem cell therapy, and even genetic engineering have become hopelessly entangled in the last 5 years. Each one is worthy of a policy debate, but I deeply believe each one would be better debated if debated separately.

As you have already discussed, there are bills now before this Congress that would ban not only the irresponsible use of cloning to make babies—a procedure we all agree is dangerous at this time—but also the responsible use of non-reproductive cloning for research or therapy. Some would even ban the importation of proven medical therapies developed abroad if their origins were entangled with cloning research.

Proponents of these bans say this is necessary in order to be assured that reproductive cloning to make children cannot occur. I disagree.

The proponents of the bans, for example, fear that once a cloned embryo exists in a laboratory, either the embryo or its so-called parent may have constitutional grounds to insist that pregnancy be permitted. But this makes no sense. It requires either that the embryo itself have a constitutional right to be born—something that the U.S. Supreme Court has specifically rejected and also has been rejected by leading State courts hearing disputes over existing frozen IVF embryos in our laboratory now—or this argument would require that people be considered to have a fundamental right to use these embryos to reproduce through cloning—in other words, to have a fundamental right to reproduce by cloning, per se, which would render the entire ban equally unconstitutional.

Now, others worry not about a constitutional ground for bringing the embryo to term but simply that the cloned embryo sitting in a lab will tempt someone to use it illegally. But I would note that the criminal penalties in bills such as S. 1758 are equally effective whether the cloned embryo already exists or is merely imagined. The deterrent is clear, and it is not strengthened by criminalizing basic research.

So if criminalizing research is not needed to guard against the unfortunate outcome of using cloning to make children, it must have another purpose. And indeed the proponents have cited the research ban being needed to protect embryos, women's health, and even the future of humanity.

In my opinion, if the purpose is to protect embryos, then criminalizing research and so-called therapeutic cloning is an odd place to begin. As Senator Durbin has already pointed out this afternoon, we know and, indeed, we fully expect that embryos will unfortunately be lost by the thousands each year at in vitro fertilization clinics, even if IVF is done perfectly, even if every woman who wants to adopt an embryo is successful.

Criminalizing research cannot alter the scale of this embryo loss, and since almost no one thinks that IVF itself could be outlawed, then banning a technique that might involve an exceedingly small number of embryos represents, at best, a symbolic effort at embryo protection.

Now, such symbolic efforts are important. They remind us that life is a gift to be experienced with awe and gratitude. But such symbols can be badly tarnished if they are adopted at the expense of pain and suffering. And as Dr. Weissman has noted and as the chairman noted when she first opened the hearing, reproductive cloning at this time is a danger to children but non-reproductive cloning might save their lives. Whether by doing research with the cells of those who have genetic diseases so we can study in a laboratory dish how the defective gene operates and develop drugs to treat, or to use it for transplantation without risk of rejection, it is potentially life-saving. But most important—and, again, as the chairman noted in her earlier remarks—studying research cloning allows us to understand how cloning reprograms adult cells, which may in the future allow us to reprogram those cells directly without cloning and without the use of embryos in order to generate tissue that could be used to alleviate paralysis or save lives.

Yes, there are other promising avenues of research, and you will hear about them this afternoon. They most certainly should be pur-

sued. But that is no argument for criminalizing this research. America is not a country in which basic research or personal choices are illegal until someone has persuaded the government to grant permission. Quite the contrary. We celebrate the freedom to think and to act and to inquire into the secrets of nature until a compelling case can be made that it must be stopped. Identifying complementary areas of research falls far short of making that case. In my opinion, at best it is an argument for shaping Federal funding priorities in a way that affords these alternative avenues every chance of success.

In my last remaining seconds, I would like to note that there are a handful of women's health and environmental organizations long known for a particularly great skepticism about medical science and biotechnology that have also testified against research cloning, saying that it is the first step on a slippery slope toward eugenics and the commodification of life. I would say that therapeutic cloning and research cloning is neither the beginning nor the end of that slippery slope, nor is it even the most important landmark.

Our power over human reproduction is as old as ancient contraceptive potions, and it was IVF that was the true landmark moment at which we were able to manipulate the embryo because it now existed outside the body.

By contrast, cloning research does not engineer or design the embryo, and, indeed, precisely because it does not involve making babies, it does not design or engineer our children. It is not basic research but, rather, our choices about its applications that will shape the future.

A moratorium on attempting pregnancy with cloned embryos is an effective and excellent speed bump on the slippery slope toward this future so many seem to predict and fear. To ask for more and to halt such basic research is to sacrifice the diabetic children, paralyzed police officers, and declining elderly of the present for a future that is neither certain nor imminent.

Criminalizing research cloning is not the way to protect embryos. It is not the way to guard against the future. It merely gambles with the hope held by many people today that they may live to see that future, whatever it may hold. Thank you very much.

[The prepared statement of Ms. Charo follows:]

STATEMENT OF R. ALTA CHARO, PROFESSOR OF LAW AND MEDICAL ETHICS, UNIVERSITY OF WISCONSIN LAW SCHOOL, UNIVERSITY OF WISCONSIN MEDICAL SCHOOL, DEPARTMENT OF THE HISTORY OF MEDICINE

Madam Chairman, members of the committee, my name is Alta Charo, and I am a professor of law and medical ethics at the University of Wisconsin.

I was a member of the N.I.H. Human Embryo Research Panel in 1993–94, and the National Bioethics Advisory Commission (NBAC) from 1996–2001. I participated in drafting NBAC's 1997 report on human cloning, but did not participate in drafting its 1999 report on human embryonic stem cells, in order to avoid any appearance of a conflict of interest due to my affiliation with the university where human embryonic stem cells were first isolated and maintained. I also had the privilege of testifying for the National Academy of Sciences (NAS) as it prepared its recent report on cloning, and have since been appointed to the NAS Board on Life Sciences.

I am pleased to testify in support of legislation that protects valuable non-reproductive uses of cloning technology while also guarding against its dangerous use to make a baby.

Such legislation is largely consistent with the recommendations of the National Bioethics Advisory Commission (whose reports recommended a moratorium on re-

productive cloning but federal funding for research on stem cells derived from surplus IVF embryos while monitoring on-going private sector research on stem cells derived from cloned embryos) and with the recommendations in the National Academy of Sciences' two reports on stem cell research and reproductive cloning. It is also consistent with the provisions of a bill passed last week by the Wisconsin State Senate, a bill that is supported by the University of Wisconsin—Madison and which is now ready for consideration by our State Assembly.

I am here today to present my own views, however, and do not represent NBAC, the NAS or my own university.

Debates over reproductive cloning, stem cell therapy, and even genetic engineering have become almost hopelessly entangled in the last five years. Each is worthy of policy debate. But each deserves a clear and separate discussion.

Cloning, that is, somatic cell nuclear transplantation, is currently too dangerous for making babies. Medical societies tell their members not to try it. The Food and Drug Administration has intervened to prevent it. It would be malpractice to attempt it, Florida has a bill to hold professionals strictly liable should they do it, and Senate Bill 1758 would criminalize it.

Clearly, there are many ways to stop the small number of publicity-hungry, irresponsible people who want to risk the health of women and children by using reproductive cloning.

But there are bills now before this Congress that would ban not only the irresponsible use of cloning to make babies, but also the responsible use of non-reproductive cloning for research or therapy. Some would even ban importation of proven medical therapies developed abroad, if their origins were entangled with cloning research.

Their proponents fear that once a cloned embryo exists in a laboratory, either the embryo or the so-called "parent" may have constitutional grounds to insist that pregnancy be permitted. But this makes no sense. It requires either that the cloned embryo has its own right to be born (a doctrine rejected both by the Supreme Court and by leading state courts hearing disputes over existing, frozen IVF embryos) or that people have a fundamental right to use these embryos to reproduce through cloning, in which case the entire ban on reproductive cloning is unconstitutional.

Others worry that a cloned embryo sitting in a laboratory will tempt someone to use it illegally to make a baby. But the criminal penalties in Senate Bill 1758 are equally effective, whether a cloned embryo already exists or is merely imagined. The deterrent is clear, and is not strengthened by criminalizing basic research.

But if criminalizing research is not needed to deter reproductive cloning, then these bills must have another purpose. Indeed, their proponents have argued that a research ban is needed to protect embryos, women's health, and the future of humanity.

But if the purpose is to protect embryos, then criminalizing research and therapeutic cloning is an odd place to begin.

We know indeed, we fully expect that embryos will be lost by the thousands every year at in vitro fertilization (IVF) clinics. Even if IVF is done perfectly, and even if everyone who wants to "adopt" an embryo is successful, thousands would still be left behind. Criminalizing research cloning cannot alter the scale of embryo loss that occurs each year. And since almost no one thinks IVF could be outlawed, criminalizing a technique that might involve an exceedingly small number of embryos represents at best a symbolic effort at embryo protection.

Such symbolic efforts are both powerful and important. They remind us that life is a gift that should be experienced with awe and gratitude. But a symbol can be badly tarnished if it is adopted at the expense of pain and suffering.

While reproductive cloning at this time is a danger to children, non-reproductive cloning could save their lives. Cloning cells from someone with a genetic disease could produce tissue in which we study how the defective gene malfunctions, and help us develop drug treatments, perhaps reducing the number of human volunteers at risk in later clinical trials. Used to generate stem cells, it might become the fastest route to transplantation without risk of rejection. And perhaps most importantly, studying how cloning reprograms adult cells will help us learn how to reprogram cells directly, without cloning and without the use of embryos, to create tissue for research, transplantation and organ regeneration to alleviate paralysis and extend healthy life.

Yes, there are other promising avenues of research, and they most certainly should be pursued. But that is no argument for criminalizing this research. America is not a country in which basic research or personal choices are illegal until someone has persuaded the government to grant permission. Quite the contrary. We celebrate the freedom to think and to act and to inquire into the secrets of nature, until a compelling case can be made that it must be stopped. Identifying complementary areas of research falls far short of making that case. At best it is an argument for

shaping federal funding priorities in a way that affords these alternative avenues every chance of success.

A handful of women's health and environmental organizations, those especially known for great skepticism about medical science and biotechnology, have also testified against research cloning, claiming it is the first step toward a world that is both unnatural and devoid of sentiment.

These, too, are concerns worthy of independent debate. But FDA regulation of cell-based therapies that require women's eggs will address issues of risk to women, and markets in eggs, sperm and other human tissue can be regulated without criminalizing basic science.

But most importantly, research and therapeutic cloning is neither the beginning nor the end of a slippery slope toward eugenics. It is not even the most important landmark.

Our power over human reproduction is as old as ancient contraceptive potions. And the first announcements about IVF were greeted with the same chorus of concerns about genetic engineering, designer babies, and the commodification of life, because it was IVF that first made the embryo amenable to study and manipulation outside the body.

By contrast, therapeutic cloning does not design or engineer the embryo, and precisely because it is not about making babies, it neither designs nor engineers our children. It is not basic research but rather our choices about its applications that will shape the future.

A moratorium on attempting pregnancy with cloned embryos, or perhaps in the future with engineered embryos, is a highly effective speed bump on the slippery slope toward the future some people predict and fear. To ask for more, to halt basic research, is to sacrifice the diabetic children, the paralyzed veterans, the skin-scorched firefighters and the declining elderly of the present for a future that is neither certain nor imminent.

In sum, we should deter those who would use cloning for reproductive ends despite its dangers. But we shouldn't throw the bath water out with the baby. Criminalizing research and therapeutic cloning is not the way to protect embryos or to guard against the future. It merely gambles with the hope held by many people today that they may live to see that future, whatever it holds.

Thank you.

Chairperson FEINSTEIN. Thanks very much, Dr. Charo.

And now we will proceed. I have Kris Gulden next, if I might, and we would very much like to welcome her. She is here on behalf of the Coalition for the Advancement of Medical Research. It represents 60 organizations and associations supporting therapeutic cloning. Ms. Gulden, a former veteran police officer in Alexandria, Virginia, received several awards for her law enforcement work. She also maintained an active schedule outside the office, including winning the women's triathlon gold medal in August 1996 at the Biannual International Police Olympics in Salt Lake City. Tragically, a car struck Ms. Gulden while she wa training for the 1998 AIDS ride, leaving her with a severe spinal cord injury. That accident changed her life. Nine days before the accident, she was participating in a triathlon in Memphis. Nine days after the accident, "Just brushing my teeth was exhausting," she said. Yet Ms. Gulden has made tremendous progress, and I am very happy she could be here today to testify.

STATEMENT OF KRIS GULDEN, COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH, WASHINGTON, D.C.

Ms. GULDEN. Thank you, Madam Chairperson, Senator Hatch, and members of the committee. I would like to thank you for the opportunity to testify today on the value of somatic cell nuclear transfer, commonly referred to as therapeutic cloning. As you know, the Coalition for the Advancement of Medical Research is an organization comprised of universities, scientific and academic soci-

eties, patients' organizations, and other entities that are devoted to supporting stem cell research. In addition, I realize that today I am the voice of millions of Americans living at ALS, MS, Parkinson's disease, spinal cord injuries, and other illnesses that may benefit from therapeutic cloning.

Along with the Coalition for the Advancement of Medical Research, I support efforts to prohibit human reproductive cloning. However, it is imperative that we protect important areas of medical research that offer hope to millions of Americans.

As a person living with paralysis caused by a spinal cord injury, I know how urgently a cure is needed. I do not expect a cure tomorrow or even next year, and I do not intend to overstate the promise of the research. But how can you overstate hope?

On May 26th of 1998, my life was changed when I was struck by a vehicle while riding my bike. At the time I set out for that bike ride, I was a healthy 31-year-old triathlete, and I was employed as a police officer in Alexandria, Virginia. I never finished that bicycle ride because I was struck by a car. In addition to a traumatic brain injury and a laundry list of broken bones, I sustained a spinal cord injury at the T4 level. The doctors told me that I had a 20 percent chance of ever walking again. My friends and family members had to incorporate the word "paraplegia" into their vocabularies. In an instance, my future changed from adrenaline rushs and thrill-seeking to wheelchairs and hand controls.

Six weeks after my accident, I discovered that I could move my legs. And in that instant, I discovered hope. I knew that if it were only a matter of strengthening the muscles in my legs, I would, in fact, walk again. And within 3 months, I was walking with a rolling walker.

In the summer of 1999, I went to the University of Miami to go through EMG biofeedback training. This proved to be an exciting therapy that gave me even more optimism that I would 1 day walk again. However, a rare complication of a spinal cord injury—a disease called syringomyelia—has caused me to lose considerable function. I have not, though, lost hope. I have returned to the University of Miami for additional sessions of biofeedback, and I remain committed to the idea of walking again. Additionally, the potential for new therapies like cloning gives hope to so many people.

I understand that the word "cloning" has caused many individuals to imagine the worst possible abuses. But allow me to make a critical distinction between cloning technology used to create a human being—reproductive cloning—and the therapeutic cloning techniques that are vital to breakthroughs in medicine, diagnostics, and potentially vaccines used to treat diseases like Parkinson's, Alzheimer's, cancers, heart disease, diabetes, and even paralysis resulting from spinal cord injuries. Therapeutic cloning cannot product a whole human being. This work should be allowed to move forward.

Somatic cell nuclear transfer may prove to be a vital tool in allowing scientists to fully develop the promise of stem cell research. Somatic cell nuclear transfer involves the use of a donor's unfertilized egg and a patient's own cells. This research could allow a patient's own genetic material to be used to develop stem cell therapies specifically tailored to that individual's medical condition,

thus not triggering an immune rejection response. In other words, using somatic cell nuclear transfer could repair patients with their own cells.

Given the scientific potential in this area, we strongly opposed any legislative action that would ban research related to therapeutic cloning. This would include criminalizing the research or the researchers, and prohibiting the importation of therapies derived from somatic cell nuclear transfer in other countries.

Madam Chairperson, it is likely that we will continue to be confronted with scientific advances that pose difficult social and ethical questions. The present momentum in biomedical research and the profound implications of what we are learning will inevitably raise public concerns. Yet an across-the-board ban on human cloning will dash the hopes of many Americans living lives that, like mine, are so radically, functionally, and emotionally different than what they once were.

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

And if I could just add one more personal story, my mom lives in Pennsylvania, and she is a constituent of Senator Arlen Specter. Back in August, my mom attended a town hall meeting that Senator Specter held, and she asked him about stem cell research. Senator Specter's quote to my mom—and I have got the newspaper article here—was, "We're not going to let you down." And I wish that Senator Specter was still in the room. I hope that he and his colleagues will live up to that promise.

In closing, I just want to thank the committee members for having me here today, and on behalf of the Coalition for the Advancement of Medical Research, the countless Americans who stand to benefit from therapeutic cloning, and the friends and family members who love them, I again thank you for having me here today.

[The prepared statement of Ms. Gulden follows:]

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

Good morning Senator Feinstein and Members of the Committee. Thank you for the opportunity to testify t oday on the value of somatic cell nuclear transfer (SCNT), commonly referred to as therapeutic cloning. My name is Kris Gulden, and I am here on behalf of the Coalition for the Advancement of Medical Research (CAMR). The Coalition is an organization comprised of universities, scientific and academic societies, patient's organizations, and other entities that are devoted to supporting stem cell research. In addition, I realize that today I am the voice of the millions of Americans living with MS, spinal cord injuries, ALS, Parkinson's Disease, and many other illnesses that may benefit from therapeutic cloning.

I, along with the Coalition for the Advancement of Medical Research, support efforts to prohibit human reproductive cloning. However, it is imperative that we protect important areas of medical research that offer hope to millions of Americans. As a person living with paralysis caused by a spinal cord injury, I know how urgently a cure is needed. I do not expect a cure tomorrow, or even next year. And I do not intend to overstate the promise of the research. But how can you overstate hope?

On May 26, 1998, I set out on a bicycle ride that would change my life. When I began, I was a healthy, 31 year old-triathlete. I was employed as a police officer in Alexandria, Virginia. I never finished that ride; it was interrupted when I was struck from behind by a motor vehicle. In addition to a traumatic brain injury and

a laundry list of broken bones, I sustained a spinal cord injury at the T4 level. The doctors told me that I had about a 20% chance of ever walking again. My friends and family had to incorporate the word "paraplegia" into their vocabularies. In an instant, my future was changed from adrenaline and thrill-seeking to wheelchairs and hand controls.

Six weeks after my accident, I discovered that I could move my legs. And in that instant, I discovered hope. I knew that if it were only a matter of strengthening my leg muscles, I would in fact walk again. And within three months, I was walking with a rolling walker.

In the summer of 1999 I went to the University of Miami to go through EMG biofeedback training. This proved to be an exciting therapy that gave me even more optimism that I would one day walk again. However, a rare complication of a spinal cord injury a disease called syringomyelia - has caused me to lose considerable function.

I have not, though, lost hope. I have gone back to Miami for additional sessions of biofeedback, and I remain committed to the idea of walking again. Additionally, the potential for new therapies like cloning gives hope to so many people.

I understand that the word "cloning" has caused many individuals to imagine the worst possible abuses. But allow me to make a critical distinction between the use of cloning technology to create a baby reproductive cloning and the therapeutic cloning techniques central to the production of breakthrough medicines, diagnostics, and potentially vaccines to treat diseases like Parkinson's, Alzheimer's, diabetes, heart disease, various cancers, and even paralysis resulting from spinal cord injury. Therapeutic cloning cannot produce a whole human being. This work should be allowed to move forward.

Somatic cell nuclear transfer may prove to be a vital tool in allowing scientists to fully develop the promise of stem cell research. Somatic cell nuclear transfer involves the use of a donor's unfertilized egg and a patient's own cells. The research could allow a patient's own genetic material to be used to develop stem cell therapies specifically tailored to that individual's medical condition, thus not triggering an immune rejection response. In other words, using somatic cell nuclear transfer could repair patients with their own cells.

Given the scientific potential in this area, we strongly oppose any legislative action that would ban research related to therapeutic cloning. This would include criminalizing the research or the researchers, and prohibiting the importation of therapies derived from somatic cell nuclear transfer in other countries.

Ms. Chairperson, it is likely that we will continue to be confronted with scientific advances that pose difficult social and ethical questions. The present momentum in biomedical research, and the profound implications of what we are learning, will inevitably raise public concerns. Yet an across-the-board ban on human cloning will dash the hopes of many Americans living lives that, like mine, are so radically, functionally, and emotionally different than what they once were.

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

On behalf of the Coalition for the Advancement of Medical Research, the countless Americans who stand to benefit from therapeutic cloning, and the family members and friends who love them, I again thank the Committee for its deliberations and for the opportunity to speak to this issue.

Chairperson FEINSTEIN. Thank you very much. Thank you for that excellent testimony.

We will now go to Andrew Kimbrell. He is a public interest attorney, activist, and author. In 1994 Mr. Kimbrell founded the International Center for Technology Assessment, an organization that is devoted to a holistic analysis of technology. He continues to serve as the center's executive director. He has authored several books and given numerous public lectures. In 1994, the Utney Reader named Mr. Kimbrell as one of the world's leading 100 visionaries.

Mr. Kimbrell, welcome.

STATEMENT OF ANDREW KIMBRELL, EXECUTIVE DIRECTOR, INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, WASHINGTON, D.C.

Mr. KIMBRELL. Thank you, Madam Chairman. I thank the committee for the opportunity to speak with you this afternoon. I would add, even though I was named one of the 100 leading visionaries, I noticed when they got us all together that we all wore very heavy lenses. We all had glasses So maybe a prerequisite to being a visionary is that you can't really see, Madam Chairman, so you should probably take that caveat on my testimony today.

I am here representing myself and also part of the Environmental Women's Health and Consumer and Health Coalition that Representative Weldon referred to that worked on his bill on the House side. I have submitted written testimony. I am going to try and summarize it here.

I am going to try and accomplish two things. One is to put this current discussion in sort of a historical context. We all remember George Santayana's truism that "Those who cannot remember the past are condemned to repeat it." And I think that is an important warning that we should take into consideration as we discuss this issue today.

Alta Charo and myself have been dealing with—and so have many on this committee—these kinds of issues for many years. When I heard Dr. Michael West of ACT say that he was going to save 3,000 lives a day, and even a 6-month halt on his embryo cloning for stem cells could cost a million and a half lives, I realized this was unadulterated hyperbole. And subsequent to that, we have seen numerous scientists say that Dr. West's claims are completely false, he has completely failed in his attempt to do that. So it is important, as Representative Weldon has said, that this technology is not working. It is not clear when we will be able to garner stem cells from embryos.

I remember about 12 years ago working with Senator Kennedy's staff and then-Senator Gordon Humphrey's staff on the gene therapy question, and we were arguing for stringent regulations on gene therapy. There were many, many unique ethical questions and scientific questions that we felt needed to be resolved before we allowed human trials to take place. Many in the research community supported us. Many did not.

Unfortunately, those who wanted a deregulated gene therapy industry essentially won the day. Now, over a decade later, hundreds of trials, not a single person has been cured with gene therapy. Many patients groups call it a big disappointment, but for many it has been more than a disappointment. Eighteen-year-old Jesse Gelsinger volunteered for a gene therapy trial in Philadelphia, and because of researcher misconduct, unregulated research, he was killed. Investigative reporting by the Washington Post showed that perhaps a half-dozen others also have been killed by these trials, and over a thousand, over 1,000 adverse reactions in this unregulated research, over a thousand reactions, including many deaths and serious injuries, were possibly linked. No cures. If we had taken a 10-year moratorium at that time, not a single disease, however tragic, would have been cured, but many lives would have

been saved if we had looked at the serious questions before we allowed these technologies to be widely disseminated.

I again worked with Senator Kennedy and with Senator Hatch's staff and, again, Senator Humphrey's staff to try and get adequate regulation of fetal tissue research. We were very concerned about the sale of fetal tissue. We were concerned that people were going to change the method and manner of abortion in order to obtain fetal tissue. We were concerned about informed consent in this regard, limitations on how that tissue could be used.

We tried bravely. We got some legislation passed. But, basically, there was inadequate regulation, inadequate legislation, inadequate enforcement. And what have we found? Unfortunately, right now there is a thriving fetal tissue market, repugnant, I am sure, to all of us. There are continued reports, verified reports of researchers changing the method and manner of abortion to get this tissue.

In the largest trial in Parkinson's disease done up to this point—and, by the way, there has been over 400 trials—again, no cures. But the side effects, which certainly could have been obtained in animal research, were devastating. Absolutely devastating, actually. According to Dr. Paul Greene, a neurologist at Columbia University College of Physicians and Surgeons who oversaw that research, he said, "It is a real nightmare, and we can't selectively turn these fetal cells off." They put them into brains, and they produce chemicals that have his patients, 15 percent of them, twitching 24 hours a day, unable to sleep, unable to eat, unable to talk. We didn't regulate it adequately. We weren't precautionary. We didn't obey the first rule of the Hippocratic oath, "First, do no harm."

Now we have the next miracle cure de jour—stem cells. I urge you this time, please, do not let this technology go out, disseminate it, become an industry without adequately, stringently regulating before we do that.

Now, with stem cells, we have this extraordinary unprecedented issue of cloning that is involved. And for the progressive community this is not a right-to-life issue. There are six major concerns, and I will summarize them very briefly in conclusion, and Representative Weldon did mention several of them that I think we need to look at.

At a minimum, before we allow the cloning of human embryos for research, we need to have regulations and legislation that deals with this, before we allow that. There is a major problem with allowing an unregulated market and the production of cloned embryos and expect there to be no reproductive cloning. Imagine, Madam Chairman and members of the committee, if we were to have a drug war where we encourage the production of cocaine and other drugs—encouraged it, had an open and unregulated industry in it, but also said we were trying to make use of drugs illegal. That is essentially what we are doing if we encourage an unregulated industry in the production of cloned embryos and still say we are against reproductive cloning. It is not going to happen.

The second is that this industry in cloned embryos leads to the commodification of life. The Patent Office as announced that they will allow the patenting of these embryos. There is no bar on the

sale of these embryos. If you sell the Congressional Medal of Honor, you demean and corrupt that medal. If you sell the Nobel Prize, you corrupt and demean the Nobel Prize. If you sell children, you corrupt and demean the meaning of parenthood. If you sell human embryos and patent human embryos, you demean and corrupt what it means to be a human.

Representative Weldon also talked, and I thought rather tellingly, about the impacts on women through this technology. According to many researchers, there are going to need to be 5 and 8 million eggs harvested from women in order to make therapeutic cloning possible. We all know the impacts on women's bodies caused by the operations and drugs required to extract eggs. Surely we are not going to let this happen without some regulation, some legislation to make sure there is not an open industry where poor women sell their eggs to researchers for therapeutic cloning, with all of the impacts that involves. Not acceptable. I don't think anybody finds that acceptable.

Finally, it is important to view embryo cloning as the ultimate choice question. None of us will know whether our hair, blood cells, cheek cells are being used to produce these research clones. There have been numerous cases, very well-known litigation, where people's cells have been used to create very valuable cell lines, and they didn't know it. None of us in this room will have a choice if we allow an unregulated industry and the cloning of human embryos for research on whether we are being cloned thousands of times, being patented and sold without our knowledge. I would view this as the ultimate choice question. We cannot preserve choice unless we at least have a moratorium or ban on embryo cloning.

Finally, I do think that it brings up the crucial issue—and here I understand where Senator Durbin is coming from, but I think it is important to note that for the very first time in human history, if we do this, if we allow embryo cloning for research, we will have produced a human life form solely for its destruction, solely for its use as spare parts. Yes, it is a question of intention, but as an attorney, we know that intention is everything, the difference. Between a non-crime and first-degree murder is intention. For the first time, we will intentionally as a human race have done this.

I think at a minimum, at a minimum, this is an ethical question that needs tremendous public debate, public hearings across the country. And, again, we should have an unlimited moratorium or ban on this form of cloning until that unprecedented question has been resolved.

Thank you.

[The prepared statement of Mr. Kimbrell follows:]

STATEMENT OF ANDREW KIMBRELL, EXECUTIVE DIRECTOR, INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT

At the outset I want too thank you for the opportunity of testifying today on this crucial issue. Over the last many months I have worked with a coalition of progressive environmental, consumer and women's health groups to attempt to ban reproductive human cloning and obtain at least a moratorium on human cloning for research, often called "therapeutic cloning." While there appears to be little disagreement on the need to ban reproductive cloning, the issue of halting research human cloning has become quite controversial. In my testimony I would like to outline a number of reasons why many in the progressive community support a ban or mora-

torium on human cloning for research at this time. However, prior to discussing the current cloning controversy, I would like to put our discussion today in the context of similar issues we have faced in the last two decades. Sometimes there is a tendency to deal with issues like cloning in an historical vacuum a kind of technological amnesia. George Santayana's truism "Those who cannot remember the past are condemned to repeat it," applies equally to technology issues a it does to political ones. Therefore I would like to begin by reviewing our past mistakes in assessing and regulating two "miracle" cures that preceded the current furor over stem cell research and human cloning. I fear that if we do not remember what happened with these prior technologies we will repeat the mistakes that have led to grossly inadequate regulation and real tragedy for many patients.

HYPERBOLE VERSUS HEALING

Last December during a hearing before the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education on the controversy over stem cells and human cloning, Michael West of Advanced Cell Technology (ACT) predicted that within six months his biotechnology company would be ready to create "magic" cells that would save no less than 3,000 lives a day. West claimed that he would soon successfully clone human embryos, and then obtain stem cells from those clones which would cure everything from heart disease and Alzheimer's, to Parkinson's disease and spinal cord injuries. West sternly warned that even a half year halt on his embryo cloning research would cost over half a million lives. Horrified by what they called "these real numbers," some Senators pronounced themselves against any limit on human embryo cloning, and vowed to "push" the technology in any way they could.

Of course, West's promise of near term success in obtaining stem cells from clones, and the subsequent healing of thousands a day, was unadulterated hype. While there have been some preliminary indications that adult, fetal and embryo stem cells may some day result in helpful therapies, no such cells have ever been obtained from cloned human embryos. In fact, West and his Massachusetts company, ACT, had just published a paper that revealed that they had completely failed to garner stem cells from cloned embryos. Dr. Donald Kennedy, editor of the highly esteemed journal Science, summarized the ACT effort, stating, "Everything I have learned about the [ACT] study suggests that it is not an advance that would interest us. This scientific effort did not succeed by any measure." Even more telling was the resignation of Dr. John Gearhart, of the Johns Hopkins Medical Institutions, from the editorial board of the magazine that published the ACT study. Dr. Gearhart, a pioneer in stem cell research, said that the experiment"should be considered a failure" and that the study should not even have been published.

Moreover, the same day West was predicting near term cloning success at the Senate hearing, his colleague at ACT, Tanja Dominko was explaining the company's failures to a medical conference. She noted that there was an unknown, unique characteristic about primates that makes them difficult to clone. "It might be that you just can't make humans this way," Dominko told the conference.

Leading experts share this skepticism about cloning and any near term success of stem cell technology. Dr. Gail Martin, the co-discoverer of mouse embryonic stem cells, warns that there are still "a gazillion issues" to be resolved. Another stem cell expert, Dr. David Solter who directs the Max Planck Institute of Germany said he had "no idea" how someone expected injected stem cells to replace sick and dying brain neurons in Alzheimer's victims.

Most of us have experienced the tragedy of disease or disability either personally or through family and friends. Facing the crucible of disease, we search for some hope when bodies and minds are cruelly decimated by illness. Yet however much we want cures, it is essential to get the real facts, the full story, about medical advances. Unfortunately, in the past we have seen a continuous pattern of researchers and companies peddling hype instead of healing. These false promises about healing are not merely harmless self promotion by research companies eager for venture capital, or benign wishful thinking by naive legislators. Researchers' hype cruelly misleads those who are suffering into thinking that cures are imminent. Perhaps even more disturbing is that this hype is often successful in "blackmailing" legislators and regulators into taking a "hands off" approach to regulation of these new technologies, lest such regulation delay cures. The resulting public policy toward new medical technologies has been misguided, inadequate and even dangerous. It has resulted in the trampling of some our most important ethical norms, and in some cases to increased suffering and mortality among the very people we seek to cure.

GENETIC "WIZARDRY"

A paradigm case of hyperbole over healing is gene therapy. In the late 1980s "gene therapy" was heralded as the new "miracle cure." Researchers were hailed as "gene wizards" and the media, policy makers and scientist/entrepreneurs predicted cures to cancer and virtually every other serious human ailment. Billions of public and private research dollars poured into biotechnology companies and human clinical trials. Despite public protest by some scientists, and law suits by health advocacy groups, human gene therapy trials were approved by the federal government with woefully inadequate oversight and virtually no enforcement. Unmonitored and virtually unregulated, the researchers themselves were relied on to report any adverse results in their test. Over the last decade there have been more than 400 gene therapy trials on patient groups. Despite all the hype, not a single person in any U.S. gene therapy trial has been cured of any disease. Abbey S. Meyers, a patients' group advocate noted, "We haven't even taken one baby step beyond the first clinical experiment. It's hardly gotten anywhere . . . I have been very disappointed."

For many, gene therapy has been far worse than a disappointment. Jesse Gelsinger was an active and altruistic 18 year old from Tucson, Arizona who suffered from a rare gene disorder. He volunteered to take part in a Philadelphia based gene therapy trial study on that genetic disorder. He hoped to participate in finding a cure. Instead, the gene therapy killed him. The media furor over Gelsinger's death resulted in revelations of serious misconduct by researchers in his case and in others' trials. Subsequently a half dozen other cases were found where patients' deaths were linked to gene therapy experiments. Eventually, it was revealed that there were over a thousand serious adverse effects potentially attributable to gene therapy trials, including numerous deaths. Left on their own, researchers had only reported 37 of these adverse events. As the hype about gene therapy held legislators and regulators at bay, researchers violated the most basic ethical tenets on the use of human subjects, which along with deficiencies in the technology, resulting in significant suffering and the death. Wide scale reporting of this scandal has led to an attempt to tighten regulation of gene therapy trials, but most agree that the new policies are far too little, and for the victims of the technology, far too late.

THE FETAL REVOLUTION

There is a similar and equally disturbing history with the hype over fetal tissue research. By the late 1980s fetal transplants were being heralded, as the "ultimate cure of the future." An editorial in the New York Times warned that "to interfere with these [fetal tissue] experiments is to interfere with progress that could save countless lives." Fueled by this hype, a moratorium on federally funding of fetal tissue transplants was lifted in 1992, and the proponents confidently predicted a cure for many of our most pernicious diseases and disabilities. Ethical concerns which had led to the moratorium were given only cursory attention. Now after 13 years of private and publicly funded trials some of the ethicists' worst fears have come to pass. There is a thriving market in the sale of various fetal parts from clinics to hospitals and researchers. There are also reports that clinics are changing the method and manner of abortions, potentially creating injury in women, in order to obtain more viable and valuable fetal tissue.

As for the hundreds of patients who have received fetal transplants, mainly for Parkinson's disease, there have yet to be proven benefits, but as with gene therapy we have seen very real and shocking health impacts. As reported last year, the most comprehensive study on the use of fetal tissue to treat Parkinson's showed no overall benefit, but researchers described side effects of the treatment as "absolutely devastating." The problem was that in a significant percentage of fetal tissue recipients the implanted cells created too much of the needed brain chemicals causing uncontrolled movements and spasm in the patients. "They chew constantly, their fingers go up and down, their wrists flex and distend," reports Dr. Paul E. Greene, a neurologist at the Columbia University College of Physicians and Surgeons and one of the researchers involved in the federally funded fetal tissue study. Greene also described patients as writhing and twisting, jerking their heads and flinging their arms about. The spasms were so severe in one patient that he could no longer eat and needed a feeding tube. For others the spasms made their speech unintelligible. Despite these effects, there is no way to remove the transplanted fetal cells or stop them from creating these impacts on the patients. "It was tragic, catastrophic," Dr Greene explained. "It's a real nightmare, and we can't selectively turn it off." As for the near future, Dr. Greene at least has seen the light: "No more fetal transplants. We are absolutely and adamantly convinced that there should be research only."

STEM CELLS AND HUMAN CLONING

As the grim histories of gene therapy and fetal tissue use are left generally unexamined, stem cell research, including the cloning of human embryos, has succeeded them as the miracle cure du jour. As the testimony of West and other researchers indicates, we are once again being subjected to a full court press of hype, as companies and researchers vie for venture capital and federal research dollars. Unfortunately we also continue to witness a continued and unconscionable gullibility in many of our policy makers. Once again they appear to have become hostages to the hype about healing. This is particularly alarming because the stakes in this debate are very high. As noted, West and many in the research community are pushing for an unregulated and unmonitored industry in cloned human embryos. West and his cohorts insist that only cells from cloned human embryos will be the panacea for all that ails us. This despite their failure to obtain stem cells from embryos, and the current availability of adult and placental stem cells for research.

Besides corporate profits West and some others in the research community have another very clear aim. They want to stop the Senate from following last year's House action in declaring a ban on human embryo cloning, and they may well be succeeding. In the next few months the Senate will be debating and voting on the human cloning issue. While there is general agreement over banning human embryo cloning to create children, there is confusion on halting the cloning of human embryos for research. Will our policymakers finally cut through the hype and ask the important questions about research cloning?

A number of those in the progressive community have several major concerns about human cloning for research. Environmentalists, consumer groups, women's and children's health advocates all want to see unprecedented regulatory and ethical questions resolved before and human embryo cloning for research is allowed. These issues include:

1) An unregulated industry and market in the production of cloned human embryos will inevitably lead to reproductive cloning. Imagine fighting the drug war by banning certain uses of drugs but allowing and even encouraging the mass production and dessemination of such drugs for 'legal' purposes. This is what those advocating a ban on human reproductive cloning but encourging human embryo cloning for research are advocating. It is irresponsible legislation. Clearly the time to regulate reproductive cloning is at the stage of the creation of the cloned embryo. Attempting to enforce a reproductive ban after a cloned embryo is implanted into a surrogate mother is a regulatory nightmare. Given the slippery slope from embryo cloning to reproductive cloning, the only scenario in which embryo cloning for research would be acceptable is if a strict regulatory procedure were in place which carefully montiored the chain of custody of each and every cloned embryo.

2) An unregulated industry in cloned human embryos will lead to unacceptable commodification of life. The U.S. Patent and Trademark office has already announced that cloned human embryos would be patentable. Additionally there is no bar on the sale of embryos or human ova necessary for this technology. Clearly if we sold the Congressional Medals of Honor we would degrade the meaning of this honor. If the Nobel Prize we up for sale it would cease to have meaning. If we buy and sell children we corrupt and demean the meaning of parenthood. Just so if we allow the patenting and sale of human embryos and human eggs we corrupt and demean what it means to be human.

3) As currently envisioned cloning of human embryos for research represents a serious threat to women's health. In recent testimony a researcher stated have stated that they could do up to 1.7 million therapies per year. this would require a minimum of 5–8 million eggs—assuming a very high success rate of 1 out of 3–5 eggs—to accomplish the therapeutic cloning required to support these therapies . Where will they get theses eggs? From women in this country or abroad. Egg donation can have significant health impacts on women including the effects of hormone therapies and other drugs administered to facilitate extraction and the extraction process itself. Most women who are lured into this process are economically disenfranchised and perform this operation for money. With research embryo cloning we could see a massive expansion in the use of women as paid egg "factories." This presents both a real threat to women and an expansion of the repugnant commodification of life discussed above.

4) Human embryo cloning for research could deprive us of our choice on when, how and where our genetic heritage will be replicated. Researchers may be able to clone "copies" of us by using cells from our hair, blood, or virtually any other tissue. There have already been several legal cases where patients have had their cells turned into valuable cell lines without their knowledge. Unless they are carefully

monitored, how will any of us know if a researcher of company is replicating our genetic makeup in any number of human embryos at any time. This is a significant "choice" issue for all of us, especially for those whose religious or moral beliefs find human cloning in any form unacceptable.

5) Does the cloning of human embryos for research divert valuable health research dollars away form proven methods into highly speculative ones? There are only limited research and health dollars available. Diseases such as cancer are complex in origin. Genetic predisposition, environmental pollution, diet, stress and social habits (such as smoking) all can contribute to this disease. While it is tempting to believe that gene therapy, fetal tissue or stem cells form cloned embryos will be the 'magic bullet' that will cure cancer, this view is hopelessly naive. We have seen in the past that prevention is the best policy when dealing with major diseases or disabilities. This means significant contribution of resources to cleaning up the environment and work places, educating about diet and lifestyle, working to reduce poverty and changing some of our unhealthy compulsive habits. While prevention may not be a good 'handle" to raise venture capital, it unlike speculative "miracle" cures has a proven record of success.

6) Cloning human embryos for research raises the key ethical issue of whether we should intentionally create any human life form solely for its exploitation and destruction. As a human community we have never done this before. Certainly there should be public hearings and wide ranging public participation on this key ethical issue before such cloning is allowed.

As we debate the human cloning issues, we must also demand responsibility and caution from those making claims about stem cell research. Many suffering from serious illnesses or disabilities have been misled by the false promises about gene therapy, fetal tissue and other medical "breakthroughs." The continued hype about stem cells is unconscionable. Moreover, Congress must establish stringent regulations that assure that no human trials using stem cells technology take place until research fully justifies such trials. Should there eventually be human trials, they must be carefully and independently regulated and monitored. Researchers cannot be left to regulate themselves. Our elected representatives owe nothing less to the families of those who have died, and the many now suffering, because of Congress' past failures to cut through the hype and appropriately regulate medical technology.

Thank you.

Chairperson FEINSTEIN. Thanks very much, Mr. Kimbrell.

I will find my little biography here. Finally, but not least, Father FitzGerald. Father Kevin FitzGerald is a research associate professor in the Department of Oncology at Georgetown University Medical Center. In addition, he is the Chair of Catholic Health Care Ethics at the University's Center for Clinical Bioethics. Father FitzGerald has received a Ph.D. in molecular genetics and a Ph.D. in bioethics from Georgetown University. His research has focused on ethical issues in human genetics. For the past 10 years, he has served as an ethics consultant to the National Society of Genetic Counselors.

Welcome, Father.

STATEMENT OF REV. KEVIN FITZGERALD, GEORGETOWN UNIVERSITY MEDICAL CENTER, WASHINGTON, D.C.

Rev. FITZGERALD. Thank you very much, Senator Feinstein, and thank you to the committee for this marvelous opportunity to join you today in this continuing conversation regarding human embryo research, specifically that research which involves transferring genetic material from a human somatic cell into an egg that has had its nuclear genetic material removed—in other words, cloning.

The key moral issue in research involving cloned embryos is, as we have heard, the creation and destruction of a human life, an embryo. Though there is no consensus in our society as to the value of this nascent human life, there is equally no denial that this research is highly contentious and controversial in our society. The

question before our society and this committee is then: How do we make the decision to proceed or not proceed with this kind of cloning research?

We Americans know from our own history with eugenics, research on minority, the mentally disabled, and even on our own military forces the tragedies that can occur when public policies concerning human experimentation are shaped according to the dictates of science. When facing the unknown or the uncertain, the answer of science is do the research. This is perfectly good science. This may not be good public policy nor the ethical thing to do.

In response to the wrongs done in the name of science mentioned previously, our society has chosen to limit what experiments can be performed on human beings, even though these limits may slow scientific progress. If human embryos indeed v some significant value to our society, as the National Bioethics Advisory Committee concluded, then considering all the basic research that still can be done using animal models, human tissue culture, non-cloned, non-embryonic stem cells, and all sorts of other molecular biology, why is there still a continuing clamor for the destruction of human embryos to fuel cloning research?

One reason almost always put forth by proponents of human embryo cloning research—and a reason we have heard several times today—as justification for the creation and destruction of cloned human embryos is the need to bring healing and cures to the millions who suffer from illnesses and diseases that may otherwise die without this research. Such an argument as this is of great significance for it connects to a fundamental principle of medicine: treat sickness and heal when you can. Yet, as the argument is states, its significance rests in part on two assumptions: one, that cloned embryo research will be necessary or superior to all other options in the treatment of certain diseases; and, two, that the thousands and millions who need the treatments will have access to any medical advances that might come from such research.

Addressing the first assumption, we need to recognize that the diseases suggested as likely targets for human cloning research are also the targets of researchers using other approaches, such as genetic therapies, drug development, adult stem cells, and other molecular biology approaches. It may well be the case that for many patients the treatments for their illnesses may come more quickly from research avenues other than cloned human embryo research, and that these alternative treatments may even be better than any treatment derived from human cloning research.

Regarding the second assumption, we need to acknowledge that even if treatments from human cloning research can prove to be the best available or are developed first, the vast majority of the millions of people who need these treatments will not have access to them. For example, no one denies that cancer research has generated many significant advances in cancer treatment over the past 30 years. This is the war on cancer. Yet the President's Cancer Panel in their 2001 report conclude that "a great many people—both the privileged and the poor—find that at the very time they need the most effective cancer care our research enterprise has devised, the health care delivery system of our Nation"—our Nation—"fails them."

Tragically, this reality, considering it, and adding to it the fact that millions of children die every year from diseases preventable by vaccines, and the fact that some of the most effective drugs we have ever developed for certain diseases are not mass produced because no one will make a profit, one must seriously question any assertion that our society should pursue human cloning based on the fact that it will benefit millions. This justification for pursuing this socially contentious and ethically controversial research is just false. Human embryos need not be created and destroyed in order that thousands or millions might be saved.

Indeed, without the continual creation and destruction of cloned human embryos, the future of medical advance will still be one of great hope. There are many avenues of medical research that can be pursued with broad ethical and societal support. As a people who value progress and justice, we can decide to pursue every avenue of medical research that is respectful of human life in all its stages, and we can work together to create a system that brings these advances in medicine to all those in need.

Thank you very much for your time and attention.

[The prepared statement of Rev. FitzGerald follows:]

STATEMENT OF KEVIN FITZGERALD, S.J., PH.D.

We are gathered today to continue the public dialogue regarding human embryo research, specifically that research which involves transferring genetic material from a human somatic cell into an egg that has had its nuclear genetic material removed—i.e. cloning.

The key moral issue in research involving cloned embryos is the creation and destruction of a human life—an embryo. Though there is no consensus in our society as to the value of this nascent human life, there is no denial that this research is highly contentious and controversial in our society. The question before our society and this committee is then, "how do we make the decision to proceed or not proceed with this kind of research?"

We Americans know from our own history with eugenics and with research on minorities, the mentally disabled, and even our own military forces, the tragedies that can occur when public policies concerning human experimentation are shaped according to the dictates of science. When facing the unknown or the uncertain, the answer of science is always to do the research. This is good science, but it may not be good public policy or the ethical thing to do. In response to the wrongs done in the name of science mentioned previously, our society has chosen to limit what experiments can be performed on human beings, even though these limits may slow scientific progress. If human embryos do have some significant value in our society, as the National Bioethics Advisory Committee concluded, then considering all the basic research that still can be done using animal models, human tissue culture, and adult stem cells, why is there a continuing clamor for the destruction of human embryos to fuel cloning research?

One reason almost always put forth by proponents of human embryo cloning research as justification for the creation and destruction of cloned human embryos is the need to bring healing and cures to the millions who suffer from illnesses and diseases that may otherwise die without this research. Such an argument as this is of great significance for it connects to a fundamental principle of medicine: treat sickness and heal when you can. Yet, as the argument is stated, its significance rests in part on two assumptions: 1) that cloned embryo research will be necessary, or superior to all other options, in the treatment of certain diseases, and 2) that the thousands and millions who need the treatments will have access to any medical advances that might come from such research.

Addressing the first assumption, we need to recognize that the diseases suggested as likely targets for human cloning research are also the targets of researchers using other approaches, such as genetic therapies, drug development, and adult stem cells. It may well be the case that for many patients the treatments for their illnesses may come more quickly from research avenues other than cloned human embryo research, and that these alternative treatments may even be better than any treatment derived from human cloning research.

Regarding the second assumption, we need to acknowledge that even if treatments from human cloning research prove to be the best available and are developed first, the vast majority of the millions of people who need these treatments will not have access to them. For example, no one denies that cancer research has generated many significant advances in cancer treatment over the past thirty years. Yet the President's Cancer Panel in their 2001 report conclude that "a great many people—both the privileged and the poor—find that at the very time they need the most effective cancer care our research enterprise has devised, the health care delivery system of our Nation fails them." Considering this tragic reality, and adding to it the fact that millions of children die every year from diseases preventable by vaccines, and the fact that some of the most effective drugs developed for certain diseases are not mass produced because no one will make a profit, one must seriously question any assertion that our society should pursue human cloning research because millions will benefit. This justification for pursuing this socially contentious and ethically controversial research is just false. Human embryos need not be created and destroyed in order that thousands or millions might be saved.

Indeed, without the continual creation and destruction of cloned human embryos the future of medical advance will still be one of great hope. There are many avenues of medical research that can be pursued with broad ethical and societal support. As a people who value progress and justice, we can decide to pursue every avenue of medical research that is respectful of human life in all its stages, and we can work to create a system that brings the advances in medicine to all those in need.

Thank you for your time and attention.

Chairperson FEINSTEIN. Thanks very much, Father, and thank you, panel. It has been an excellent panel, and I think very interesting to hear your respective arguments.

I would like to begin, if I can, with you, Dr. Weissman. This goes to the argument made that, well, there has really been no bona fide work in the area of somatic nuclear cell transfer. And as I understand it, stem cells injected into mice have partially repaired a spinal cord injury and allowed the mouse to walk. Human embryonic stem cells have been induced to form pancreatic tissue, providing hope that youngsters suffering from juvenile diabetes might receive replacement insulin-producing cells. And I think just recently scientists have announced that they have used cells derived from cloned cow embryos that function and are not rejected when implanted into adult cows, marking the first time cloning technology has been used to grow personalized genetically matched organs for transplantation.

Could you talk a little bit about specific research in the area of therapeutic cloning and stem cell research and explain what is happening that can make this more real to people other than just something very esoteric?

Dr. WEISSMAN. Sure. Actually, I believe the first paper that was published which showed that you could take mouse embryonic stem cells, convert them to neural cultures, and then use those neural cultures to treat a disease in mice, a demyelinating disease, was done by Bressler and Makai and published actually several years ago. I am surprised that Congressman Weldon didn't know about this. And this led to a reinsulating of the neural fibers of these animals that could not walk and led to a restoration, at least a partial restoration of the function.

The experiments you talk about with spinal cord injury are at the beginning. They are as you reported them. What we like to do in science—and I think it is very important for this panel to understand—is that we need to have publications that are peer-reviewed before we understand what the phenomenon is and then independ-

ently replicate it. This is a very nascent field. It is just at its beginning.

There are lots of claims that are now coming across in the media about substitutes for stem cell research. Most of them in the last 2 weeks have come from unpublished papers. So we don't understand yet what might or might not be there, and, of course, they are not yet verified. So I want to be cautious in any claims about whether it works for spinal cord injury or other things yet.

Certainly, you are right. Insulin-producing cells have been produced by the same group, Makai's group, from embryonic stem cells. There is no doubt about that, and they have also shown that they could restore neural function, as I said, in a mutant that lacked these insulating fibers. But the only way we are going to go forward on this research is if we can do the research.

Chairperson FEINSTEIN. Thank you.

Dr. Greely, could you explain the difference between somatic cell nuclear transfer to produce stem cells and the parthenogenic technique used by Advanced Cell Technology?

Mr. GREELY. Can I pass that one back to Dr. Weissman? My bachelor's degree from Stanford is in science, but it was political science.

[Laughter.]

Senator KENNEDY. Then you ought to have an answer.

[Laughter.]

Mr. GREELY. I can, but I am actually old and wise enough now to know that he would have a better answer.

Chairperson FEINSTEIN. Well, let me tell you where I am going——

Senator DURBIN. You didn't think that would be on the final, did you?

Chairperson FEINSTEIN. Where I am going is: Is it accurate to say that in both somatic cell nuclear transfer and parthenogenesis the egg cell is never fertilized by the sperm?

Dr. WEISSMAN. That is right. And so in parthenogenesis, you activate the cell now to start dividing with the nucleus that it has. So it is only going to be a replica of that woman's egg.

Chairperson FEINSTEIN. I have one here for Dr. Charo and then—I have so many papers here.

Doctor, in his testimony today, Father FitzGerald, if I may, makes one moral argument and two policy statements against therapeutic cloning. His first policy argument is that other research avenues exist for curing diseases and treating ailments besides therapeutic cloning. And a second policy argument is that even if therapeutic cloning results in promising therapies, many people may not have access to them.

How do you respond to these two policy arguments?

Ms. CHARO. With regard to the first point, I don't accept the premise. I don't believe that adult stem cell research can replicate all the areas of research that can be done using nuclear transplantation technology, specifically when we are looking at the replication of cells from a person with a particular genetic disease and we want to study how the defective gene operates in tissue that is being studied in the laboratory.

Further, the basic research on the reprogramming of adult cells can only be done with embryonic stem—sorry, with nuclear transplantation. And, again, for further details I might refer back to Dr. Weissman.

With regard to the question of the actual range of people who would obtain a therapy, I share his view that if we are going to be arguing based on a balancing of the equities, and cures are being held as one important equity, that it is important to see how many people would actually obtain those cures.

On the other hand, again, I find both in his testimony and, to a large extent, in Mr. Kimbrell's testimony as well, a list of very important issues for congressional debate: access to health care, regulation of markets in human tissue, improved regulation of the protection of human subjects in human experimentation generally, FDA regulation of risks to women associated with cell-based therapies, and so forth. But none of these will be solved by criminalizing research that uses nuclear transplantation.

These are a collection, a pack of very large dogs, and this little tail simply can't wag hard enough to answer all of these problems and solve all of these dilemmas. And so I think there is more than enough evidence that there are enough people and enough potential of unknown magnitude to justify the use of this kind of research in the hope that it will achieve some outcomes for some people and ultimately for everybody.

Chairperson FEINSTEIN. Thanks, Doctor. My time is up.

Senator Hatch?

Senator HATCH. Let me start with the lawyers. Professor Greely's testimony characterizes the FDA's assertion of jurisdiction over cloning as "questionable."

Mr. GREELY. Yes.

Senator HATCH. From the Federal perspective, what is the legal status of cloning, both reproductive and therapeutic, vis-a-vis the FDA and its statutes? Do you think that the FDA view could prevail in court? Let's start with you, Dr. Greely.

Mr. GREELY. I think the FDA view could prevail in court. I think it is most likely not to. In order to be a device under the statutory jurisdiction of the FDA, in order to be regulated under the statutory jurisdiction of the FDA, human reproductive cloning would have to involve a drug, a device, an article, a product, a long list of nouns, for none of which human embryo seems a good fit.

On the other side, it also has to be used for the treatment of disease or the cure of a medical condition.

Now, arguably, if it is done for treatment of infertility, it is for the treatment of a disease or condition. But if an otherwise fertile couple chooses to have a human clone, it is very hard to see what medical disease or medical condition is being treated.

There are a couple of law review articles on this—I would be happy to provide the citations to your staff—that come to a similar conclusion.

Lurking in the background of this question there is also a Commerce Clause issue. Although, frankly, my view is Congress does have the power to empower the FDA to regulate this or to ban it directly, it just hasn't done so thus far.

Senator HATCH. Would anybody else care to comment?

Mr. KIMBRELL. Yes, Senator. In 1989, the FDA was asked whether it could view fetal tissue as a device and was not convinced they could or could not. They decided they basically could, but Congress intervened and through the legislation made sure that didn't happen.

I think the real problem is it is very questionable, and the last thing we want to see is this thing resolved in court when somebody actually litigates against the FDA for being arbitrary and capricious and going beyond its statutory authority in doing this when the cloning is already in process. So I think it is a very risky business indeed to think that the FDA could regulate this.

Ms. CHARO. Senator, if I may, of course, ask three lawyers, you will get three opinions. I disagree with both my colleagues. I think the FDA's jurisdiction here is unproblematic, although certainly Congress could help by making that easier to understand.

Senator HATCH. So Congress could pass a law in this——

Ms. CHARO. Congress absolutely could. But what I would like to draw to your attention is the distinction between FDA jurisdiction over reproductive cloning to make babies versus non-reproductive cloning to produce embryos from which cell-based therapies are derived.

With regard to reproductive cloning, questions have been raised about its jurisdiction, and although Professor Greely feels that they might lose in court, my experience looking at this field is that courts will be extremely deferential to agencies' own interpretations of their authorizing legislation.

But more to the point, when it comes to non-reproductive cloning, its jurisdiction is far clearer because its entire Division of Biologics, which regulates a range of cell-based therapies and which has been regulating more and more aggressively in the last 5 years a variety of therapies and markets that involve human tissue, in this area the FDA's jurisdiction is, as far as I can see, unproblematic and extremely useful in guarding against exactly the kind of concerns about retrieval of eggs being risky or markets being unduly coercive.

Mr. GREELY. I agree entirely with Professor Charo on that second point.

Senator HATCH. Let me ask Mr. Kimbrell and Father FitzGerald this question: Would your views on so-called therapeutic cloning—I would call it DNA regenerative therapy. I think "cloning" is a stupid title, between you and me. I heard one of the Congressmen thought that was, you know, just a semantic change, but I don't think it is. But would your views on therapeutic cloning change if the cloned stem cells were derived from an egg that was rendered incapable of implantation in a woman's womb?

Rev. FITZGERALD. How would you do this manipulation of the egg to make it incapable of implantation?

Senator HATCH. I am asking the question.

[Laughter.]

Rev. FITZGERALD. Unfortunately, I mean, I guess it would——

Senator HATCH. I didn't even have political science.

Rev. FITZGERALD. As is the case in a lot of this area, it is unfortunate that oftentimes the complexities of the science do have direct impact on what particular ethical or public policy conclusions

one might come to. But I would have to say that it might be important how one intends to render that inability to be implanted the case. I could think of a variety of ways one could do that without necessarily abrogating the potential of this entity that is derived once some minor manipulation had occurred into be reactivated and being allowed to implant.

Senator HATCH. Let me just ask Dr. Weissman——

Mr. KIMBRELL. I have a quick answer to that, if I could, Senator, because I do think it is a very important question. With parthenogenesis, people are asking this question more and more, and I do think that it resolves a couple of the major problems here. One is clearly the only regulatory scheme—and England is trying to do this—that would work for cloning of human embryos for research that would sort of alleviate the problem of having this whole store for people who want to break the law would be to have a chain of custody. You wouldn't need a chain of custody in the scenario that you talk about, and the fear that you would have these research clones available for reproductive cloning wouldn't be there. So it would alleviate that major concern.

As far as some of the other concerns, such as, you know, commodification and choice, it would not alleviate those concerns. But it would deal with that first concern that you have a slippery slope and providing so many embryos out there in an unregulated way that would lead to reproductive clones.

Senator HATCH. Dr. Weissman?

Dr. WEISSMAN. There are two scientific ways that you could imagine would be used to render the blastocyst or a pre-blastocyst stage from being implantable. The first and most direct—and it could be done today—is to remove the outer lining of trophoblast cells. That would be entirely effective. You cannot implant without those cells.

There is a second and theoretical way—theoretical because nobody has done it. We now know the genes, many of the genes that are required for making the trophoblast. So one could employ current technologies to test whether you could introduce into that egg those genes to be expressed during that early stage that would prevent the development of the trophoblast.

So scientifically it could be done.

Senator HATCH. I have two more questions, if the Chair——

Rev. FITZGERALD. If I could answer—do you want me to answer that?

Senator HATCH. Sure, but I just have a little bit more time. The chairman has agreed to give me additional time to ask a couple more questions. But go ahead, Father.

Rev. FITZGERALD. I would say, quickly, if one gets to the point where you can remove the trophectoderm—that is the cells outside the inner cell mass—from the perspective of many people you would already be destroying an embryo, so that would not necessarily solve the problem I think you are trying to solve.

The second one is if you go in and attempt to render the genes inactivated—and one doesn't necessarily have to do that at the DNA level; they could do it at an epigenetic level, which is slightly different. But then, again, I guess it goes to that more legal and

philosophical intention discussion that we heard earlier, and that is where you would have to have that somewhat resolved.

Senator HATCH. OK. Well, I think this is an area that is very intriguing to me.

Rev. FITZGERALD. Just one other issue. Parthenogenesis is not therapeutic cloning.

Senator HATCH. No, no. I understand.

Rev. FITZGERALD. So we wouldn't want to blend the two.

Senator HATCH. That I do understand.

Let me ask you, Ms. Gulden, you know, I hope and I will pray that you will be able to run again and play basketball and be a police person, as you have been in the past. And I want to thank you for the courage that you have had in coming here today and telling us about yourself and about your views. Everyone wants you to get out of that wheelchair and be able to do what you want to do. And we all want research, so long as it is ethically appropriate.

Now, this is a tough question, but I think you can probably handle it very well, so I feel that I am fair in asking it of you. How do you respond to the concerns of those who believe that therapeutic cloning entails the killing of another person, that is, the cloned embryo? How do you respond to that statement?

Ms. GULDEN. I would defer to Dr. Weissman.

[Laughter.]

Ms. GULDEN. Senator Hatch, in my opinion, another person is not being killed. We are talking about a cluster of cells perhaps the size of a pencil eraser. I don't think that that is a person. I am a real person sitting here before you, and I just don't think that the cells we are talking about constitute a living human being.

Senator HATCH. Well, whether they do or not, you seem to be saying that, look, they would be helping you and others similarly situated to live and to have a better life and to be able to do what is good in your life or good for others, that you might be able to be even a more productive human being if you could resolve these health problems that you have had to suffer from.

These are tough questions for me because, you know, I am pro-life, but I also believe we ought to help the living and we ought to solve problems of disease and difficulties if we can. And it is important that we help people to live. So it has been a very, very difficult thing for me.

If I could just ask one other question, Madam Chairman, and that is this—and I would ask it for the panel at large. Cloned human beings do not exist in nature. I think that is a fair statement. In reproductive cloning, as I understand it, an egg is never fertilized with sperm. And while twins share virtually identical DNAs, they are the product of haploid gametes, as I understand it, of their parents and not from a single diploid parental cell.

Now, would a diploid being created through reproductive cloning be a person in the same scientific, legal, and moral or religious sense, as we ordinary haploid-haploid mortals? We will start with you, Dr. Weissman.

Dr. WEISSMAN. Well, I think you have made the right definition scientifically. I have nothing to add to it. The only thing I will say is that from the animal experience, this is very important——

Chairperson FEINSTEIN. Perhaps you would put in lay language what he was saying.

Dr. WEISSMAN. What he is saying is that in nature there is no such thing as a diploid cell that has been used to create clones, other than twinning, which does occur when two cells separate or four cells separate that did have the identical nucleus.

But what I think is important is that the procedure to make these is one in which—that is, to make clones is one in which you have to add a nucleus in. I have nothing else scientific to add to your judgment.

Mr. GREELY. Senator Hatch, I don't have the expertise to give a religious answer to that, but as a lawyer, I can tell you that should reproductive cloning produce a baby that cries, that eats, that sucks, that recycles its nutrition and needs to be changed, I as a lawyer would feel very, very confident arguing that that baby would be a person for purposes of the 14th Amendment, entitled to all the rights and liberties of any other person, regardless of the way in which it came to be born. And although one should never try to predict with certainty how courts will react, I feel confident about this one. Babies will be held to be people.

Mr. KIMBRELL. I totally agree with Professor Greely. It seems to me—and I don't think anybody would seriously argue that cloned animals would not be covered under the current Animal Welfare Act, that we would make sure that those animal were not subject to cruelty and had the basics they needed to live. Just because they were cloned animals, I don't think we would suspend from them the legislative protections that we grant animals, and I am sure the same would be true for people, should, God forbid, they ever be cloned.

Ms. CHARO. Senator Hatch, not only do I agree with Professor Greely, but I would even take away the suggestion that the baby needs to be able to cry and suckle. In the United States, if you are human and you are born, you have the equal protection of the laws and of the Government, and that is all it takes. Nothing more.

Rev. FITZGERALD. I actually very much appreciate your question because I think it raises the much deeper issue that we are going to wrestle with, not just here but with many of the biological advances that are in the pipeline; and that is that our concepts such as personhood predate the biological information that is coming to us so rapidly, such that our philosophical, our theological, and our legal concepts of what it means to be human and to be a person do not necessarily correspond with the biological data since this is something we have only been able to uncover relatively recently in our history.

So we are going to have to continue to struggle with making that bridge and understanding the scientific information in perhaps ethical and cultural frameworks which are somewhat outmoded to integrate it.

Senator HATCH. I want to thank you all, and I certainly want to thank you, Madam Chairman.

Chairperson FEINSTEIN. Thank you, Senator. Appreciate it.

Senator Durbin, you are next.

Senator DURBIN. Thank you, Madam Chair, and thank you to the panel. I want to thank Kris Gulden for putting a human face on

this debate. We spend a lot of time talking about scientific terminology and law, and you have reminded us what the bottom line is in this debate. Thank you for being here.

And I want to thank Dr. Weissman for serving as the lifeline for this panel. Time and again they have called you, and your answers have worked out just fine.

I have listened to this debate and tried to reflect on a trip I took several months ago and found to my surprise on the South Side of Chicago at the little company of Mary Hospital that it was the first hospital in the United States in the 1950's to have a successful kidney transplant. It was just a fluke. It never should have happened. But it did, and they are quite proud of that fact.

And I recall growing up Dr. Christiaan Barnard and heart transplantation, and I tried to put myself in the place of those who were considering organ transplantation in the 1950's and 1960's and listen to the arguments from this panel and wonder how that would have come out using the same standards. Because I listened to Dr. Kimbrell, and he suggested organ transplant—well, I think you could argue organ transplantation created many hopes that have not been realized. You said the same for gene therapy and other things. Many recipients of organ transplants have died, and, of course, that has happened with many other therapies that have been tried.

Allowing organ transplantation was an open invitation to commercialization and even murder. It could have happened. Maybe it has. I don't know.

In addressing Father FitzGerald's logic, even successful organ transplantation techniques are not available to everybody, rich and poor, in America. So using this same logic and thinking, I am just curious as to how some of the critics of therapeutic cloning would have come down on organ transplantation using the same standards. But I think what it boils down to is this: Research is research, and it doesn't always lead to a cure. The question we have to ask is whether we can cross that ethical threshold to justify it.

Father, I am trying to recall theology courses from a long time ago. I think you have a morally consistent position, the church does on this, that would even oppose in vitro fertilization. Am I correct?

Rev. FITZGERALD. The church's official position, yes.

Senator DURBIN. And I listened earlier to the response from Congressman Weldon, and I think, frankly, who owns the sperm and the cell and what their intent is should be kind of secondary to the moral question if you are going to take the church's position. But he thought they made all the difference in the world, and I think Dr. Kimbrell and others have agreed with him.

So let me try to pursue this, Dr. Kimbrell, if I can. Do you believe that we should prohibit in vitro fertilization as some artificial use of science? And how would you draw a distinction between in vitro fertilization, if you wouldn't prohibit it, and this whole approach that uses nuclear transplantation or therapeutic cloning?

Mr. KIMBRELL. I wish Senator Wyden were with us because he has been a real courageous leader in trying to regulate one of the, to me, most egregious offenders of our ethics, which is the IVF industry. It is virtually unregulated.

My plea was not to ban IVF, but to make sure before we disseminate these technologies—and I used a couple of other examples, but organ transplantation is as good an example as I could ever come up with—you want to make sure that you resolve the issues before the technology becomes disseminated, commercialized, patented, and there is all this incentive.

For example, in 1984 and 1985, I was here on the Hill with then-Representative Al Gore trying to pass the Organ Transplantation Act. In this country, we allowed the sale of organs. There were ads in USA Today, in the newspapers, for eyes, for kidneys. The World Health Organization has just declared this an international emergency as companies go into the Third World and take the organs from people. These are live donors, Senator.

You know, certainly before we get that technology out, we need to deal with the fundamental commercialization and ethical issues. That was the plea I was making, not to get rid of it but to make sure for once that we act maturely and take legislative and regulatory responsibilities to——

Senator DURBIN. Isn't that what the Feinstein-Kennedy bill is all about, to establish some standards for regulation, some standards in research, not to ban it in its entirety, to throw out all the possible good things that could come from it, if we imagine all the bad things that might come from it?

Mr. KIMBRELL. Let me answer that briefly, if I could, and Senator Feinstein is a hero of mine. I have an office in San Francisco, which is just about my favorite city in the world, and I respect her enormously. But I don't think that her bill, frankly, does either of these things. Unfortunately -and I could submit this to the record; we have done a legal analysis—there is some carelessness in the language and definitions that would actually allow reproductive cloning, for instance, from fetal tissue and from embryos.

So there are some problems with the bill. What the bill does not do is in any way regulate research human cloning, human cloning for research. There is no regulation whatsoever. Each of the issues that I addressed is completely is unaddressed, whether it be the commercialization, whether it be sale, whether it be patenting, whether it be a line of custody that we would establish through regulation. None of that is addressed in the Senator's bill. It is, admittedly, what it is supposed to be: a reproductive cloning ban. It is not meant to address these other issues at all, and it does not.

Senator DURBIN. Would you agree, then, that if there is appropriate regulation, as we put in place for organ transplantation, that therapeutic cloning and research in that area should go forward?

Mr. KIMBRELL. I believe that if we take the time—and I believe there should be an indefinite moratorium until we do this. We don't want to, again, provide all of the incentive, have a whole industry in place, and then try and retroactively -we have seen how impossible that is in the environmental field. We know it is impossible trying to retroactively regulate successfully. Let's, before we allow this, answer these important regulatory and ethical questions so we know what we are about when we begin it. We need to have a consensus and robust national debate on this before it happens.

Senator DURBIN. But you are not opposed to this research if it is regulated?

Mr. KIMBRELL. Not by definition, but by consequence.

Senator DURBIN. Let me ask you, if I have a moment?

Chairperson FEINSTEIN. Yes, please go ahead.

Senator DURBIN. Dr. Weissman, if I could ask you, could you give me an indication, what would the implications of a complete ban on therapeutic cloning be for stem cell research and what therapeutic interventions specifically might be halted or slowed down?

Dr. WEISSMAN. Sure, so long as we call it nuclear transplantation of stem cells. Well, of course, it would end all of the research that I described to you that used to be on that panel. We could now directly look at how, for example, a cancer cell—I think that Dr. FitzGerald should have sympathy for this—how the mutations that occur after a woman has been born with a heritable predilection for cancer, how it actually happens that she gets it and her sister doesn't?

Senator DURBIN. Breast cancer, for example.

Dr. WEISSMAN. Breast cancer, colon cancer. You can go through every one of the cancers. You have heritable predilections for this disease, but we still don't understand how the disease develops. Mutations develop, and in the unlucky cell in the unlucky person, cancer develops. We don't understand it yet. We are trying to go very systematically through it, but it would be enormously helpful to have the nucleus from that cancer cell making a cell line, which we can then study in mice, as to what are the true important events and which are the unimportant events. So that is just one application.

But I do want to correct, which I have now heard several times from other members of the panel and Congressman Weldon, that one does not gain from some forms of research important, large-scale therapies. So recombinant DNA research—that is, putting together two DNAs from different life forms, bacteria humans, bacteria mice—was fought on almost exactly the same grounds in 1975 to 1980. I was at the first Asilomar Conference where scientists say we need to stop for a second and talk among ourselves what are the experiments that will allow us to go forward or not, and then a regulatory body, the Recombinant Advisory Committee was set up, and today it is not false to say that hundreds of thousands of lives, people living right now are saved or made better by the products of that research: erythropoietin, GSCF, interferons, human insulin growth hormones, and so on. I can't even go through the list.

So if we have the same potential, which I believe we do, from the kind of research we are talking about, irrespective of the therapeutic cloning, just for the research itself, I believe it has the same enormous potential as recombinant DNA research and, unpredictably, it will come out with the kinds of research that leads bright scientists to develop eventually therapies.

Senator DURBIN. Thank you, Doctor.

Thank you.

Chairperson FEINSTEIN. Thanks, Senator.

Senator DeWine?

Senator DEWINE. Madam Chairman, let me thank you for holding this hearing and thank our panel, and, Ms. Gulden, thank you for your testimony. We appreciate it very, very much, and I would

just echo what everyone else on the panel has said. We appreciate you coming in, your courage.

I don't know that there is much at this point that we can add. This panel I think has illuminated very well the national debate that we are having, and I think almost all points of view are represented on this panel, and you have done a very good job, each one of you, of articulating the different arguments. In fact, you have added a great deal to those arguments.

My understanding is, as lay person, that the cells that develop in an embryo for purposes of therapeutic or reproductive cloning are really indistinguishable from that of a naturally fertilized egg. That is a basic question. That is correct, is it not? What we end up with at this point is indistinguishable genetically? Anybody disagree with that? OK——

Rev. FITZGERALD. I think you might want to be a little more careful. We don't know. I think the answer is—I think that would be accurate to say that we could not definitively say one way or the other.

Dr. WEISSMAN. The important data is that with a naturally fertilized egg, you have a high probability of going on to a blastocyst, and when it implants, even from an IVF clinic, a very high probability that it goes through a normal pregnancy. All the losses occur in the first few months. But with nuclear transfer, to clone, to do reproductive cloning, the reprogramming doesn't work very well. You have a much lower incidence making the blastocyst, and then you have a 100fold loss so that only 1 percent of the implanted embryos make it through pregnancy for a live birth, and even after that there are many losses. So it's not exactly the same.

Rev. FITZGERALD. Right. But, again, we have to be careful because the consequences of the probabilities could be based on very similar mechanisms, and what is going wrong mechanistically in the cells might not be that distinguishable. There could be cells that are the result of the fertilization process that, once one looked at them on a molecular level, would be difficult to distinguish between some of the cells that were created by somatic cell nuclear transfer.

As Dr. Weissman said, we are very much at the infancy of our understanding of all this.

Senator DEWINE. All right.

[Laughter.]

Dr. WEISSMAN. But go ahead.

Senator DEWINE. I will try one more time with you, though, Dr. Weissman, because what I hear you saying is that the process of what will happen in the future may be different. You are talking about different odds. It sounds like you are saying different odds of survival, is what you sound like you are telling me. But the snapshot of what you are looking at or what that is at that moment, it sounds like you are saying it looks to you, at least, as if it indistinguishable. Now, is that what you are saying?

Dr. WEISSMAN. No. No, I am not.

Senator DEWINE. All right.

Dr. WEISSMAN. What may look to the naked eye as a blastocyst derived from nuclear transfer and a blastocyst derived by sperm-and-egg fusion, if it makes it that far, to the naked eye you can't

tell the difference. But when you look at that set of imprinted genes, that is, the gene expression profile that normally happens, you can easily tell the difference. It has been published before that certain genes aren't turned off that should have been turned off. Other genes aren't turned on that should have been turned on. And we expect that those are the kinds of genes that are important for the early development that leads to this high loss during fetal life.

So a sophisticated molecular biologist today could tell the difference.

Chairperson FEINSTEIN. But only that person? Only a sophisticated——

Dr. WEISSMAN. I think that, yes—that is, not just that person. You could, of course, develop a laboratory that would assay the 42 or more imprintable genes and know whether they were appropriately turned on or turned off. A common laboratory could do that as easily as the DNA fingerprinting laboratories establish identity.

Senator DEWINE. Dr. Weissman, in your testimony before the Appropriations Subcommittee, you stated and provided a handout—this was your testimony on January 24th—demonstrating that the clone used in research is no different in kind or nature from one destined for implantation; in other words, whether the purpose is going to be for implantation or whether the purpose is going to be the, quote, therapeutic, as the term is being used.

Dr. WEISSMAN. At that stage——

Senator DEWINE. At that stage.

Dr. WEISSMAN. If you were doing an animal cloning experiment, because that is the only experience we have, the only experience, then that blastocyst could be implanted and suffer, as I told you, losses or stem cells could be derived from it, which have been done, and you give rise to stem cell lines which, on their own, cannot make a whole organism and in a test tube cannot make an organ directly.

Senator DEWINE. Well, let me just thank all of you again. I found Mr. Kimbrell's testimony, one particular statement, very significant. I found a lot of his testimony, frankly, to be chilling and give us a lot for thought. But his quote that this is the first time that we would have produced a human life form with specific intent to destroy it, I think that gives us all something to think about.

Thank you.

Chairperson FEINSTEIN. Thank you. But as I understand it, it isn't. Am I wrong?

Ms. CHARO. In fact, Senator DeWine, I would have to disagree with Mr. Kimbrell about that because——

Senator DEWINE. You certainly have the right to do that. That is why we have a panel.

Ms. CHARO. Embryos have been created specifically for research purposes and then been destroyed for decades, and it was exactly how in vitro fertilization was originally developed.

Senator DEWINE. So we have done this before.

Ms. CHARO. Yes, for decades. And surveys of laboratories around the United States that were done by Government agencies, includ-

ing the National Bioethics Advisory Commission, in fact, had documented that fact to some extent.

Senator DEWINE. Doctor? Mr. Kimbrell?

Mr. KIMBRELL. Two issues on that. That is what you were getting to, Senator, when you started; you know, Dolly didn't just come from a cluster of cells. Dolly came from a sheep embryo, so this euphemism of trying to call it a cluster of cells, nuclear transplantations, this is just euphemism. This is an embryo that would be appropriate for implantation. That is what makes it so dangerous as far as being out there.

Second is that IVF is a rogue industry. There may have been those who broke various laws, various things to try and accomplish various aims in the IVF industry. But the IVF industry is not an industry designed with the intention of producing embryos solely for their destruction and the use of spare parts. That is new. It is an ethical question. We cannot avoid or slip through by thinking it is happening again. For or against this technology, it is the ethical question we need to deal with, and the public should have a voice in dealing with it, not just here at the panel or our legislators. It should be a robust public debate, I think.

Senator DEWINE. And, Madam Chairman, I would just again call your attention, everyone's attention to the professor's comment wherein she said it has been done before. And I guess my answer to that is, if it has been done before, it doesn't mean it is necessarily right. I think the creation of human life for its destruction is not right. And I have the right to have that opinion, and she has the right to have a different opinion, and that is why we have a debate.

Thank you.

Chairperson FEINSTEIN. Senator Brownback, you have shown great patience.

Senator BROWNBACK. It is a great topic, and you have done a great job putting together the panel, and I appreciate the panel's discussion of it.

I am very pleased today to be able to announce as well that Senator Mary Landrieu is cosponsoring the bill I put forward to ban all human cloning. It is modeled after the House bill, and so I am pleased that she is going to be the lead Democrat cosponsor of the bill and is willing to take a bold, principled position on this.

I think if we back up—this has been a very good panel—and look at where the situation and the issue stands today, the House has passed a broad-based ban on human cloning. This would be both what people refer to as the reproductive and the therapeutic cloning ban, total ban, a 100-vote margin in the House of Representatives that passed to ban all forms of human cloning, whether it is for research, destructive, somatic cell nuclear transfer, whatever term you want to use, that has passed the House.

The President has called for a ban on human cloning of all forms. He doesn't think we should create life for the purposes of destroying it and is now asking the Senate to pass a similar ban as to what the House has passed by a broad bipartisan margin. And now we need to take the issue up, and a broad-based coalition is coming together to do that.

I would note, I would like permission to enter into the record, Madam Chairman, a statement in support of legislation to prohibit cloning, cloning of all types—therapeutic cloning, and reproductive cloning. It is signed by 77 different people of various organizations, including Norman Mailer, a writer; Judy Norsigian, who was previously cited, executive director of Boston's Women Health Book Collective; and a number of others. And I would ask unanimous consent to enter this into the record.

Chairperson FEINSTEIN. Without objection.

Senator BROWNBACK. I also ask unanimous consent to enter in the record and then would like to ask Dr. Weissman about an article that appeared about the ultimate stem cell discovery in "New Scientist." This is about an adult stem cell that is in each of our bodies presently that can turn into every single tissue in the body, and I am quoting from it. "It might turn out to be the most important cell ever discovered." Dr. Weissman, you are quoted in this article as well, saying it is very dramatic kinds of observations, is reporting the findings, if reproducible, are remarkable.

Then I would note another article that I would ask to be put in the record, the Journal of Clinical Investigation, that there was reproduced the findings in this study that were in the "New Scientist."

The reason I put that forward is, I don't think anybody has commented on this yet. I believe, Professor Charo, you were on the NBAC Board under Clinton, and you noted in your report, if there is another way of doing this without destroying an embryo, that is a better way of doing it. And if we have this coming about and these now are verified in the adult stem cell, that we have adult stem cells that are pluripotent, and can go into all forms, can be reproduced outside of the body, I think the whole panel would agree that this is a marvelous thing and this is the exact way that we could all agree we should pursue.

Dr. Weissman, since I first put that to you, I——

Dr. WEISSMAN. Sure, let me respond. That is why—and I think it is very important that we all understand. The reason that I said what I said just a little bit ago that how scientists operate is to publish their results in peer-reviewed journals to demonstrate a phenomenon, and then look for independent verification. And, Senator, although the "New Scientist" has made this report, it is not a scientific or peer-reviewed journal.

So the finding by Dr. Catherine Verfaillie at the University of Minnesota has not yet been published, and so we cannot examine whether her conclusions about her data would fit with general scientific ideas. The paper has not been published.

Now, let me just say that I, therefore, asked Dr. Catherine Verfaillie to send to you, which you have in your office, and to you, Senator Feinstein, and to Senator Kennedy, an exact point of what she has and would her findings be important enough or even relevant to the issue of nuclear transfer to create embryonic stem cell lines. And I could read it to you, or you could read it because you have it in your office. I will read just a couple small parts.

She said, "It is far too early to say whether"—the cells—"they will stack up when compared to embryonic stem cells in longevity and function. Further, we will not know which stem cells, adult or

embryonic, are most useful in treating a particular disease without side-by-side comparison of adult and embryonic cells."

And then she went on to say, "We support studies aimed at developing techniques for therapeutic cloning—that is, cloning of human embryonic stem cell lines—because they may provide immune-compatible cells to treat a number of diseases, and because cloning of embryonic stem cells may be critical to the study of adult-onset diseases caused, for instance, by mutation in the DNA of cells after birth."

And there are a lot of qualifications, she goes on, but the important point here is the one person who has published the only paper where it—not published, who through the media, in a pre-publication media blitz, has reported—she didn't do this herself. This is the media who has pushed this very hard—that there may be such a cell in the body, says no, it does not substitute for embryonic stem cell research or nuclear transfer research, particularly because she can't make those cells from the somatically mutated cells in adults.

Senator BROWNBACK. Could I ask you, Professor—could I have a couple more minutes, Madam Chair?

Chairperson FEINSTEIN. Of course. Take the time you need.

Senator BROWNBACK. If we can do what you are desiring to do from adult stem cells, would you agree that that is the far more preferable way to go?

Dr. WEISSMAN. You mean to take the nucleus from, say, a breast cancer cell or a Lou Gehrig's disease cell and show that you can now study for all of the cell differentiation that an embryonic stem cell can do, both in vitro and in animal models, the development? That is science fiction today.

Senator BROWNBACK. If we could do with adult stem cells the work of curing ALS, of dealing with Alzheimer's, wouldn't you agree that that is the better way to go?

Dr. WEISSMAN. Let me just respond for the scientific part. I am committed, as you know, to finding adult stem cells for the treatment of human diseases. That is my only commitment. That is what I do. I do no research on embryonic stem cells or nuclear transfer, have no connections. But even if we could treat one disease, or two or five or ten, with adult stem cells that are around, I would not block the research, the important research that would open up whole fields, like taking disease cells or body cells from people with heritable diseases, I would not foreclose that because then I would be taking the responsibility to slow down the pace of discovery and the loss of lives that might have been saved. I could not do that.

Senator BROWNBACK. Mr. Kimbrell, if I could ask you, what is the worst-case scenario if we proceed, no laws in place, no regulations, no limitation, United States doesn't act, House has said we want a full ban, the President says we want a full ban, Senate doesn't act on it or takes another route so no bill gets through, so we continue on this unlimited, unregulated market situation we are in presently? What is the worst-case scenario that could develop in this situation?

Mr. KIMBRELL. As a preface to that, and following along with Dr. Weissman, one of the things we do need to be careful here—and

I will be careful, too—is that we shouldn't have science by press release. I think we can all agree with that, and we are seeing that more and more often, frankly, to try and garner venture capital for these companies. And we can't have policy based on that. We cannot have the media do what they do, which is aggrandize these things. And talk about science fiction. Right now the idea of garnering stem cells from cloned human embryos is just that—science fiction.

Dr. John Gearhart, who is the Senate's consultant on this, resigned from the editorship of the journal—excuse me, the editorial board of the journal that published Dr. West's study because he said it shouldn't have been published. Even as they were talking about getting stem cells from cloned embryos, numerous scientists were saying this is just not going to happen. So it is not just one side that is science fiction, Doctor. It is also the whole idea right now of getting stem cells from cloned human embryos is definitely science fiction.

Should it happen, however, I don't think there is any doubt that the time and the place to regulate this is at the creation of the embryo. If we were to regulate this at the creation of the embryo, which I am suggesting, that is a relatively easy place to regulate it because you are simply banning the creation of these embryos. If we want until implantation to regulate, then we already have the embryo implanted; we have got a surrogate mother who is bearing this child, and what do we do? What is the answer to that? Certainly not abortion.

Chairperson FEINSTEIN. Sam, would you allow me just to poke in here for 1 second with a question?

Senator BROWNBACK. Yes, if I can continue after you.

Chairperson FEINSTEIN. Yes, absolutely.

Mr. Kimbrell, the rest of the world is going to move in this direction. European countries are moving in this direction. Embryonic stem cells, the nuclear transplantation offers so much promise for, you know, remedial efforts with all kinds of diseases. Let's say we ban therapeutic cloning and it was available in Europe. Ms. Gulden, would you go to Europe? Of course you would.

I don't know how you effectively stop people from looking for hope when they have a condition or a disease or a problem that might otherwise be changed.

Mr. KIMBRELL. Two quick answers, if I might, Senator. One is we want to make sure that they have hope, not hype. As I explained in gene therapy and fetal tissues, in the hearings very similar to the ones we are having today, it turned out to be a lot more hype than healing. Some money was made, but people were injured not healed. We need—again, I insist on not being technologically amnesia when we look at this.

But the second thing is look at what England has done. Yes, it is true that England has said let's go ahead with this, though there has been some legal issues there that have actually stopped that and now may continue again, but with strict regulation that has a complete line of custody for each and every embryo so created to avoid many of the worst-case scenarios that I was just discussing with the Senator.

That kind of regulation, that kind of regulatory system, is the only thing that is to prevent at least one of the worst-case scenarios that we talk about. They realize that. I know the German parliament is looking at this, and the United Nations is currently looking at this. And I am convinced that they will not allow an unregulated—just as England has not, an unregulated industry in the creation of cloned human embryos for research.

Chairperson FEINSTEIN. I would very much appreciate it, if you would care to—you said there were faults with our bill, and I have no doubt, you know, it is an imperfect vehicle right now. We admit that. We would like to improve it. I would be very happy to receive any of your comments as to how to strengthen it or any of the regulatory—we were just reviewing them up here, and my staff feels that it is pretty good so far that way. Now, you say it isn't.

So, you know, I for one would love to have your comments, if you would care to submit them.

Mr. KIMBRELL. Senator, I have spent hours of my life trying to do effective legislative writing, and I realize what a humbling process it is, and it is a lot easier to have 20–20 hindsight. As Senator Hatfield once said to me, where were you when the paper was blank? So I realize it is a daunting task, and I would be—thank you, I would be very, very happy to give you some of the suggestions that we have.

Chairperson FEINSTEIN. Thank you. I didn't mean to——

Senator BROWNBACK. No, no, thank you, Madam Chairman.

I guess, Mr. Kimbrell, what I am asking about is, last summer we were engaged in the discussion about embryonic stem cell research, and everybody was pointing out, well, these are so-called "leftover" embryos, which I question the designation of "leftover embryo," but they are leftover. They are going to be destroyed, and it is just this, and no, we are not going to clone human beings, no, we are not going to create embryos for research purposes. It was stated by a number of people at that time that we are not going to clone, we are not going to do this, this is just about the embryonic stem cell, period.

Now here we are 8 months, 9 months later from that point—not even that far later, and people are now saying we have to clone for therapeutic purposes if we are going to cure a number of diseases, which I support curing these diseases. I support doubling the NIH funding. I am a co-chairman of the Cancer Caucus. Cancer runs in my family. I have had it. I mean, it is not that I don't have passion for those issues as well. It is, OK, now we are on to cloning.

Then if we don't do anything on this, which may be the case, and so it just moves on forward, what is the next step? I hear people talk about germ line manipulation in the egg and sperm cells of adding outside genetic material or altering the material already there to correct defect that may be in there. Where are we headed to with all of this? Because it does seem like we are on a sequential path that we have continued to follow.

Mr. KIMBRELL. There are those—and there is much published literature which I would be happy to put into the record on this—that are looking toward what they call a post-human society, where they very much believe that our carbon bodies are not adequate to deal with the slings and arrows of outrageous fortune and that we

should re-create ourselves in a number of different ways through germ line therapy, which part of what Dr. Weissman was talking about, the Asilomar Conference and others, there has been an informal ban on germ line therapy until now. People are talking about rebuilding our cells molecule by molecule, and, by the way, we are spending about a billion dollars of our taxpayer money on this to rebuild ourselves through nano-technology. And MIT and others are trying to rebuild us with silicon chip bodies. Senator, you would be delighted to know, I know our taxpayer dollars are going to that.

So there really is—and I am not sure how widespread it is, to be honest, but there certainly is a rather chilling movement called the post-human society which views us as inefficient in our current forms, as something that is not a given good at all, but somebody can be re-created through technology to better deal with the future completely. That is obviously the worst-case scenario because, clearly, when we have lost what it means to be human, we have lost the ability that all of us have to communicate and even discuss these issues. So it is the wrong kind of final solution.

One quick note on that, which is that I have had to deal with a great many instances of cancer in my own family, and one of the things you learn when all of us who face this with a wife and child, we know that it is a very complicated thing. Disease is complicated. Is it genetic predisposition? Was it an environmental poison that came in? Was it a workplace poison? Was it diet? Was it stress? Or did all these combine?

And I sometimes think that we are a little bit too—and I am one—I feel this myself. We are little too prone to a magic-bullet approach, there is one easy answer, fetal tissue, gene therapy, germ line, stem cells, cloning. And rather than say, listen, this is a difficult job. Prevention is going to be a difficult job. It means environmental cleanup. It means making our cars safer. It means the difficult job that it is going to take to get rid of all of these resources. It is much more tempting, and I think somewhat childish, unfortunately, to say we are going to have a magic bullet, particularly if it means this post-human society that some would lead us toward, Senator.

Senator BROWNBACK. Thank you. I want to say, Madam Chairman, too, I don't challenge anybody's motives or ethics that participate in this panel here. I think everybody has a wonderful notion in mind of what they want to see in the future of there being healing in America and healing around the world and that we have got this chance to do this and that we should pursue it.

I don't challenge anybody's motive or ethics, and the Chair has been absolutely phenomenal on cancer and dealing with that. And I have been pleased to be a part of that. What I do think we have to have, as several of you, I think Professor Greely, you mentioned it, a robust debate about this. I have one more point, let's pause, let's pause and have the robust debate, and thoroughly, before we would move forward. I understand a lot of other people would say let's move forward and debate as we go. But I think we are at a momentous time, and we need to have that sort of debate—let's hold up let's really debate this before we move forward.

Madam Chairman, I appreciate your willingness and your interest and your holding of this hearing.

Chairperson FEINSTEIN. Thanks, Senator Brownback.

As you know, the debate is going on. I mean, we began this, what, a year and a half ago, I think. So the debate is going on.

I just want to extend the same offer to Dr. Charo, Dr. Greely, anyone else that would like to submit any improvements in our bill. We would very much appreciate them.

I must say I feel very strongly that we should move to ban human cloning. I think our Nation should go online and say that and be clear about it.

Now, I am one that very strongly supports the somatic nuclear transfer for therapeutic improvements, and I think it is going to happen if we do nothing. I think there is a point to legislating in a proper way to see that the right protocols are there, the right ethics, the right regulations, all of that, and that we shouldn't delay.

You know, I am aware of people leaving universities here, going to Europe because they feel there is more opportunity or more this or more that. But clearly, our law doesn't relate to what is a burgeoning new area, and it is going to burgeon without the law, and perhaps more transgressions take place, because I think there are people out there who are Machiavellian and who will do the wrong thing and want to make profit above all things, all the rest of it. And yet there are people like Ms. Gulden who look at this as something that, you know, really may offer them longer life, better quality of life, all of the above. So we have got a lot of challenges on our plate.

I want to thank this panel. It has been one of the best, and I really appreciate the different points of view, and thank you for coming the distances you did. We will keep the record open.

I would like to submit a statement by the chairman of the committee, Senator Leahy.

Chairperson FEINSTEIN. The meeting is adjourned.

[Whereupon, at 4:50 p.m., the committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

Questions submitted to Dr. Weissman by Senator Feinstein

Question 1: As I understand it, nuclear transplantation is a very broad technique that need not involve embryos or even stem cells.

- Could you explain some applications of nuclear transplantation that do not involve embryos or stem cells?

Question 2: I know that DNA regenerative research (also called therapeutic cloning) offers enormous potential for providing cures for diseases such as cancer, diabetes, cystic fibrosis, and heart disease as well as conditions such as spinal cord injuries, liver damage, arthritis, and burns.

- Could you explain which diseases and conditions are most likely to be curable or treatable through DNA regenerative research?
- Has anyone been cured or treated yet through DNA regenerative research? If not, when do you expect this could happen?

Question 3: It was reported recently that, in order to produce stem cells, Advanced Cell Technology in Massachusetts has created a monkey embryo through parthenogenesis, that is, without the use of sperm. As I understand it, unlike embryos created from an egg (oocyte) and sperm, parthenogenetic embryos do not go to term if placed in a womb and that any stem cells produced could only be used in the women who produced the eggs.

- Could you explain the difference between somatic cell nuclear transfer to produce stem cells and the parthenogenetic technique used by Advanced Cell Technology?
- Is it accurate to say that in both somatic cell nuclear transfer and parthenogenesis the egg cell is never fertilized by the sperm?
- What is your view about the medical promise of producing stem cells through parthenogensis?
- Was parthenogenesis to produce stem cells considered by your panel as it was preparing the National Academies report?

Question 4: There has been much talk about whether adult stem cells are as versatile as embryonic stem cells. Some have even said that research with adult stem cells shows that we do not need nuclear transplantation to produce stem cells.

- Based on your panel's analysis of the medical literature, would you agree that adult stem cells demonstrate sufficient potential that it would be appropriate to stop doing nuclear transplantation?

Questions submitted to Professor Greely by Senator Feinstein

Question 1: In *U.S.* v. *Lopez*, 514 U.S. 549 (1995), and *U.S.* v. *Morrison*, 529 U.S. 598 (2000), the Supreme Court held that the Commerce Clause gives Congress authority to pass legislation regulating intrastate activity where it substantially affects interstate commerce. In my view, it seems clear that a federal law banning human reproductive cloning would pass muster under Lopez and Morrison. Much of the equipment, materials, funding, and personnel required for cloning, as well as the individuals seeking cloning services, would likely have traveled in interstate commerce.

- Do you agree? Why or why not?

Question 2: In January 1998, in response to concern over a statement by Dr. Richard Seed that he would soon clone himself, the Food and Drug Administration (FDA) announced that it had regulatory jurisdiction over human cloning under existing federal statutes. The FDA also noted that anyone seeking to do human cloning would need to get permission from the FDA for such experiments and it suggested that it would not give such permission.

- In your view, does the FDA have jurisdiction over human reproductive cloning?
- Does the FDA have jurisdiction over DNA regenerative research (also called therapeutic cloning)?
- To your knowledge, has anyone sought permission from the FDA to attempt to conduct human reproductive cloning?

Question 3: Some commentators have whipped up a frenzy about cloning, raising the specter of a Brave New World of eugenics and designer babies. However, others note that, as is the case with many medical technologies, it is not cloning techniques that are the problem but some of their potential applications. For example, few people would argue that we should ban organ transplantation even though we are concerned about the sales of human organs or the transplant of organs from executed prisoners. Still, there are those who would completely ban somatic cell nuclear transplantation. This is in spite of the fact that the overwhelming majority of the scientific, medical, and patients' advocacy community opposes such a complete ban.

- Is there any precedent for completely banning an area of research against the wishes of the overwhelming majority of the scientific, medical, and patients' advocacy community?
- Would you agree that it is generally appropriate and desirable for the law to discriminate between proper and improper applications of a medical or scientific technique rather than completely ban research into the technique?

Question 4: You testified that the California Advisory Committee on Human Cloning concluded that the state should regulate DNA regenerative research by, among other things, "forbidding all research with cloned human embryos after the appearance of the so-called 'primitive streak' at about 14 days from its creation." I believe that United Kingdom law also draws the line at 14 days.

- Can you explain the basis of the committee's recommendation?
- Do you believe that there is an "emerging consensus" that DNA regenerative research should be permitted before the two week period but not after?

Questions submitted to Professor Charo by Senator Feinstein

Question 1: The right to make decisions about whether to bear children is a fundamental liberty protected by the Constitution. A federal court has held that the right to make such decisions includes medically assisted reproduction, such as in vitro fertilization and the use of donated embryos [see *Lifchez* v. *Hartigan*, 735 F. Supp. 1361, 1377 (N.D. Ill. 1990)]. I believe that University of Texas Law Professor John A. Robertson has suggested that cloning might be a protected constitutional liberty in some instances.

- Do you believe that cloning is protected by the Constitution? If so, under what circumstances?

Question 2: One of the major arguments put forth by those opposed to DNA regenerative research (also called therapeutic cloning) is the notion of a "slippery slope." According to adherents of this view, if the government banned human reproductive cloning but not DNA regenerative research, it would be extremely difficult to prevent cloned human embryos from ending up being implanted in women.

- How persuasive is this "slippery slope" argument?
- In your view, can the government effectively regulate cloned human embryos? If so, how?
- What lessons have we learned from government's experience with embryos derived from in vitro fertilization?
- How effective has government regulation of these embryos been?

Question 3: One of the witnesses at the hearing, Father FitzGerald, argued that the potential for obtaining benefits from scientific and medical research regardless of how significant such benefits may be or who may stand to be helped by them does not in itself translate into a license to engage in that particular research. However, it is undeniable that the potential benefits of DNA regenerative research must be considered as a strong argument in favor of such research.

- In your view, how should Congress balance the potential benefits of cures and therapies derived from clonal research with any alleged potential harm?
- What principles should frame the debate?

Questions submitted to Mr. Kimbrell by Senator Feinstein

Question 1: As I understand it, there are a number of different methods of mammalian cloning, including (1) molecular cloning, which involves replicating sections of DNA known as genes and has been useful in the production of insulin for diabetes; (2) cellular cloning, which involves duplication of somatic cells and allows scientists to test the impact of medicines without using actual human subjects; (3) blastomere separation, which occurs naturally in the process that results in identical twins but can also be induced by scientists; and (4) somatic cell nuclear transplantation, in which genetic material is removed from a somatic cell of one organism and transferred into the enucleated egg of another organism. And recently researchers have begun using parthenogenesis getting unfertilized eggs to start dividing as if they were embryos which some also consider a form of cloning.

- Do you believe that all forms of mammalian cloning and induced parthenogenesis should be banned, including somatic cell nuclear transfer?
- If so, do you believe that this ban should be permanent or temporary?

Responses of Irving L. Weissman, M.D. to questions submitted by Senator Feinstein

Question 1: As I understand it, nuclear transplantation is a very broad technique that need not involve embryos or even stem cells.

- Could you explain some applications of nuclear transplantation that do not involve embryos or stem cells?

Answer: The term "nuclear transplanation" has been taken as an abbreviation for "nuclear transplantation for the production of stem cells", which itself could be qualified more precisely in the context of the Committee's deliberations to mean

"nuclear transplantation for the production of *human pluripotent* stem cells." In that context it is specified to be a procedure of transplantation of the nucleus of a normal or diseased human body cell into an enucleated human egg for the production of pluripotent stem cell lines, these lines being cell culture derivates from the inner cell mass of blastocysts that result from the procedure. If one takes only the term nuclear transplantation, it could mean any procedure involving the transplantation of the nucleus from any donor cell into an enucleated cell of any type of host cell. By today's technology only the nuclear transplantation of the nucleus into an enucleated egg will allow the production of pluripotent stem cell lines.

Question 2: I know that DNA regenerative research (also called therapeutic cloning) offers enormous potential for providing cures for diseases such as cancer, diabetes, cystic fibrosis, and heart disease as well as conditions such as spinal cord injuries, liver damage, arthritis, and burns.

- Could you explain which diseases and conditions are most likely to be curable or treatable through DNA regenerative research?

Answer: There are at least 4 distinct uses for nuclear transplantation (in your terms DNA regenerative research) that could and should lead to new medical techniques derived form new medical knowledge.

1) To use nuclear transplantation methods to expand the genetic base of human ES lines to be inclusive rather than exclusive. If we assume human ES cells are today limited to the designated approximately 64 human cell lines, and that these derive primarily from *in vitro* fertilization clinic blastocysts, they represent cell lines solely from infertile couples, and these are a small subset of the ethnic, racial, etc. human groupings. As such, any benefits of studying human developmental biology from these lines will exclude most major segments of U.S. society, and of course could be skewed to humans who are infertile. Thus to provide full potential benefits from this research for all subgroups of our society, nuclear transplantation from diverse donors is the most efficient way to address this limitation.

2) To use nuclear transplanation methods to create new human ES lines representing humans who not only have an inherited genetic risk for disease, but who are unlucky enough to get one or more of these diseases. These include people with cardiovascular diseases (stoke, aneurysm, coronary artery disease, etc.); autoimmune diseases such as type I (juvenile) diabetes, rheumatoid artritis, multiple sclerosis, systemic lupus erythematosus, hemolytic anemias, ankylosing spondylitis, etc.; neurodegenerative diseases such as Alzheimer's disease, Lou Gehrig's disease (amyotrophic lateral sclerosis), Huntington;s disease, probably Parkinson's disease, Batten's disease, Tay-Sachs disease, Gaucher's disease, the mental retardation of Down's Syndrome, perhaps schizophrenia, etc.; blood disorders such as sickle cell anemia, thalassemia (Mediterranean forms and Korean forms), etc.; allergic disorders; many if not all cancers; hereditary blindness, hereditary deafness, and many, many more.

3) To use nuclear transplantation methods to produce human lines from the nuclei of cells that underwent somatic (not inherited from parents) mutations as part of the disease process. In these diseases the only body cells that have nuclei that represent the life history of the development of those diseases are the disease cells themselves. these include all cancers, leukemias, and lymphomas, and huntington's disease.

The study if diseases in categories 2) and 3) involves establishment of the cell lines, study of how they make the cells involved in the disease in test tubes (for example, motor nerves and the muscle cells they can innervate in ALS); and transfer of developing cells into the corresponding tissues of newborn or developing immunodeficient animals to understand how disease develops in the context of the native tissues. in all of these cases, if the disease is replicated, one can use the model to test which genes are involved, and which treatments are possible. These treatments could include "therapeutic coloning" (see 4), with dene-corrected cells.

4) To use nuclear transplantation methods to produce human pluripotent stem cell lines from an individual to treat that individual when his/her own cells or organs have been irreversibly damaged (therapeutic cloning or DNA regenerative research, to use your term). As donor and host are closely similar, minimal immunosuppression should be required. Damaged tissues could include liver failure, stroke, anemia, Parkinson's disease, blood vessel repair, etc.

- Has anyone been cured or treated yet through DNA regenerative research? If not, when do you expect this could happen?

Answer: Nuclear transfer to produce human pluripotent stem cell lines is not currently practiced in the U.S. now, largely due to the legal uncertainties and the difficulties in making this potential therapy real. In a mouse model of severe combined immunodeficiency (SCID), the genetic disorder that the "bubble boy" had in Texas, scientists from the Whitehead Institute at the Massachusetts Institute of Technology produced pluripotent stem cell lines with that disorder by nuclear transplantation. They then used gene therapy techniques to correct the genetic defect in the pluripotent cell line, and allowed the cells to become blood-forming cells. These blood-forming cells were modified with another gene to allow them to mature from a primitive stage of blood formation suitable for a fetus only to more adult blood-forming cells suitable for an adult. These adult-type blood-forming cells were transferred to the SCID mouse strain, and low levels of cells yielding protective immunity resulted. This is the first recorded case of "therapeutic cloning" in any species. The lessons learned look applicable to man, with considerable research required.

Question 3: It was reported recently that, in order to produce stem cells, Advanced Cell Technology in Massachusetts has created a monkey embryo through parthenogenesis, that is, without the use of sperm. As I understand it, unlike embryos created from an egg (oocyte) and sperm, parthenogenetic embryos do not go to term if placed in a womb and that any stem cells produced could only be used in the women who produced the eggs.

- Could you explain the difference between somatic cell nuclear transfer to produce stem cells and the parthenogenetic technique used by Advanced Cell Technology?

Answer: In parthenogenesis the egg chromosomes are stimulated to duplicate, bring the DNA level in the cell from half the normal amount to the normal amount. (Usually the sperm provides half and the egg supplies half.) As each egg contains only half the maternal chromosomes, when they are duplicated in parthenogenesis they now have an unique set of genes, not the same as the mother. However, as the mother has 1 copy of each parthenote's genes, an organ or solid tissue (e.g., kidney, liver, skin) stem cell transplant from the parthenote will usually not be seen as foreign by the mother. But because there are an unusual set of immunity cells (natural killer cells) that can reject blood-forming tissue transplants, the mother likely would reject a blood-forming stem cell transplant from the parthenote. Therefore the use of partenogenesis to provide transplants would only be useful for the egg donor, and not in all cases.

F Is it accurate to say that in both somatic cell nuclear transfer and parthenogenesis the egg cell is never fertilized by the sperm?

Yes.

- What is your view about the medical promise of producing stem cells through parthenogensis?

It would have the limited use for therapies described above in Q2P1. As these cells have only half the genetic diversity of the mother, even if the mother had a heritable disease or cancer, her parthenogenetic pluripotent stem cells would almost certainly not contain the full set of genes to be useful for the other 3 objectives of nuclear transplantation research outlined in the answer to Q2.

- Was parthenogenesis to produce stem cells considered by your panel as it was preparing the National Academies report?

Only minimally, as its potential uses were minimal, as described above. It does require a blastocyst intermediate.

Question 4: There has been much talk about whether adult stem cells are as versatile as embryonic stem cells. Some have even said that research with adult stem cells shows that we do not need nuclear transplantation to produce stem cells.

- Based on your panel's analysis of the medical literature, would you agree that adult stem cells demonstrate sufficient potential that it would be appropriate to stop doing nuclear transplantation?

Answer: No. There are no peer-reviewed published reports of adult stem cells that are pluripotent. Usually public policy should only deal with robust phenomena that are independently confirmed. We threrefore have no way to assess the properties of such cells, if they exist. There are many tissue-specific adult stem cells already discovered (e.g., blood-forming, skin, muscle, brain), and pure blood-forming stem cells as well as skin cells enriched in stem cells have been used successfully in therapies. But we have, as yet, no stem cells for pancreatic islets (lost in diabetes), liver, heart, blood vessels, etc. They are the focus of promising research. Most adult stem cells have properties that make them not useful for most of the goals of nuclear transplanation research outlined in the answer to Q2. Specifically, *no adult stem cells exist for goals 1–3* in Q2, and it is as yet unclear whether the full

panoply of adult stem cells will be discovered for all organs and tissues that need external cells for regeneration.

Answer: There have been several claims that stem cells are plastic in their differentiation potential, e.g. in mouse experiments muscle, brain, or fat to blood, blood to muscle, blood to liver, etc. No claims for pluripotent or plastic human stem cells have been published. Recent evidence shows most of these to be contaminating blood-forming stem cells that circulate through all tissues. When the real stem cells from muscle or brain were isolated, they could not make blood. And blood-forming stem cells make little else than blood.

Given the current status of stem cell research (as of March 20, 2002), banning nuclear transplantation to produce human pluripotent stem cells will not result in comparable research with adult stem cells, and so for scientific and medical reasons *both* kinds of research deserve focus and funding. Those responsible for banning such research are surely responsible for the lives lost that could have benefited from such research done in a timely fashion.

I hope this aids you in your deliberations.

Responses of Hank Greely to questions submitted by Senator Feinstein

Answer 1: The Commerce Clause

Predicting the Supreme Court's position on the sweep of the Commerce Clause seems impossible to do with any confidence. Imagine a scenario where the patients, doctors, and most of the equipment for human reproductive cloning all came from within one state. This is not unlikely; human reproductive cloning, if possible at all, would seem to require little equipment. Assume the clinic avoids, as far as possible, any interstate advertising or even the use of instrumentalities of interstate commerce like the mails or the telephone. Add the fact that human reproduction hasn't usually been viewed as an item in interstate commerce. And, just to make the scenario as extreme as possible, assume further that the cloning is attempted without seeking a profit—perhaps even by a non-profit organization.

Under those circumstances, I can imagine a court, struggling with Lopez and Morrison, concluding that the Commerce Clause does not stretch to that behavior and I could make that argument with a straight face. On the other hand, I think it is more likely a court would hold the opposite. Although the conventional method of reproduction has not been commercial, *in vitro* fertilization and other forms of assisted reproduction are most certainly been commercial—and a thriving commerce at that. Both Lopez and Morrison involved activities that were not themselves part of an ongoing business, but that were claimed to have effects on interstate commerce. The problem there may have been as much "commerce" as "interstate." In the case of reproduction—seems clear in our society. That makes me think that a court probably would distinguish Lopez and Morrison and hold such a statute constitutional—but I would not predict that outcome with great confidence.

(Of course, human non-reproductive cloning, aimed at medical treatment, would seem much easier to find a part of interstate commerce.)

Answer 2: FDA Jurisdiction

a. Over Human Reproductive Cloning

I do not think the Food and Drug Administration currently has statutory jurisdiction over human reproductive cloning. I generally agree with the conclusions on statutory jurisdiction of two law review articles on this subject (although I think the Price article is generally somewhat better).

Elizabeth C. Price, Does the FDA Have Authority to Regulate Human Cloning, 11 Harv. J.L. & Tech. 619 (1998);

Gregory J. Rokosz, Is the Reach of FDA Authority Too Far a Stretch? 30 Seton Hall L. Rev. 464 (2000)

The articles focus on two Points: for the FDA to have jurisdiction, there must be a drug, device, or biological. This must be an article, product, or similar noun, that is either a) applicable to the prevention, treatment, or cure of a disease or condition of human beings (to meet the definition of a biologic under the Public Health Service Act), or b) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man [or] to affect the structure or any function of the body of man (to meet the definition of drug under the Federal Food, Drug, and Cosmetic Act).

It is quite possible that a court would find that a human embryo is *not* an article or product. It seems to me even more likely that a court would find that reproductive cloning (at least where the people involved were otherwise fertile) would not

meet the second part of the definitions—it would neither be for the prevention, treatment, or cure of a disease or condition, nor "to affect the structure or any function of the body of man."

Of course, the courts give substantial deference to agencies in interpreting their empowering statutes. On the other hand, the Supreme Court has recently struck down FDA regulation of cigarettes (which common sense would seem to group as a device for delivering nicotine, an addictive drug). The jurisdiction of the FDA over such cloning under existing statutory authority can only be said to be uncertain.

b. Over DNA Regenerative Research

It seems clear that cells (or other substances) produced from human non-reproductive cloning would be biologics under the terms of the Public Health Service Act and thus subject to FDA jurisdiction as well as, most likely, drugs under the FFDCA. Note, though, that this jurisdiction is only triggered by their use in human subjects, either experimentally or in human subjects, either experimentally or in treatment. Research short of human trials would not, I believe, be subject to FDA regulation.

c. Has anyone sought FDA approval for human reproductive cloning?

Not as far as I know.

Answer 3: Banning Versus Regulating

a. Precedent for completely banning an area of research against the wishes of the scientific, medical, and patients advocacy communities?

No. The closest I can come at the federal level is various restrictions on nuclear fission and fusion information after World War II that had the effect of classifying all weapons-related research and concentrating it in the federal government. I suppose bans on chemical and biological weapons also ban some research on those weapons, even under federal government auspices. In neither of those examples was there public support for such research. Several states have laws banning some forms of human embryo research; again, in those states, at the time the laws were passed (usually in the early 1980s), such research had no substantial constituency.

b. It is generally appropriate—and desirable—for the law to discriminate between proper and improper applications of a technique rather than completely ban research into the technique?

Yes, when the applications can be sufficiently separated. I believe that non-reproductive cloning, a proper application, can be separated entirely from reproductive cloning, an improper application.

Answer 4: The Primitive Streak

a. The basis for the California recommendation

Based on scientific evidence, the development of a "primitive streak" seems to mark the first appearance of any precursor to the nervous system. Although the primitive streak itself does not seem to *be* a nervous system, it is a visible and conservative marker that shows that before its formation, the embryo seems incapable of experiencing any sensation.

b. Do I believe there is an emerging consensus for a two week research period for DNA regenerative research?

Yes. The United Kingdom as well as various US advisory bodies have recommended the two week period.

Responses of R. Alta Charo to questions submitted by Senator Feinstein

Answer: Your first question concerns my opinion on whether there is a fundamental right to use reproductive cloning. I will answer that query in this email, and will send answers to the other questions in a follow-up email this weekend.

Your question first asserts that *Lifchez* v. *Hartigan* (735 F. Supp. 1361, N.D. Ill. 1990) holds that the right to make decisions concerning whether to bear children includes the right to use IVF and donated gamete. The question then asks whether I believe that cloning is protected by the Constitution.

First, I do not agree with your characterization of the Lifchez case. Lifchez concerned an Illinois statute that attempted to ban fetal experimentation. The statute specifically stated that it was not intended to prohibit IVF, and thus the Court's review of the statute never required it to reach the question of whether Illinois might constitutionally prohibit IVF. Its suggestion that the reproductive privacy cases suggest a fundamental right to use technologies that bring about pregnancy is not a holding, merely dicta.

Further, this is no way clarified the view of this federal court, let alone the view of other federal courts, on whether the right to reproductive privacy also includes a right to make decisions about the kinds of children one might have (via gamete selection, embryo selection, or in the future, gamete or embryo genetic alteration), a right to use donated gametes, or a right to purchase and sell gametes. None of these medical and social developments are central to the issue of whether or not to become a parent.

Decisions about gamete and embryo selection concern the scope of parental entitlement to shape the parental experience, by influencing the kinds of children who will be conceived or brought to term. And use of donated or purchased gametes by an individual does not let him or her reproduce genetically, thus, again, going beyond the scope of prior decisions concerning the right to "beget" a child. (Arguably, the use of donated or purchased ova does, however, allow a woman to "bear" a child even though she has no usable ova of her own, and thus this may possibly fall squarely within prior cases; those cases, however, were written long before it was possible to separate "bearing" from "begetting" in the context of female reproduction, so the intent of the authors of those legal opinions cannot be determined with any precision.)

More to the point, you ask if I believe cloning is protected by the Constitution.

Before responding, it is essential to note that whether or not cloning is protected by the Constitution can be determined only by the Supreme Court. Until it has ruled, the issue is unresolved. I would predict, however, that if the Supreme Court were presented with this question, it would rule that reproductive privacy does not extend to cloning.

First, from a genetic point of view, the donor of a somatic cell for cloning will not be conceiving a child but will be conceiving a genetic twin. There are no cases that suggest a fundamental right to have a sibling. While this may seem semantic or genetic sleight-of-hand, I believe it is in fact a substantive point, as the earliest cases, such as *Skinner* v. *Oklahoma* [316 U.S. 435 (1942)], were clearly based on a model of vertical genetic transmission across genetic generations. This, in turn, appeared to reflect a belief in the impermissibility of government interference in an activity that is at the center of both personal and human experience throughout human history. As cloning represents something sui generis as a form of family formation, it would be wrong to assume that these early cases would necessarily be extended to apply to this new technology.

Speaking more broadly, to the spirit of the reproductive privacy cases, I believe one finds distinctly different strands of reasoning, only some of which would tend to support a fundamental right to use cloning as a form of human reproduction. Further, the one strand of reasoning that would provide such support, to wit, a liberty interest in psychological autonomy, is the very same strand of reasoning that the Supreme Court has declined to interpret broadly.

Various aspects of this reproductive privacy right have been articulated in a number of landmark Supreme Court cases, including *Griswold* v. *Connecticut* [381 U.S. 479 (1965) (striking down statute which forbid use of contraceptives on grounds that statute invaded zone of privacy surrounding marriage relationship)]; *Eisenstadt* v. *Baird* [405 U.S. 438 (1972) (striking down statute forbidding distribution of contraceptives to unmarried persons on equal protection grounds, but observing in dicta that: "If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.")]; *Roe* v. *Wade* [410 U.S. 113 (1973) (establishing unrestricted right to an abortion in first trimester)]; and Planned Parenthood of *Missouri* v. *Danforth* [428 U.S. 52 (1976) (striking down provisions of abortion statute requiring spousal consent and parental consent)]. In *Carey* v. *Population Services International*, 431 U.S. 678 (1977), the Court reviewed its prior privacy cases and declared that "The decision whether or not to beget or bear a child is at the very heart of this cluster of constitutionally protected choices."

What is striking about many of the early contraception cases, which laid the ground for the subsequent abortion cases, is their emphasis on the marital relationship. It was the intrusion of government policy into that marital relationship, and by extension, into the marital bed (by virtue of making sexual relations between husband and wife difficult or unpleasant due to the need to avoid conception without the benefit of contraceptives), that animates the visceral reaction that these policies are an intrusion on "privacy."

In Eisenstadt, this concern about marital privacy is combined with the *Skinner* v. *Oklahoma* concern about impermissible intrusion into the realm of an individual's reproductive capacities, resulting in an extension of the right to contraception to unmarried individuals. It is important to note that, in Skinner, the issue concerned

the bodily integrity of felons who were faced with forcible sterilization. The Eisenstadt case, however, necessarily goes beyond this concern with bodily integrity when it extends the right to contraception to men as well as women. For women, who are at risk of pregnancy, prohibitions on contraception threaten their interest in controlling the state of their bodies, as well as their psychological interest in freely deciding whether to become a parent. For men, however, the interest is purely psychological. Thus, as of 1972, it would appear that the Supreme Court was working toward an understanding of reproductive privacy that extended to concerns about psychological autonomy, a form of liberty that might support a claim of constitutional protection for the use of cloning techniques to produce a child.

But subsequent abortion and right-to-die cases have backed away from this regard for psychological autonomy and have emphasized instead either gender equality or the liberty interest in bodily autonomy. While Justice O'Connor's opinion in *Pennsylvania* v. *Casey* does speak to the notion that "at the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life, " her subsequent statements reflect a concern more for gender equality in society than for unfettered personal choice in all matters touching, no matter how remotely, on human reproduction. ("The mother who carries a child to full term is subject to anxieties, to physical constraints, to pain that only she must bear. That these sacrifices have from the beginning of the human race been endured by woman with a pride that ennobles her in the eyes of others and gives to the infant a bond of love cannot alone be grounds for the State to insist she make the sacrifice. Her suffering is too intimate and personal for the State to insist, without more, upon its own vision of the woman's role, however dominant that vision has been in the course of our history and our culture. The destiny of the woman must be shaped to a large extent on her own conception of her spiritual imperatives and her place in society.")

The dissenters in that case launched a pointed attack, too, on the notion that fundamental rights to privacy bespeak unfettered liberty of choice in all personal matters. In a scathing dissent, Justice Scalia wrote: "The best the Court can do to explain how it is that the word "liberty" must be thought to include the right to destroy human fetuses is to rattle off a collection of adjectives that simply decorate a value judgment and conceal a political choice. The right to abort, we are told, inheres in "liberty" because it is among "a person's most basic decisions," it involves a "most intimate and personal choice," it is "central to personal dignity and autonomy," it "originates within the zone of conscience and belief," it is "too intimate and personal" for state interference, it reflects "intimate views" of a "deep, personal character," it involves "intimate relationships" and notions of "personal autonomy and bodily integrity," and it concerns a particularly "'important decision." But it is obvious to anyone applying "reasoned judgment" that the same adjectives can be applied to many forms of conduct that this Court has held are not entitled to constitutional protection—because, like abortion, they are forms of conduct that have long been criminalized in American society. Those adjectives might be applied, for example, to homosexual sodomy, polygamy, adult incest, and suicide, all of which are equally "intimate" and "deeply personal" decisions involving "personal autonomy and bodily integrity," and all of which can constitutionally be proscribed because it is our unquestionable constitutional tradition that they are proscribable." [citations omitted].

Indeed, the Supreme Court has rejected the notion that a psychological autonomy embedded in fundamental liberty interests extends to choices about sexual practices such as consensual anal intercourse between men [*Bowers* v. *Hardwick*, 478 U.S. 186 (1986)]. And in Washington vs. Glucksberg, 521 U.S. 702 (1997), the Supreme Court rejected the argument that psychological autonomy extends to a right to commit suicide, allowing only that when bodily integrity is threatened by unwanted medical intervention, there is a fundamental right to refuse treatment, even at the risk of death. In these cases, which concern sexuality and dying, the Court has declined to announce that fundamental liberty interests extend to all aspects of defining one's self and controlling one's future, and instead has emphasized repeatedly that only those interests that are considered to be central to ordered liberty and are historically grounded in common practice will be viewed as fundamental.

Thus, cloning as an exercise of psychological autonomy is unlikely to receive the protection of fundamental rights analysis, and as prohibitions on cloning neither invade the body nor tread on a historically common practice, it is unlikely to gain fundamental rights protection on either of those grounds either. Only if it is viewed as closely connected to the choice to bear or beget a child is there any significant chance that it would be considered protected as a fundamental right. And this, of course, returns the discussion full circle to the question of whether it should be viewed as a variation on human reproduction or as something wholly new unto

itself. It is my best guess that the Supreme Court would view cloning as something wholly new, despite the fact that it could be used as a substitute for sexual reproduction through intercourse or even reproduction through the use of laboratory techniques to achieve conception by male-female gamete combinations in a laboratory dish.

On a final note, I would like to mention that this analysis of Supreme Court decisions does not reflect my personal preferences concerning the relationship between liberty and personal choices. I must confess that on matters concerning sexuality, marriage, family formation, reproduction, dying and death, I would prefer that the Supreme Court adopt an expansive vision, so that any state encroachments on these choices would be impermissible absent a compelling state purpose. I believe that this is not only politically preferable, but also that it is a defensible interpretation of these cases, all of which acknowledge the importance of liberty interests that go far beyond bodily autonomy. Nonetheless, I believe that a fair reading of the cases and the jurisprudential theories favored by the current Supreme Court make it unlikely that a congressional ban on reproductive cloning would be struck down as undue interference in an individual's fundamental right to reproductive and familial privacy.

Answer: Your second question concerns slippery slope arguments and the effectiveness of government regulation.

I do not find the slippery slope arguments persuasive, because taken to their most logical conclusion, they would argue most strenuously for a ban on in vitro fertilization, as it is IVF that allows us to maintain and manipulate embryos outside the body. To the extent that slippery slope concerns focus on genetic screening and genetic engineering, it is IVF that is the major avenue toward such manipulations, not cloning, but it is cloning, and not IVF, that would be banned.

More profoundly, slippery slope arguments are by their nature simplistic. In the late 1970s, when concerns were raised about the power of recombinant DNA technology, many people called for an indefinite moratorium on use of the technique. If that moratorium had been adopted, the entire biotechnology industry would have been stopped in its tracks.

Slippery slope arguments are for the timid. The courageous recognize the complexity of technology, appreciate that it almost always offers both good and bad applications, and fight through the uncertainty, confusion and fear in order to develop nuanced policy that salvages the good while guarding against the bad.

Fortunately, there are some governmental mechanisms already available to do just that.

FDA has the authority to regulate medical products, including biological products, drugs, and devices. The use of cloning technology to clone an embryo for therapeutic purposes would be subject to both the biologics provisions of the Public Health Service (PHS) Act and the drug and device provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act.

In October 1993, FDA published a notice in the Federal Register, 58 FR 53248 (October 14, 1993), clarifying the application of FDA's statutory authorities to human somatic cell therapy and gene therapy products. The notice stated that somatic cell therapy products are biological products under the PHS Act as well as drugs under the FD&C Act and are subject to investigational new drug (IND) application requirements. In the notice, FDA defined somatic cell therapy products as "autologous (i.e., self), allogeneic (i.e., intra-species), or xenogeneic (i.e. inter-species) cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics ex vivo to be administered to humans . . .."

Subsequently, in March 1997, the Agency proposed a more comprehensive regulatory approach for cellular and tissue-based products that includes somatic cell therapy products (62 FR 9721 March 4, 1997). In January 2001, after issuing and reviewing comments on a proposed rule, FDA issued a final rule that establishes the regulatory approach for human cells, tissue, cellular and tissue-based products and requires establishments to register with the Agency and list their products.

Thus, clinical research using cloning technology to clone an embryo is subject to FDA regulation under the PHS Act and the FD&C Act. Before such research could begin, the researcher must submit an IND request to FDA, which FDA would review to determine if such research could proceed.

A researcher may not conduct a clinical study unless an IND is in effect. Sponsors are required to submit to FDA an IND describing the proposed research plan and other pertinent scientific information, to obtain authorization from an independent Institutional Review Board, and to obtain the informed consent from all participating individuals. The sponsor must wait at least 30 days after submitting its proposal to FDA before beginning any study. During this time, FDA may take action

to prohibit a sponsor from conducting the study by placing the study on "clinical hold" for a variety of reasons, including but not limited to, situations where the Agency finds that "human subjects are or would be exposed to unreasonable and significant risk of illness or injury" or that "the IND does not contain sufficient information required. . .to assess the risks to subjects of the proposed studies." (Title 21, Code of Federal Regulations 312.42.)

On the basis of these powers, FDA could withhold approval of studies using cloned embryos if those studies did not ensure that risks to egg donors were acceptable, that egg donation was informed and voluntary, and that procedures were in place to track the cloned embryos so that they could not be diverted to reproductive or other unauthorized purposes.

Government regulation would, of course, be enhanced if federal funding were available to a broader range of embryo research projects. It is the absence of federal funding for embryo research throughout the 1980s that accounts for the virtually unregulated and explosive growth of clinical applications of IVF and other reproductive technologies. Federal funding in the 1980s would have given researchers an incentive to proceed in a more measured fashion, and would have permitted diffusion of the techniques to be accompanied by a set of social norms represented in the federal funding restrictions. Instead, in the absence of federal funding, we observed rapid expansion of medical indications for reproductive technologies and a relative dearth of controlled studies on the safety and efficacy of the techniques. It is fortunate that to date there have been so few medical problems associated with the techniques, but government funding would have ensured that this result was due to planning rather than luck.

SUBMISSIONS FOR THE RECORD

Statement of The American Society for Cell Biology

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, and 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 gnome sequence. Similarly, Cloning DNA is critical to fight against bioterrorism and has already been

used in the determination of the entire gnome 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.

Statement of Hon. Sam Brownback, a U.S. Senator from the State of Kansas

Thank you.

First, I would like to thank in particular, the Chairperson, Senator Feinstein for calling this hearing. I have nothing but the greatest respect for Senator Feinstein. Senator Feinstein and I have recently had the opportunity to work very closely together to begin the process of building a health care infrastructure that we hope will eventually lead the way in finding a cure for cancer and also to ensure that Congress commits the resources to finding that cure.

No matter what disagreement may exist between the members of this committee, those who are here to testify, or the public at large on the issue of cloning I do not believe there is any disagreement that we must all work hard to find a cure for the diseases that plague humanity.

I look forward to the testimony that is about to be presented.

The Chairperson and I have very different approaches to the very important issue of human cloning.

As most of you know, I am sponsoring the Human Cloning Prohibition Act of 2001 which differs from the Chairperson's bill in several important ways. And I am proud to announce today, at this hearing, that Senator Mary Landrieu has decided to join me, as the Chief Democrat sponsor of my legislation to ban all forms of human cloning.

Senator Landrieu and I believe it is vital that the Senate fully consider this issue. The House of Representatives has spoken, and so has the President now the Senate must follow suit.

The issue of human cloning demands the public's attention, in part, because it revolves around the meaning of human dignity and the inalienable rights that belong to every person.

Some will argue that the issue simply needs to be studied before any research begins, or that cloning be allowed to proceed in a limited fashion such a notion clearly does not respect the new life that is created through human cloning.

Some do not want a permanent ban, as you will hear today they want a limited ban on "reproductive" cloning but not on so-called "therapeutic," research or destructive cloning.

The notion that human cloning can be "therapeutic" is both misleading and disingenuous.

"Therapeutic" cloning, as some of the proponents of cloning in the biotech industry refer to it, is really the process by which an embryo is specially created for the directly intended purpose of subsequently killing it for its cells. Some proponents of human cloning claim that an embryo created in this manner will have cells that are a genetic match to the patient being cloned, and thus the cells would not be rejected by the patient's immune system.

But to describe the process of destructive human cloning as "therapeutic," when the intent is to create a new human life that is destined for its destruction, is deeply misleading.

The act of cloning a human being for the purposes of study, to make "designer" replacement cells is wrong. It makes a child into a piece of property. The child's sole purpose in creation is to be destroyed for someone else's benefit. This is no way to operate in a civil society, especially the United States, which leads the world in human rights concerns.

All human cloning is reproductive in that it creates new human life. What is done with that life is what the Feinstein bill mandates the Feinstein bill mandates that in most cases that life must be destroyed for the benefit of others.

I do not believe that we should create life just to destroy it yet that is exactly what is being proposed by those who support cloning in limited circumstances; however they might describe those circumstances whether it's nuclear transplantation, "therapeutic" cloning, therapeutic cellular transfer or whatever the latest euphemism. Cloning is wrong, period.

The bill being sponsored by the Chairperson calls for the creation of human embryos for the purposes of their immediate destruction.

Among the obvious concerns that I have just mentioned, I have other concerns, which I hope some of the witnesses today will be able to discuss.

The first is that the Feinstein bill seems to put law enforcement in a rather difficult position that of having to police intentions, rather than actions in particular, in those cases where actions are cloaked under the veil of doctor-patient confidentiality.

I also have some serious concerns regarding the excessively broad nature of the definitions sections which would grant exclusions that I believe would lead directly to reproductive cloning.

Finally, I would like to comments from a story that appeared in New Scientist, "A stem cell has been found in adults that can turn into every single tissue in the body. It might turn out to be the most important cell ever discovered.

"Until now, only stem cells from early embryos were thought to have such properties. If the finding is confirmed, it will mean cells from your own body could one day be turned into all sorts of perfectly matched replacement tissues and even organs.

"If so, there would be no need to resort to therapeutic cloning - cloning people to get matching stem cells from the resulting embryos. Nor would you have to genetically engineer embryonic stem cells (ESCs) to create a 'one cell fits all' line that does not trigger immune rejection. The discovery of such versatile adult stem cells will also fan the debate about whether embryonic stem cell research is justified."

Science continues to prove that destructive embryonic stem cell research and so-called, "therapeutic cloning" is unnecessary.

As this debate continues, we need to constantly examine and re-examine the scientific facts with a fully-informed moral conscience.

I hope that we can have a full and healthy exchange on these, and related issues, and I welcome the panel of witnesses.

Statement of Hon. Maria Cantwell, a U.S. Senator from the State of Washington

Thank you Madam Chairwoman. I am pleased that you have convened this hearing today to give all of us the opportunity to learn more about the human cloning debate and its implications for medical research.

Every day in this country we learn of exciting new scientific discoveries that hold the promise of dramatically improving both our daily lives and future medical treatments. There is no doubt that as science advances, our country must continually re-evaluate and reaffirm the legal and ethical guidelines surrounding these advances. As science on cloning and stem cell research develops, some have focused on the possibility, however distant, that this new knowledge will lead to the creation of human clones.

Last November's announcement of the privately funded cloning of a human embryo for therapeutic purposes by Advanced Cell Technology of Worcester, Massachusetts has refocused attention on the ethical concerns of this emerging science. Researchers described their work as an important step toward producing stem cell as treatments for diabetes, heart disease, spinal injuries, and many other ailments. But the value of this achievement must be balanced against the ethics of the means to achieve it.

In fact, the scientific community has spoken clearly, and often, that the pursuit of human clones is unwarranted and probably beyond our current technological or biomedical capabilities. Furthermore, as some of today's witnesses will describe, such reproductive cloning is unsafe and ultimately likely to fail. But scientists have also made it quite clear that there are ethical paths of research into therapeutic cloning for legitimate biomedical reasons that we should not close with far-reaching legislation.

While I strongly oppose cloning for reproductive purposes, I do support therapeutic cloning and believe that imposing absolute proscriptions on this research would unnecessarily stop valuable biomedical research across the country. Finally,

I am especially concerned that unilateral bans could be read to prohibit DNA replication, which is necessary for important biotechnology research.

Thank you, Madame Chairwoman for convening this hearing so that we can learn more about this issue. I look forward to the testimony of our distinguished panelists.

Statement in Support of Legislation to Prohibit Cloning

We, the undersigned, support legislation to prohibit the cloning of human embryos for either medical experimentation or for giving birth to a human being. Although we may differ in our views regarding reproductive issues, we agree that a human embryo should not be cloned for the specific intention of using it as a "resource" for medical experimentation or for producing a baby. Moreover, we believe that the market for women's eggs that would be created by this research will provide unethical incentives for women to undergo health-threatening hormone treatment and surgery.

We are also concerned about the increasing bio-industrialization of life by the scientific community and life science companies and shocked and dismayed that clonal human embryos have been patented and declared to be human "inventions". We oppose efforts to reduce human life and its various parts and processes to the status of mere research tools, manufactured products, commodities and utilities. We are also deeply troubled that at present there is no legal or ethical framework in place to regulate the accelerated commercial exploitation of this research.

We are mindful of the tragic history of social eugenics movements in the first half of the 20th century, and are united in our opposition to any use of biotechnology for a commercial eugenics movement in the 21st century.

**Title and Organization Listed for Identification Purposes Only

First Name	Last Name	Title	Organization
Stanley	Aronowitz		The Graduate Center, CUNY
Benjamin	Barber	Kekst Professor of Civil Society	University of Maryland, Democracy Collaborative
Susan E.	Bell	A. Myrick Freeman Professor of Social Sciences	Bowdoin College - Dept of Sociology and Anthropology
Philip L.	Bereano		University of Washington, Dept of Technical Communication
Wendell	Berry		
Rajani	Bhatia	Coordinator	Committee on Women, Population and the Environment
Norman	Birnbaum	Professor Emeritus	Georgetown University
Madeline	Boscoe		Canadian Women's Health Network
Fritjof	Capra	Director	Center for Ecoliteracy
Erwin	Chargaff	Professor Emeritus of Biochemistry	Columbia University
Harvey	Cox	Professor of Divinity	Harvard University
Phyllis	Creighton	Research Associate, Faculty of Divinity	Trinity College, University of Toronto
Irene W.	Crowe	President	Pettus Crowe Foundation
Herman	Daly	Professor	University of Maryland
Alice J.	Dan	Director, Center for Research on Women and Gender; Professor, College of Nursing and School of Public Health	University of Illinois at Chicago
Kristin	Dawkins	Vice President	Institute for Agriculture and Trade Policy
Margrit	Eichler	Director, Institute for Women's Studies and Gender Studies	New College - University of Toronto
Matthew	Fox	President	University of Creation Spiritual
Elizabeth	Fox-Genovese	Eleonore Raoul Professor of the Humanities	Emory University
Eugene D.	Genovese		
Todd	Gitlin	Professor of Culture, Journalism and Sociology	New York University
Donna	Haraway	Professor	University of California at Santa Cruz

**Title and Organization Listed for Identification Purposes Only

First Name	Last Name	Title	Organization
Debra	Harry	Executive Director	Indigenous Peoples Council on Biocolonialism
Paul	Hawken	Director	Natural Capital Institute
Hazel	Henderson	Author	
Martha R.	Herbert	Pediatric Neurologist	Massachusetts Gen Hospital; Harvard Medical School
Ruth	Hubbard	Professor Emeritus	Harvard University
Deborah	Kaplan	Executive Director	World Institute on Disability
Anne S.	Kasper, PhD	First Chair, Board of Directors	National Women's Health Network
Naomi	Klein	Journalist and Author "No Logo"	
David	Korten	President	People-Centered Development Forum
Sheldon	Krimsky	Professor	Tufts University-Urban and Environmental Policy
Michael	Lerner	Editor	Tikkun Magazine
Judith	Levine	Author and Activist	
Abby	Lippman	Professor	McGill University
Norman	Mailer	Writer	
Jerry	Mander	President	International Forum on Globalization
Charles	Margulis	Greenpeace Genetic Engineering Campaign	Greenpeace
Jacob	Needleman	Professor of Philosophy	San Francisco State University
Stuart	Newman	Professor of Cell Biology and Anatomy	New York Medical College
Rina	Nissim	Naturopath and Author	
David	Noble	Professor of History	York University
Judy	Norsigian	Executive Director	Boston Women's Health Book Collective
Cheri	Pies, MSW DrPH	Associate Dean for Student Affairs	University of California, Berkeley
Barbara	Pillsbury, PhD	Vice President	International Health & Development Associates
Marcus	Raskin	Co-founder of Institute for Policy Studies	Institute for Policy Studies
Susan M.	Reverby	Professor of Women's Studies	Wellesley College
Jeremy	Rifkin	President	Foundation on Economic Trends
Mark	Ritchie	President	Institute for Agriculture & Trade Policy

**Title and Organization Listed for Identification Purposes Only

First Name	Last Name	Title	Organization
Theodore	Roszak	Professor of History	California State University, Hayward
Margie	Schaps	Executive Director	Illinois Women's Health Coalition
Juliet	Schor	Professor of Sociology	Boston College
Lillian	Shirley	Director	Multnomah County Health Department
Evelyne	Shuster, PhD	Board Member of Global Lawyers and Physicians	University of Pennsylvania
Huston	Smith	Professor	Syracuse University
Wesley J.	Smith	Author / Consumer Advocate	
Margaret O'Brien	Steinfels	Editor	Commonweal
Maureen	Sullivan	Assistant Professor, Department of Sociology	Northern Illinois University
Marty	Teitel, PhD	President	Council for Responsible Genetics
Nancy M.	Theriot	Professor and Chairperson, Women's Studies	University of Louisville
Leonore	Tiefer, PhD	Clin Assoc Prof of Psychiatry	New York University School of Medicine
Maria Isabel Ibarrola	Uriarte	General Coordinator	CIDHAL, A. C.
Judy	Wicks	President	White Dog Café
Patricia	Williams		
Susan	Yanow	Director	Abortion Access Project
Quentin D.	Young, MD	Former President of the American Public Health Association	American Public Health Association
Howard	Zinn, PhD		

**Title and Organization Listed for Identification Purposes Only

Article submitted by Jeffrey P. Kahn, Ph.D., M.P.H., Director, Center for Bioethics, University of Minnesota

PRINTED BY CNN—ON THE PATH TO CLONING?—NOVEMBER 26, 2001

CLONING IS MAKING ITS WAY BACK INTO THE NEWS, WITH ANNOUNCEMENTS BY A MASSACHUSETTS BIOTECHNOLOGY COMPANY, ADVANCED CELL TECHNOLOGY.

ACT claims it has created "normal" cows through cloning and is making public the results of its successful human embryo cloning effort—and the "recipe" for creating cloned embryos. The company says it created the clones for research into how it might produce stem cells for therapeutic purposes, and has no intention of allowing any of the embryos to be implanted into a woman's womb to create a pregnancy.

But the announcement of a successfully cloned human embryo, even for research purposes, rekindles the fear that cloning identical copies of humans cannot be far off. The technical reality is still a distant prospect but the successful cloning of embryos is another step along the path: What are the appropriate limits on stem cell research and the application of cloning technologies?

THERAPEUTIC VERSUS REPRODUCTIVE CLONING

ACTs research focuses on so-called therapeutic cloning, where a cloned embryo is made using the DNA of a patient who could benefit from a stem cell transplant. The cloned embryo would then be allowed to divide only a few times, after which the embryonic stem cells would be collected and used to grow genetically- matched tissues or specific cell type needed to treat the same patient.

Cloning embryos for their stem cells is controversial for two reasons.

For many people the intention for which embryos are created is critically important in thinking about the ethics of their use. For them, using embryos that were creating in fertility clinics—originally intended for use in reproduction—is more acceptable than creating embryos expressly for the purpose of research. In this view, creating embryos expressly for research purposes does not treat them with adequate respect. But for others, the moral costs of creating early stage embryos exclusively for research purposes are outweighed by the promise of significant medical benefits.

While therapeutic cloning is morally very different from trying to create an identical copy of a human through reproductive cloning, the newly published techniques used to create the embryos would be exactly the same. But instead of collecting stem cells, doctors would place the cloned embryo in a woman's uterus in the hope that it would result in a pregnancy and the birth of a cloned baby. For some, this implies that therapeutic cloning will inevitably lead to reproductive cloning.

1STOPPING THE SLIPPERY SLOPE

If we believe that the benefits of therapeutic cloning outweigh its moral costs, how can we prevent the same technology being used to clone humans? As is the case for many medical technologies, it is not cloning techniques that are unethical, but some of their potential applications. For example, we reject the transplant of organs from executed prisoners, but we don't prevent it by banning, organ transplantation. The challenge for stem cell research policies is to create appropriate parameters to allow its benefits while preventing abuses or unethical applications.

The Bush administration had an important opportunity to set federal policy when it considered whether to allow funding for stem cell research, and if so, with what limitations.

Such decisions often have far-reaching implications—even though they technically apply only to publicly funded research, they tend to set the standard for practice in both publicly- and privately-funded research. By limiting funding to only those cell lines that existed as of August 2001, the administration was silent about what rules or parameters ought apply to the creation of embryos—whether by in vitro fertilization or cloning technologies—leaving a gaping policy vacuum.

We're long overdue for a reasoned public debate on how far stem cell research ought to go, and how to limit the creation of embryos to ways that our society deems acceptable.

If we want to realize the benefits of therapeutic cloning but prevent reproductive clones, then we'll have to level serious penalties against anyone who allows cloned embryos to develop past a certain point, or to be implanted in a woman's uterus. This could include everything from harsh fines to long prison sentences, or both.

There is every reason to think we can distinguish therapeutic from reproductive cloning and create policies that make the distinction stick. Clearly the science will move forward, but with no obvious brakes or steering. A workable policy is key to determining how far we go and how fast we get there.

Statement of Coalition for the Advancement of Medical Research Position Statement on Somatic Cell Nuclear Transfer

("THERAPEUTIC CLONING ")

The Coalition for the Advancement of Medical Research (CAMR) supports efforts to prohibit human reproductive cloning while protecting important areas of medical research, including stem cell research.

Somatic cell nuclear transfer (SCNT), commonly referred to as therapeutic cloning, may prove to be a vital tool in allowing scientists to fully develop the promise of stem cell research. SCNT involves the use of a donor's unfertilized egg and a patient's own cells. The research could allow a patient's own genetic material to be used to develop stem cell therapies specifically tailored to that individual's medical condition, thus not triggering an immune rejection response. In other words, using SCNT could repair patients with their own cells.

Given the scientific potential in this area, CAMR strongly opposes any legislative or regulatory action that would ban research related to SCNT. This would include criminalizing the research or the researchers, and prohibiting the importation of therapies derived from SCNT in other countries.

The Coalition for the Advancement of Medical Research is comprised of universities, scientific and academic societies, patients' organizations, and other entities that are devoted to supporting stem cell research.

COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH MEMBERS

ALS Association
American Association of Neurological Surgeon/ Congress of Neurological Surgeons
American College of Obstetricians and Gynecologists
American Diabetes Association
American Foundation for AIDS Research (AMFAR)
American Infertility Association
American Medical Association
American Pediatric Society
American Society for Cell Biology
American Society for Microbiology
American Society for Reproductive Medicine
American Society of Hematology
Association of American Medical Colleges
Association of American Universities
Association of Medical School Pediatric Department Chairs
Association for Research in Vision and Ophthalmology
Association of Reproductive Health Professionals
Biotechnology Industry Organization
Canavan Research Illinois
Cancer Research Foundation of America
Cedars-Sinai Health System
Children's Neurobiological Solutions
Christopher Reeve Paralysis Foundation
Coalition of Patient Advocates for Skin Disease Research
Columbia University
Duke University Medical Center
Genetic Alliance
Hadassah
Harvard University
International Foundation for Anticancer Drug Discovery (IFADD)
International Longevity Center—USA
Jeffrey Modell Foundation
Johns Hopkins Medicine
Juvenile Diabetes Research Foundation (JDRF)
Steven and Michele Kirsch Foundation
Lymphoma Research Foundation of America
Monash University
National Association for Biomedical Research
National Association of State Universities and Land-Grant Colleges
National Coalition for Cancer Research (NCCR)
National Coalition for Cancer Survivorship
National Council on Spinal Cord Injury
National Health Council

Parents of Infants and Children with Kernicterus (PICK)
Parkinson's Action Network
Project A.L.S.
Research ! America
Resolve: The National Infertility Association
Rett Syndrome Research Foundation
Society for Pediatric Research
Society for Women's Health Research
Stanford University
Tuberous Sclerosis Alliance
University of California System
University of Rochester Medical Center
University of Wisconsin-Madison
Washington University in St. Louis
WiCell Research Institution/ Wisconsin Alumni Research Foundation
Wisconsin Association for Biomedical Research and Education

Statement of Hon. Richard Durbin, a U.S. Senator from the State of Illinois

Madam Chairwomen, I want to thank you for holding this important hearing. I rise today to give my support to the Human Cloning Prohibition Act sponsored by Senators Feinstein and Kennedy.

The Feinstein-Kennedy bill specifically addresses a course of action we all agree on, namely, prohibiting the use of cloning technology specifically for the purpose of creating an embryo for implantation in a women's uterus. Further, this bill takes the important step of outlining significant civil and criminal penalties for those who fail to respect this prohibition.

I would also however like to address a point on which there is some disagreement: the banning of therapeutic cloning in addition to reproductive cloning. Unlike reproductive cloning, therapeutic cloning or somatic cell nuclear transfer aims not to create an identical and complete human being but to create a number of genetically identical cells which could become an organ or a tissue that one day would be used to treat individuals suffering from disease.

These genetically identical cells can be thought of as similar in some respects to someone donating blood for their own use later on except with far more potential. Just as is the case with blood transfusions, the risks of rejection or other adverse consequences in a transplant scenario with cloned cells are greatly reduced because the body recognizes itself.

While I support therapeutic cloning, I strongly believe that vigilant oversight will be critical for preventing the improper use of this technology. We have heard the argument that such oversight will be impossible and therefore only a complete ban on any and all forms of cloning will be able to prevent reproductive cloning.

That once we accept therapeutic cloning, we will never be able to prevent reproductive cloning. This is the slippery slope argument and I do not accept it. I believe that society has the ability to recognize the differences between the harm of reproductive cloning and the benefits of therapeutic cloning and to regulate or ban harmful applications while still allowing beneficial applications.

The Feinstein-Kennedy bill outlines significant criminal and civil penalties for violators who attempt to carry out reproductive cloning. In spite of this, there may be a few bad actors in the world who will attempt reproductive cloning out of greed, desperation, or misguided beliefs. They will be brought to justice. However, the existence of a total ban on cloning will not stop them anymore than a ban on reproductive cloning will stop them. It is the researcher looking for novel therapies, the researcher searching for cures and treatments, and the patients who stand to benefit from this research who will be most affected by a complete cloning ban. It is they who have the most to lose.

As a recent article on the creation of kidney-like organs from embryonic stem cells shows, this research holds great promise. With continuing research, we may be able to use embryonic stem cells to repair injured spinal cords or damaged livers or to grow new kidneys or hearts for those desperately awaiting transplants. Not, however, if we ban this research.

As J. Benjamin Younger, Executive Director of the American Society for Reproductive Medicine has said: "We must work together to ensure that in our effort to make human cloning illegal, we do not sentence millions of people to needless suffering because research and progress into their illness cannot proceed."

Statement of Hon. Edward M. Kennedy, a U.S. Senator from the State of Massachusetts

Thank you, Senator Leahy, for holding today's hearing on cloning, and thank you, Senator Feinstein, for your important leadership on this issue.

Today's hearing is about hope—hope for millions of Americans who face debilitating and life threatening diseases with no known cure. It's about our elderly facing Alzheimer's disease. It's about finding the cure for cancer. It's about helping children battle leukemia. It's about winning the struggle with diabetes.

I believe that we should ban human cloning. About that, there should be no debate. It's one thing to produce Dolly the sheep. It's quite another to produce another human life. Human cloning should be illegal.

But the issue today whether to permit another branch of medical science to move forward—and that's nuclear transfer. This procedure does not produce a new human being. But it does produce new cells that hold great promise for the miracle, life-saving cures of tomorrow.

Just as it's wrong to permit human cloning, it's also wrong to ban nuclear transfer research to cure disease and save human life.

The National Academy of Sciences says yes to nuclear transfer research. The National Bioethics Advisory Commission says yes. Major medical societies and patients' groups all say yes as well.

Senator Feinstein has introduced a straightforward bill that clearly prohibits the use of cloning to reproduce a human being, and I strongly support her legislation. Senator Harkin and Senator Campbell have offered similar proposals. I believe that every Member of the Senate opposes the use of cloning to reproduce a human being, and Congress should enact legislation to make such a practice illegal.

Yet there are some who are trying to muddy the waters by labeling legitimate medical research as "cloning". Medical research involving the transfer of DNA from one cell to an unfertilized human egg is not cloning. It does not produce a child or a pregnancy or a living human being.

But this essential medical research does bring the precious hope of a cure to the millions of Americans like Kris Gulden, who are suffering from spinal injuries, severe burns, diabetes, and countless other illnesses. Nuclear transfer research can unlock the limitless potential of stem cell research. With this research, doctors can make stem cells that are a perfect genetic match for a patient's own body. Without the research, patients may be condemned to a vicious cycle of tissue rejection and the renewed onset of disease.

We must not allow misplaced fears to extinguish the hope that nuclear transfer research brings to patients around the nation. We should enact sensible legislation to ban the use of cloning to reproduce a human being and not prevent doctors from continuing their life-saving research.

I look forward to the testimony of our witnesses today on this Issue.

Statement of Hon. Patrick Leahy, a U.S. Senator from the State of Vermont

Earlier generations had the luxury of speculating about human cloning when the idea was merely science fiction. We will not have that luxury, now that human cloning has arrived on the threshold of becoming science fact.

This is yet another area in which our scientific knowledge and technical prowess are outpacing our law and our social consensus. And this is yet another instance in which decisions will be needed if we are to keep science our servant and not our master.

This committee has a role in helping to advise the Senate so that the Senate's actions are as informed as possible by the facts and by the implications of what we choose to do or not to do. I greatly appreciate the willingness of Senator Feinstein to chair this important hearing and her leadership on this matter. She, and Senator Kennedy, have authored a major bill on this issue which is before this committee, along with other bills on the cloning issue such as the one introduced by Senator Brownback.

I have been advised that the Democratic Leader has made a commitment to take up this issue on the Senate floor to debate these matters.

We are fortunate that our Committee includes as Members several Senators who have devoted considerable thought to these issues—especially Senator Hatch, Sen-

ator Kennedy, Senator Brownback, Senator Specter, Senator Feinstein and Senator Schumer. This hearings presents a great opportunity for all Members to ask the questions and learn more about the complex issues raised in the various bills before the Committee.

Last August Senator Hatch and I had a long discussion during an executive meeting about the need for the Committee to hold a hearing on the issue of cloning. I agreed, and we decided to schedule it, but the events of September 11 and its aftermath have delayed this hearing until now.

We can probably all agree on one point: The religious, medical, ethical, privacy, Constitutional and scientif1c aspects of cloning are controversial. This necessarily will be a debate infused with human values and the suffering and the hopes of our fellow human beings.

One of my values involved in this debate is my strong belief that there is constitutional right to privacy which includes reproductive rights.

On the other hand, a guest column in *The New York Times* from Jan. 3?0, entitled the *Cloning Conundrum*, pointed out that two divided Rehnquist Supreme Court decisions raised significant federalism issues that could be relevant to this hearing.

The article argues that in *U.S.* v. *Morrison*, which struck down a federal civil remedy for victims of gender-motivated violence found in the Violence Against Women Act, and in *U.S.* v. *Lopez*, which struck down a federal criminal law regarding gun-free school zones, Chief Justice Rehnquist raised issues which suggests a limit on federal authority to criminalize or regulate cloning.

In addition, as Senator Hatch pointed out in August, many are hopeful that so-called therapeutic cloning, done in a manner which cannot result in creating a cloned human, could produce cures that would save lives and perhaps ameliorate life-threatening medical disabilities. For example, many scientists hope that therapeutic cloning could lead to cures of Parkinson's Disease, Alzheimer's Disease, muscular dystrophy, and Lou Gehrig's Disease, as well as allow those with spinal chord injuries to walk again.

Indeed, related assisted reproductive technologies have already aided couples in having children which are genetically related to one, or both, parents.

In the United States, and throughout the world, pharmaceutical companies and scientists are attempting to develop these life-saving cures and solutions to fertility problems and hope that central government regulation will not prevent this medical research from being completed. This hearing will explore the various arguments for and against therapeutic cloning, and related technologies, and also examine other aspects of this important issue.

We should bear in mind as we further study these issues a comment by Albert Einstein who noted that "the right to search for truth implies also a duty: one must not conceal any part of what one has recognized to be true."

The goal of scientific research is to achieve truth, or to develop ever more precise answers, but it has never promised mankind peace, happiness or redemption.

Article in NewScientist.com by Sylvia Pagán Westphal

A stem cell has been found in adults that can turn into every single tissue in the body. It might turn out to be the most important cell ever discovered.

Until now, only stem cells from early embryos were thought to have such properties. If the finding is confirmed, it will mean cells from your own body could one day be turned into all sorts of perfectly matched replacement tissues and even organs.

If so, there would be no need to resort to therapeutic cloning—cloning people to get matching stem cells from the resulting embryos. Nor would you have to genetically engineer embryonic stem cells (ESCs) to create a "one cell fits all" line that does not trigger immune rejection. The discovery of such versatile adult stem cells will also fan the debate about whether embryonic stem cell research is justified.

"The work is very exciting," says Ihor Lemischka of Princeton University. "They can differentiate into pretty much everything that an embryonic stem cell can differentiate into."

REMARKABLE FINDINGS

The cells were found in the bone marrow of adults by Catherine Verfaillie at the University of Minnesota. Extraordinary claims require extraordinary proof, and though the team has so far published little, a patent application seen by New Scientist shows the team has carried out extensive experiments.

These confirm that the cells—dubbed multipotent adult progenitor cells, or MAPCs—have the same potential as ESCs. "It's very dramatic, the kinds of observations [Verfaillie] is reporting," says Irving Weissman of Stanford University. "The findings, if reproducible, are remarkable."

At least two other labs claim to have found similar cells in mice, and one biotech company, MorphoGen Pharmaceuticals of San Diego, says it has found them in skin and muscle as well as human bone marrow. But Verfaillie's team appears to be the first to carry out the key experiments needed to back up the claim that these adult stem cells are as versatile as ESCs.

Verfaillie extracted the MAPCs from the bone marrow of mice, rats and humans in a series of stages. Cells that do not carry certain surface markers, or do not grow under certain conditions, are gradually eliminated, leaving a population rich in MAPCs. Verfaillie says her lab has reliably isolated the cells from about 70 per cent of the 100 or so human volunteers who donated marrow samples.

INDEFINITE GROWTH

The cells seem to grow indefinitely in culture, like ESCs. Some cell lines have been growing for almost two years and have kept their characteristics, with no signs of ageing, she says.

Given the right conditions, MAPCs can turn into a myriad of tissue types: muscle, cartilage, bone, liver and different types of neurons and brain cells. Crucially, using a technique called retroviral marking, Verfaillie has shown that the descendants of a single cell can turn into all these different cell types—a key experiment in proving that MAPCs are truly versatile.

Also, Verfaillie's group has done the tests that are perhaps the gold standard in assessing a cell's plasticity. She placed single MAPCs from humans and mice into very early mouse embryos, when they are just a ball of cells. Analyses of mice born after the experiment reveal that a single MAPC can contribute to all the body's tissues.

MAPCs have many of the properties of ESCs, but they are not identical. Unlike ESCs, for example, they do not seem to form cancerous masses if you inject them into adults. This would obviously be highly desirable if confirmed. "The data looks very good, it's very hard to find any flaws," says Lemischka. But it still has to be independently confirmed by other groups, he adds.

FUNDAMENTAL QUESTIONS

Meanwhile, there are some fundamental questions that must be answered, experts say. One is whether MAPCs really form functioning cells.

Stem cells that differentiate may express markers characteristic of many different cell types, says Freda Miller of McGill University. But simply detecting markers for, say, neural tissue does not prove that a stem cell really has become a working neuron.

Verfaillie's findings also raise questions about the nature of stem cells. Her team thinks that MAPCs are rare cells present in the bone marrow that can be fished out through a series of enriching steps. But others think the selection process actually creates the MAPCs.

"I don't think there is 'a cell' that is lurking there that can do this. I think that Catherine has found a way to produce a cell that can behave this way," says Neil Theise of New York University Medical School.

Articles in the New York Times, January 19, 2002

TWO APPROACHES TO CLONING

The National Academy of Sciences called yesterday for a legally enforceable ban on human reproductive cloning aimed at creating a child—but strongly endorsed cloning to derive stem cells that hold great promise for curing a wide range of human diseases. That is precisely the distinction that should be drawn by Congress as it wrestles with competing bills that would determine whether and how cloning research in this country is permitted to advance.

The academy's report on human reproductive cloning, when coupled with an earlier academy analysis that discussed stem cells derived by cloning, offers a sound guide through these contentious issues. Unfortunately, President Bush, pandering to religious conservatives, opposes cloning for any purpose, whether to produce a

child or to cure disease. The House has passed a bill that would impose a total ban on human cloning and subject any violators to criminal penalties and huge civil judgments. The Senate will consider both a total ban and a more discriminating bill that would allow therapeutic cloning and simply ban reproductive cloning.

Sadly, there seems little chance that a new bio-ethics council appointed by the president will do anything to reverse the administration's support of a total ban. That panel held its first meetings this week under the leadership of Leon R. Kass, an ethicist on leave from the University of Chicago, who has publicly urged that both therapeutic and reproductive cloning be banned. He will hardly let his 1 7-member panel do anything that could embarrass the president or change his adamant opposition.

Indeed, Mr. Kass may have signaled his intentions by opening this week's meeting with a discussion of a short story by Nathaniel Hawthorne, called "The Birthmark," in which a scientist who marries a beautiful woman with a blemish on her cheek inadvertently kills her while trying to remove it. That sounded as if Mr. Kass was more intent on curbing any perceived excesses of science than in facilitating medical advances.

By contrast, the academy's panel of experts reiterated the academy's support for therapeutic cloning to produce stem cells that are genetically equivalent to a patient's own cells. Such cloned cells could help overcome the tendency of the body's immune system to reject stem cell treatments it perceives as "foreign."

But the academy agreed with the president and the House on the need to prevent cloning to produce a child. It argued persuasively that human reproductive cloning would be dangerous for the woman, the fetus and any newborn child, and would probably fail in most cases. The academy panel took no stand on whether, if the safety problems can be overcome, it would be acceptable to clone a child. That contentious issue was left to another day.

Article by Jack M. Balkin, the New York Times, January 30, 2002

THE CLONING CONUNDRUM

NEW HAVEN—Human cloning and hate crimes would seem to have little in common. But in a series of shortsighted decisions on the constitutional limits of Congressional power, the United States Supreme Court has managed to create legal precedents that may make it difficult for the federal government to ban cloning as well as hate crimes. This will no doubt come as a surprise to opponents of abortion, who oppose cloning on a moral basis and have been eager to outlaw it.

Since the New Deal, Congress has been free to regulate any activity so long as it had substantial effects on interstate commerce. In the last decade, however, the five-person conservative majority on the Rehnquist court has created a set of federalism doctrines forbidding Congress from regulating what the court calls "noneconomic" activities. In order to preserve the boundary between what is national and local, the court insists, Congress must keep its hands off "traditional" local subjects like crime and the family.

Thus in 1995 the court said that Congress could not prohibit guns in or near elementary and secondary schools, because this usurped local authority to make decisions about what activity should be made criminal. It also struck down a federal law that let women sue their attackers in federal court. Violence against women isn't economic, the court said; it's about crime and families. The new states' rights doctrines would also

undermine any future Congressional effort to pass hate-crime legislation. Although hate crimes, like domestic violence, clearly have an economic impact, under the court's logic they are defined simply as assaults.

In 1994, many conservatives opposed the passage of the Violence Against Women Act because they said it infringed upon states' rights; today many make the same argument against federal efforts to outlaw other hate crimes or to regulate guns. They have cheered the Supreme Court's defense of state prerogatives. Now the tables are turned.

Conservatives who decry the use of cloning to make humans want the federal government to make the practice criminal; last year, the House passed a ban on cloning for any reason, including for new medical therapies.

But cloning is both an economic activity and a family-related issue. In this case, the lines the court has drawn make no sense.

In the 2000 campaign, President Bush said he admired conservative stalwarts like Justice Antonin Scalia and Justice Clarence Thomas, who have championed the new restrictions on Congressional power. Now he may understand the pitfalls of getting what you wish for.

This result is hardly surprising. Support for states' rights has often been opportunistic, driven by substantive goals like the defense of slavery or opposition to women's suffrage, economic regulation or civil rights. The standard defense of federalism is that it preserves liberty. But the real issue is what sort of liberty we are trying to protect.

tor years liberals have pointed out that the liberty to lynch people wasn't worth preserving. Now conservatives may conclude the same thing about the liberty to clone. And if a single state-say Oregon-explicitly permits cloning, they may find the old arguments for decentralization ring hollow.

Congress can use lawyers' tricks to get around these new federalism doctrines. It can withhold federal funds from hospitals that perform cloning, or require proof that the doctors or the tools they use have moved in interstate commerce. And it's entirely possible that the Supreme Court will say that cloning is just different and uphold a direct criminal prohibition. But if it does so, it won't be because of a principled commitment to federalism. It will be because the justices wanted a certain political result and stretched the law to get there, as they did in *Bush* v. *Gore*.

But there should be no need for Congress to jump through legalistic hoops or for the court to engage in doctrinal duplicity. Cloning is an issue of national concern, meriting a national debate. It is irrelevant whether it can be classified as "economic" or "noneconomic." The Supreme Court should scrap its ill-considered doctrines and recognize that the national government has the power to make all laws that it considers to be in the national interest. Then we can focus on the real question of our moral responsibilities in a new and difficult age of scientific achievement.

Jack A! Balkin is a professor at Yale Law School and author, most recently, of "*What Brown* v. *Board of Education Should Have Said.*"

Article by Steven L. Teitelbaum, FASEB President-Elect, St. Louis Post, December 3, 2001

COMMENTARY

BIOETHICS

Therapeutice coloning is designed to help people, not create new ones

Reports of "human cloning" experiments conducted by scientists in Massachusetts have generated a flurry of debate and widespread concern, but many people are still confused about what cloning is.

The term "cloning" describes a process where by a cell is replicated many times producing other identical individual cells. "Reproductive cloning" involves the development of a full individual from a single body cell "Therapeutic cloning" refers to the replication of cells for the purpose of repairing damaged tissue or replacing malfunctioning cells.

In reproductive cloning, the nucleus of an adult cell containing the DNA and genetic information of an individual is used to replace the nucleus of an egg (ovum) cell, and the product is allowed to develop to full term. This is the process by which Ian Wilmut created the sheep "Dolly."

Human reproductive cloning is neither needed nor desirable. Many animal studies have shown that cloning tends to produce less healthy individuals. There is no medical condition that needs reproductive cloning as its cure. Because it is potentially harmful, morally dubious and medically unnecessary, most responsible scientific organizations have spoken out against doing reproductive cloning. Only fringe elements have supported its development. Reproductive cloning should be prevented, by force of law if necessary.

Therapeutice cloning or the replication of cells for cell-based therapies, however, has enormous potential for treating disease. Therapeutic cloning is not a reproductive process, as no whole organism results. Stem cells, because they can grow into a wide range of cells and tissues, are an important result of this process. For that reason, scientists have been very excited about new developments in this area.

One very important source of stem cells is embryos because—at the current time—they have the most potential to become other types of cells. For many people, the use of human embryos in research is morally troubling. For others, it is an ac-

ceptable option in the search for treatment of such illnesses as severe heart conditions, diabetes, Parkinson's disease, Alzheimer's disease and spinal cord trauma.

President George W. Bush found the narrow terrain between these two viewpoints with this compromise position on federal funding of human embryonic stem cell research. While advocates of neither viewpoint were entirely happy, the compromise allows embryonic stem cell research to proceed while scientists explore potential uses of stem cells.

Before stem cells can become the basis for wide spread therapeutic application, however, two major scientific problems must be overcome. First, we must learn how to "coax" stem cells into becoming the types of cells and tissue desired. At the same time, we must figure out ways to ensure that a recipient's body does not reject the stem cells, if they are transplanted into the patient. Both are significant biological and scientific challenges.

To overcome rejection, some scientists have proposed giving the stem cells the DNA code of the patient so the resulting cells will be perceived as normal by the patient's immune system. One way to accomplish this is to take the nucleus from a cell of a patient, which contains his or her DNA, and implant it into an egg cell whose own nucleus has been removed. This technique is called somatic cell nuclear transfer.

The highly publicized experiments reported by Advanced Cell Technologies Corp. in Massachusetts used SCNT to create clusters of cells that would then be used to harvest embryonic stem cells. Reports of the Massachusetts experiments have unleashed a torrent of criticism, some justified and some misinformed. As we consider what was done, we must remain cognizant of the fact that they were not cloning human beings. Equally important is that their results were to preliminary to be claimed as evidence of the production of embryonic stem cells, a crucial step in developing cures for many diseases.

The nation's largest organization of medical researchers, the Federation of American Societies for Experimental Biology, is strongly opposed to reproductive human cloning, but supports the use of therapeutic cloning techniques to produce molecules and cells for research and therapeutic use. We fear that hastily crafted legislation will prevent these important therapeutic uses of cloning technology and block essential biomedical research.

Research on the most effective and useful ways to derive stem cells must continue and should be given federal support so that it can be conducted in the open at the nation's leading medical research institutions within guidelines established by the National Institutes of Health.

Waiting List

Updated Monthly. Snapshot For December 31, 2001

- Snapshot of Patient Registrations on the National Transplant Waiting List by: Organ & Overall | Blood Type | Gender | Age | Ethnicity | Region | Date

Updated Annually. Last Update: December 28, 2001

- Reported Deaths on the Waiting List By Organ and Year of Removal or Death: January, 1998 - August 31, 2001

This report provides frequency counts for certain demographic and logistic factors (blood type, gender, age, ethnicity, UNOS Region) for patients awaiting transplantation on the OPTN kidney, liver, pancreas, kidney-pancreas, intestine, heart, heart-lung, and lung organ-specific waiting lists.

The counts in this report are based on a recent "snapshot" of the OPTN Waiting List, i.e., the waiting list as it existed around midnight on the date specified. The data contained in the OPTN system are not conveyed via paper forms, but are entered electronically by the UNOS members who list a particular potential recipient. UNOS members have direct responsibility for maintaining and monitoring all data from the time a patient is listed until they are removed from the list.

Note that some patients are multiply listed: at different centers for the same organ, or for multiple organs (e.g. kidney and heart). The data in this report are not adjusted for multiple listings. However, the data are adjusted for multiple listings at the *same* center; thus, a patient is counted only once per center, per organ. Therefore the totals reflect numbers of registrations rather than numbers of patients. The degree of multiple listing of the same patient at different centers has been difficult to determine accurately, but is estimated to involve less than five percent of all patients and appears to have declined over time. The currently estimated number of patients listed on the waiting list by organ and overall is as follows:

Estimated number of patients listed on the National Transplant Waiting List by organ and overall:

Organ	Number of Patients
Kidney	50,803
Liver	18,744
Pancreas	1,220
Kidney-Pancreas	2,454
Intestine	180
Heart	4,123
Heart-Lung	212
Lung	3,795
*Overall	79,367

The overall value is less than the sum of the organs. This is due to the fact that some patients list for multiple organs. These patients are counted under each organ they are waiting for, but only once in the overall.

This report is updated monthly.

Number of Patient Registrations on the National Transplant Waiting List
By: Blood Type

Blood Type	Kidney	Liver	Pancreas	Kidney-Pancreas	Intestine	Heart	Heart-Lung	Lung	Total
	No. %	No. %	No. %	No. %	No. %	No. %	No. %	No. %	Number
Type O	28204	9645	584	1358	80	2334	113	1885	44203
	52.7	50.6	47.0	53.1	44.0	56.4	53.3	49.1	
Type A	14898	6674	473	774	61	1315	76	1411	25682
	27.8	35.0	38.1	30.3	33.5	31.8	35.8	36.7	
Type B	9060	2188	150	372	34	410	15	400	12629
	16.9	11.5	12.1	14.5	18.7	9.9	7.1	10.4	
Type AB	1398	559	36	53	7	78	8	145	2284
	2.6	2.9	2.9	2.1	3.8	1.9	3.8	3.8	
Total	53560	19066	1243	2557	182	4137	212	3841	84798
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	

Number of Patient Registrations on the National Transplant Waiting List
By: Gender

Gender	Kidney	Liver	Pancreas	Kidney-Pancreas	Intestine	Heart	Heart-Lung	Lung	Total
	No. %	No. %	No. %	No. %	No. %	No. %	No. %	No. %	Number
Female	22807	8111	587	1123	84	912	119	2204	35947
	42.6	42.5	47.2	43.9	46.2	22.0	56.1	57.4	
Male	30753	10955	656	1434	98	3225	93	1637	48851
	57.4	57.5	52.8	56.1	53.8	78.0	43.9	42.6	
Total	53560	19066	1243	2557	182	4137	212	3841	84798
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	

Number of Patient Registrations on the National Transplant Waiting List
By: Age

Age Group	Kidney	Liver	Pancreas	Kidney-Pancreas	Intestine	Heart	Heart-Lung	Lung	Total
	No. %	No. %	No. %	No. %	No. %	No. %	No. %	No. %	Number
0-5 Years	85	569	6	1	93	132	13	18	917
	0.2	3.0	0.5	0.0	51.1	3.2	6.1	0.5	
6-10 Years	136	208	1	0	22	38	6	49	460
	0.3	1.1	0.1	0.0	12.1	0.9	2.8	1.3	
11-17 Years	486	365	6	1	21	73	17	152	1121
	0.9	1.9	0.5	0.0	11.5	1.8	8.0	4.0	
18-49 Years	25762	6901	1036	2131	32	1191	145	1757	38955
	48.1	36.2	83.3	83.3	17.6	28.8	68.4	45.7	
50-64 Years	20696	9128	191	417	14	2188	30	1743	34407
	38.6	47.9	15.4	16.3	7.7	52.9	14.2	45.4	
65+ Years	6395	1895	3	7	0	515	1	122	8938
	11.9	9.9	0.2	0.3	0.0	12.4	0.5	3.2	
Total	53560	19066	1243	2557	182	4137	212	3841	84798

	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	

Note: Some patients are listed with more than one transplant center (multiple listing), and therefore the number of registrations may be greater than the actual number of patients

Number of Patient Registrations on the National Transplant Waiting List
By: Ethnicity

Ethnicity	Kidney	Liver	Pancreas	Kidney-Pancreas	Intestine	Heart	Heart-Lung	Lung	Total
	No. %	No. %	No. %	No. %	No. %	No. %	No. %	No. %	Number
White	22664	13954	1070	1879	114	3201	160	3189	46231
	42.3	73.2	86.1	73.5	62.6	77.4	75.5	83.0	
Black	18809	1409	95	412	38	550	26	384	21723
	35.1	7.4	7.6	16.1	20.9	13.3	12.3	10.0	
Hispanic	7778	2534	60	207	25	289	18	189	11100
	14.5	13.3	4.8	8.1	13.7	7.0	8.5	4.9	
Asian	3007	757	9	35	3	58	3	42	3914
	5.6	4.0	0.7	1.4	1.6	1.4	1.4	1.1	
Other	1291	400	9	24	2	36	4	36	1802
	2.4	2.1	0.7	0.9	1.1	0.9	1.9	0.9	
Non-Hispanic Multiracial	11	12	0	0	0	3	1	1	28
	0.0	0.1	0.0	0.0	0.0	0.1	0.1	0.0	
Total	53560	19066	1243	2557	182	4137	212	3841	84798
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	

Number of Patient Registrations on the National Transplant Waiting List
By: UNOS Region of Transplant Center

UNOS Region	Kidney	Liver	Pancreas	Kidney-Pancreas	Intestine	Heart	Heart-Lung	Lung	Total
	No.	No.	No.	No.	No.	No.	No.	No.	Number
Region 1	2029	1194	65	76	0	109	1	236	3710
Region 2	8411	2745	356	474	73	585	65	761	13470
Region 3	6192	1403	83	234	18	560	20	225	8735
Region 4	3775	1254	57	164	2	445	5	209	5911
Region 5	11139	4405	137	416	13	716	27	423	17276
Region 6	1256	309	26	98	0	91	0	29	1809
Region 7	4947	2217	275	392	13	288	29	306	8467
Region 8	2308	907	35	161	30	244	29	698	4412
Region 9	4986	2351	40	131	27	321	6	224	8086
Region 10	3852	946	117	233	1	310	3	254	5716
Region 11	4665	1335	52	178	5	468	27	476	7206
Total	53560	19066	1243	2557	182	4137	212	3841	84798

Reported Deaths on the Waiting List By Organ and Year of Removal or Death: January, 1998 - August 31, 2001

Organ	Year				Total
	1998	1999	2000	2001	
	#	#	#	#	#

Heart	768	719	599	458	2,544
Heart-Lung	43	53	43	29	168
Intestine	45	43	22	29	139
Kidney	2,419	3,205	2,875	2,025	10,524
Kidney-Pancreas	97	171	191	150	609
Liver	1,380	1,782	1,686	1,347	6,195
Lung	505	587	481	361	1,934
Pancreas	14	19	15	25	73
Total	5,079	6,331	5,800	4,320	21,530

Reported Deaths Table Based on OPTN data as of December 28, 2001. Data subject to change based on future data submission or correction.

Note: Date of death on the waiting list has been collected since the launch of UNET on 10/25/99. Prior to that date, only the date of waiting list removal was collected.

**The total number of deaths may not equal the sum of the organs due to patients listed for multiple organs.

The number of deaths reported for 1999 includes:
1) Patients removed from the waiting list in 2000 with a death date in 1999 and
2) Patients removed from the waiting list between 1/1/99 - 10/24/99 for whom the death date could have been prior to 1999. Therefore, deaths on the waiting list from 1998 on are not directly comparable and should not be compared to data prior to 1998.

Copyright © 1995-2002. United Network for Organ Sharing. All Rights Reserved.

UNIVERSITY OF MINNESOTA
MINNEAPOLIS, MN 55455
February 4, 2002

Senator Dianne Feinstein
SH–331 Hart Senate Office Bldg.
Washington, DC 20510

Subject Stem Cell Research

Dear Senator Dianne Feinstein:

In light of recent discussions in the press on work done in the Stem Cell Institute at the University of Minnesota, I would, as director of like University of Minnesota's Stem Cell Institute, like to clarifyour position on our research and its potential as we know it today.

First, as was discussed in the press last week, it is correct that we have found adult stem cells in bone marrow of humans as well as mice or rats, rats, great growth potential and great versatility, much like we've have seen in embryonic stem cells. Parts of these studies have been published, and partsare currently being peer-reviewed. That said, it is far too early to say whether they will stack up when compared to embryonic stem cells in longevity and function. Further, we will not know which stem cells, adult or embryonic, are most useful in treating a particular disease without side by side comparison of adult and embryonic stem cells.

Second, we support studies aimed at developing techniques for therapeutic cloning, i.e. cloning of human embryonic stem cell lines, because they may provide immune compatible cells to treat a number of diseases, and because cloning of embryonic stem cell lines may be critical to the study of adult onset diseases, caused by for instance, mutations in the DNA of cells after birth. This does not mean that the University of Minnesota's Stem Cell Institute supports reproductive cloning.

Finally, I want to emphasize our belief that stem cell research should be done in public, federally funded institutions, such as the University of Minnesota. It is in these institutions that the public and policymakers can be assured effective and thorough oversight of the research and the protocols being explored. While we are excited by our adult stem cell findings, it is not our intention to stop here. There are still too many unknowns for researchers or policymakers to begin closing doors to opportunities of learning.

I appreciate your attention to these issues and remain at your disposal should you have any questions about our research.

Sincerely,

CATHERINE VERFAILLIE, M.D.
Professor of Medicine and Director, Stem Cell Institure
University of Minnesota

Editorial in the Washingon Post, January 22, 2002

HOW TO APPROACH CLONING

AS THE SENATE prepares to plunge anew into the human cloning debate, the range of voices in that debate is growing broader. The president's new council on bioethics held the first of a projected five or six meetings last week designed to produce a report on the topic by summer. At the same time, the National Academy of Sciences issued a report urging that any attempt to clone an actual human baby be banned on safety grounds, but that promising disease research involving the cloning of human embryonic cells be allowed to go forward. Meanwhile, state legislatures are beginning their own debates. A California panel echoed the NAS approach, recommending that the state legislature ban human cloning for reproduction but not research. A Florida lawmaker has filed a bill that would allow a cloned child to sue the scientist who cloned him for parental support and emotional damages.

The ferment of different approaches could help shed light on the central dilemma confronting the U.S. Senate, which is whether to back the sweeping ban on all human cloning passed by the House—one that would levy harsh criminal penalties on any scientist who cloned a human embryo, whatever the purpose, and stop all such research in its tracks—or whether to craft a more limited ban that would focus on preventing the implantation, gestation or birth of a cloned baby. We favor the latter approach. To the prohibition of birthing human clones there appears to be lit-

tle credible opposition. As the academy report makes clear, risks to both the cloned fetus and its mother put human cloning outside the pale of ethical scientific experimentation barring significant further breakthroughs.

The safety issue makes it proper to ban bringing human clones to birth without reaching the knottier ethical questions of whether duplicating human genomes transgresses fundamental social values. That's more difficult with the sweeping research ban, but proponents have likewise offered some practical arguments: Some, among them bioethics council chair Leon Kass, have argued that banning the creation of cloned embryos for research is the only sure way to avoid their implantation in a human womb. Others (including Mr. Kass in other contexts) stress the importance of respecting even several-cell forms of human life.

In contrast to the respect-for-life question, the assertion that adequate safeguards cannot be drawn to separate research and implantation can be challenged and debated on practical and factual grounds. Mr. Kass's first council meeting seemed determined to hew to a high philosophical line of thought, weighing literature, love and ethical boundaries—urged to it by the president, who launched them with an exhortation to help clarify "how to come to grips with how medicine and science interface with. . .the notion that life is—you know, that there is a Creator." But the Senate should take a less ambitious approach. Seeking to speak for Americans from all walks of life on such ultimately religious matters is a daunting and not necessarily advisable task for a legislative body. The Senate debate ought to address the pragmatic details of how best to prevent the dangerous experimental prospect of human-clone pregnancies and births. But it should leave scientists free to work on the experiments that offer others great hope.