THE HUMAN CLONING PROHIBITION ACT OF 2001 AND THE CLONING PROHIBITION ACT OF 2001

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ON

H.R. 1644 and H.R. 2172

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WEDNESDAY, JUNE 20, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:15 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Greenwood, Burr, Ganske, Norwood, Cubin, Wilson, Shadegg, Bryant, Buyer, Pitts, Tauzin (ex officio), Brown, Waxman, Strickland, Barrett, Deutsch, Stupak, Engel, and Green.

Also Present: Representatives Stearns and DeGette.

Staff present: Marc Wheat, majority counsel; Brent Del Monte, majority counsel; Kristi Gillis, legislative clerk; and John Ford, minority counsel.

Mr. BILIRAKIS. Come to order. The Chair apologizes for his tardiness, and this hearing will come to order. I want to thank our witnesses for their time and effort in joining us today for this very important hearing.

Today, the Subcommittee on Health will continue where the Subcommittee on Oversight and Investigations, chaired by Congressman Gene Greenwood, left off. We will examine two measures, which, in many ways, reflect the discussions of that hearing: H.R. 1644, sponsored by Congressmen Weldon and Stupak, and H.R. 2172, sponsored by Congressmen Greenwood and Deutsch.

This is a difficult issue, to say the least, and it involves many new and complex concepts. But we should all be clear, I think, about the controversies related to human cloning. The term "therapeutic cloning," which many people use to mean any type of cloning that is not intended to result in a pregnancy, is confusing.

It really includes two, distinct procedures, one of which is controversial, while the other, I think, is not. The non-controversial concept of therapeutic cloning is the cloning of human tissue that does not give rise to an embryo.

The controversial aspect involves the creation of a human embryo. This latter meaning is also the subject of both of the bills we will discuss today.

H.R. 1644 seeks to ban the creation of these cloned human embryos. H.R. 2172 seeks to prevent those who clone human embryos from implanting them in a surrogate mother.

What are we to make of the discussion today? Some patient groups want cloned embryos to be created because their tissue may prove to be valuable in biomedical research. Some companies would like to clone human embryos because it will lead to a cheaper way to manufacture tissue.

Writing in 1947, C.S. Lewis observed in "The Abolition of Man" that man's conquest of nature would be complete when he finally, and I quote him because I think this kind of says it, "has obtained full control over himself. Human nature will be the last part of nature to surrender to man. The battle will then be won. We shall have taken the threat of life out of the hand of Cloe, and be henceforth free to make our species whatever we wish it to be. The battle will, indeed, be won. But who, precisely, would have won it? For the power of man to make himself what he pleases means, as we have seen, the power of some men to make other men what they please."

Human cloning rises to the most essential question of who we are and what we might become if we open this Pandora's box. I look forward to the testimony of our witnesses who will help us understand just what might be in that box.

The Chair now yields to Mr. Brown.

Mr. BROWN. Thank you very much, Mr. Chairman, and thank you for calling this hearing. I want to thank our witnesses, Mr. Allen especially, for testifying before us. I also want to thank my colleagues, Mr. Deutsch and Mr. Greenwood, Ms. DeGette, Mr. Stupak, and Mr. Weldon for their tireless work on this extraordinarily complicated issue.

The issue today is not about whether to ban the cloning of a human being, but how to ban cloning in a way that—that best serves society. Cloning grabbed the spotlight in 1997, as we know, with the cloning of the sheep Dolly in Scotland.

This remarkable breakthrough in science was followed by public scrutiny and largely fear. How far away was the science to clone humans?

President Clinton and the Congress responded immediately. The President issued a memorandum to the heads of all executive departments and agencies, making it clear that no Federal funds would be used for cloning.

Several bills were introduced banning human cloning research and banning human cloning altogether.

And now, 4 years after scientists developed Dolly, Congress has remained divided on what we think is the most appropriate way to ban the cloning of humans.

I want to first thank Mr. Stupak, my colleague, for his work on this issue. While I may not favor his approach, I respect his views on this difficult topic.

Congressman Deutsch and Congressman Greenwood have introduced legislation that I believe is a responsible approach to banning cloning without restricting promising research. Like the Weldon-Stupak bill, the Greenwood-Deutsch bill bans human so-

matic cell nuclear transfer, the technique used for cloning, with the intent to initiate a pregnancy.

But in regards to the scope of this bill, their bill protects all other types of cloning, including therapeutic embryo cloning.

As the biotech industry will attest to, we are dramatically close to providing cures and treatment for a wide variety of illnesses, such as Parkinson's, and Alzheimers, and spinal cord injury, and heart disease, and diabetes, and kidney disease, and stroke.

Additionally, with the type—this type of research, it is possible, medical researchers and scientists tell us, that we could virtually eliminate the need for organ transplants and toxic immuno-suppressive drugs.

In terms of preventing human cloning, banning all science related to human cloning is no more effective than banning the act of human cloning itself. It would be irresponsible of this Congress, I believe, to stifle promising medical research under the auspices of banning human cloning.

What is at risk if we close the door to this type of research? The ability to regenerate a failing organ, rather than waiting for a transplant and then hoping the body won't reject that organ? The ability to stop the onset of juvenile diabetes so a young child doesn't have to endure injections 3, 4, 5 times a day? The ability to restore the nervous system for an accident victim left paralyzed? The ability to reverse forms of muscular dystrophy which rob children of full mobility and, all to often, tragically, rob them of their adulthood?

Too much is at risk to stop the research before its potential is fully understood. Thank you, Mr. Chairman.

Mr. BILIRAKIS. And I thank the gentleman. And I would ask the members to try to limit their opening statements to as close to 3 minutes as they possibly can. Mr. Stearns for an opening statement? You do have seniority, you know?

Mr. STEARNS. Mr. Chairman, I bow to your wisdom, and seniority, and good sense, and I appreciate the opportunity to give my opening statement. I introduced in the 105th and 106th Congress my own legislation to prohibit Federal funding for the cloning of human beings.

The bill I introduced is H.R. 1372, and it also calls for an international ban on human cloning. I am also a co-sponsor of H.R. 1644, introduced by my colleague, Mr. Weldon and Mr. Stupak of Michigan.

The quotation you used for C.S. Lewis, "Abolition of Man," is terrific. I don't know if you have read that book, but that book sums up what we are here talking about. C.S. Lewis was on the leading edge of understanding human rights and the relationship to human beings and his Maker.

Cloning is a form of playing God since it interferes with the natural order of creation. We should be very cautious on how we address this issue. Besides the obvious moral implications, there are several other compelling reasons why we should not be cloning human beings.

By far, however, the most compelling is that man lacks the ability to predict or control the possible consequences of cloning. The Boys from Brazil, do you remember that movie? That movie would

no longer be fiction. We are actually living in a world where the cloning of human beings is a very real possibility.

Ever since the world was made aware of Dolly and then the infamous Dr. Seed and the possibility of cloning human beings, significant actions have been taken to outlaw this practice.

As we all know, former President Clinton called for a ban on the use of Federal funds for research on cloning of human beings, and President Bush supports a total ban on cloning, I believe legislation to ban Federal funding on human cloning is necessary. And the European Convention on Human Rights and Bio-Medicine, covering not just the European Union, but all European states, has already outlawed this practice.

Currently in the United States, four States prohibit cloning, and eight more States have legislation pending to ban human cloning.

Let us take a look, my friends, at the California law. It imposes a 5-year moratorium on cloning of an entire human being. The word "entire" is key because some of us consider an embryo to be a human being.

That is why we must be very cautious in the terminology that is used because you will hear the words, not for reproductive purposes, being used frequently in debates about cloning. That is just one of the many problems associated with technology that may be used to close humans.

At least seven States have bans to prohibit transferring the nuclei from a human cell and a human egg. But that doesn't address the possibility of transferring a human nucleus into a nonhuman egg. But that is not the only loophole.

Seven States' proposals ban the creation of genetically identical individuals, but that leaves another loophole. An egg cell, donated for cloning, has its own mytochondrial DNA, which is different from the mytochondrial DNA of the cell that provided the nucleus. The clone will, therefore, not truly be identical.

There are many issues raised by the possibility of cloning humans, including the medical risks that are inherent in such procedures. These risks should cause great alarm for each of us this morning.

In 1998, the Farm Animal Welfare Council of the United Kingdom Minister of Agriculture called for a moratorium on commercial uses of animal cloning because of serious welfare problems encountered when animal species have been cloned.

So, to attempt such a technique on humans, which has caused deformities, large fetuses, and premature deaths in sheep and cattle is not being responsible.

Let us not forget that it took 273 tries to develop a Dolly. That begs a question: what about the other 272 animals? Most of them were either aborted, destroyed, or maimed. Obviously, we do not want to do this to human beings.

There are also compelling and serious ethical and moral implications involved with the cloning of humans. Theologians—theologians and ethicists have raised three broad objections. Cloning humans could lead to a new eugenics movement where, even if cloning begins with a benign purpose, it could lead to the establishment of scientific categories of superior and inferior people.

Cloning is a form of playing God since it interferes with the natural order of creation, and cloning could have long-term effects that are unknown at this time.

Mr. BILIRAKIS. Would the gentleman finish up? The time has expired.

Mr. STEARNS. People have a right to their own identity and their own genetic make-up. And so, Mr. Chairman, I look forward to our distinguished panels and hearing their answers.

[The prepared statement of Hon. Cliff Stearns follows:]

PREPARED STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Thank you, Chairman Bilirakis, for holding this important hearing on legislation to ban the cloning of human beings.

Because I felt so strongly about this issue I introduced legislation in the 105th and 106th Congresses to prohibit federal funding for the cloning of human beings. I reintroduced this legislation in this Congress. The bill is H.R. 1372 and also calls for an international ban on human cloning. I am also a cosponsor of H.R. 1644, introduced by my colleague from Florida, Mr. Weldon and Mr. Stupak of Michigan.

Cloning is a form of playing God since it interferes with the natural order of creation. We should be very cautious in how we address this issue. Besides the obvious moral implications, there are several other compelling reasons why we should not be cloning humans. By far, however, the most compelling is that man lacks the ability to predict or control the possible consequences of cloning.

The Boys from Brazil is no longer fiction. We are actually living in a world where the cloning of humans is a possibility.

Ever since the world was made aware of Dolly, and then the infamous Dr. Seed and the possibility of cloning human beings, significant actions have been taken to outlaw this practice.

As we all know, former President Clinton issued a memorandum calling for a ban on the use of federal funds for research on cloning of human beings and the European Convention on Human Rights and Biomedicine, covering not just the EU, but all European states has already outlawed this practice.

President Bush and Secretary Thompson oppose the use of human somatic cell nuclear transfer either for reproductive purposes or for therapeutic purposes.

Even though President Clinton called for the prohibition of federal funds for cloning of human beings and President Bush supports a total ban on human cloning, I believe legislation to ban federal funding of research on humans is necessary.

Currently, in the United States four states prohibit cloning and eight more states have legislation pending to ban human cloning.

Let's take a look at the California law. It imposes a five-year moratorium on cloning of an entire human being. The word entire is key because some of us consider an embryo to be a human being. That is why we must be very cautious in the terminology that is used because you will hear the words not for reproductive purposes being used frequently in debates about cloning. That is just one of many problems associated with technology that may be used to clone humans.

At least seven states have bans to prohibit transferring the nucleus from a human cell into a human egg, but that doesn't address the possibility of transferring a human nucleus into a "nonhuman egg."

But, that is not the only loophole. Seven state proposals ban the creation of "genetically identical" individuals, but that leaves another loophole. "An egg cell donated for cloning has its own mitochondrial DNA, which is different from the mitrochondrial DNA of the cell that provided the nucleus. The 'clone' will therefore not be truly identical."

There are many issues raised by the possibility of cloning humans, including the medical risks that are inherent in such procedures. These risks should cause great alarm for each and every one of us. In 1998 the Farm Animal Welfare Council of the UK Minister of Agriculture called for a moratorium on commercial uses of animal cloning because of serious welfare problems encountered when animal species have been cloned. So, to attempt such a technique on humans, which has caused deformities, large fetuses and premature deaths in sheep and cattle is the height of irresponsibility.

Let's not forget that it took 273 tries to develop Dolly. That begs the question, what about the other 272 animals? Most of them were either aborted. destroyed, or maimed. Obviously, we do not want to do this with human beings.

There are also compelling and serious ethical and moral implications involved with cloning of humans. Theologians and ethicists have raised three broad objections. Cloning humans could lead to a new eugenics movement, where even if cloning begins with a benign purpose, it could lead to the establishment of "scientific" categories of superior and inferior people. Cloning is a form of playing God since it interferes with the natural order of creation. Cloning could have long-term effects that are unknown and harmful. People have a right to their own identity and their own genetic makeup, which should not be replicated.

I look forward to hearing from our distinguished panel of witnesses about this complex and compelling problem.

Mr. BILIRAKIS. The Chair recognizes Mr. Waxman for an opening statement.

Mr. WAXMAN. Thank you, Mr. Chairman. Today's hearing—hearing involves research that holds a great deal of promise for defeating disease and repairing damaged organs.

The hearing also involves a great deal of confusion, much of it spilling over from the ongoing political debate about abortion. I hope the hearing—I hope that the hearing can further the research and clear up the confusion.

Let me start that effort by clarifying what we mean by cloning research, because the term means different things to different people. Some cloning research involves, for example, using genetic material to generate one adult skin cell from another adult skin cell. I know of no serious opposition to such research.

Some cloning research starts with a human egg cell, inserts a donor complete genetic material into its core, and allows the egg cell to multiply to produce new cells genetically identical to the donor's cells. These cells can, in theory, be transplanted to be used for organ repair or tissue regeneration without risk of allergic reaction or rejection. There is controversy about this research, as we will hear today.

Some cloning research starts with a human egg and donated genetic material, but is intended to go further in an effort to create what is essentially a human version of Dolly the sheep, a full-scale, living replica of the donor of the genetic material. I know of no serious support for such research.

To keep things clear in discussion today, I will use different terms for these three different aspects of cloning research. The first widely supported field I refer to as tissue generation. And I understand that some people call it cell-line propagation.

The second controversial field I will refer to as genetic cell replication. Other call—others call it therapeutic cloning.

And the third unsupported field is widely known as reproductive cloning. In order to tilt the debate about genetic cell replication research, some opponents lump it with Dolly the sheep. No one benefits from such confusion.

If some think research is good and others think it is wrong, that dispute should be aired clearly and not blurred by blending subjects or exaggerating claims. If a field of research is to be prohibited or allowed, we should do so on its merits.

Some also argue to prohibit genetic cell replication research because it might, in the wrong hands, be turned into reproductive cloning research. I cannot support this argument.

So a—such a prohibition is no more reasonable than to prohibit all clinical trials because researchers might give overdoses deliberately. It is as much overreaching as prohibiting all organ transplant studies because an unscrupulous person might buy or sell organs for profit.

All research can be misused. That is why we regulate research, investigate abuse of subjects, and prosecute scientific fraud and misconduct.

If researchers give drug overdoses in clinical trials, the law requires they be disbarred and punished. If someone were to traffic an organ, the law requires they be prosecuted. We should clearly define what we believe is wrongdoing, prohibit it, and enforce that prohibition.

But we should not shut down beneficial work, clinical trials, organ transplants, or genetic cell replication because of a risk of wrongdoing.

In closing, I want to acknowledge that principled people do differ in this area. Some believe that a fertilized egg, whether it is inside a womb or inside a test-tube, is the same as a human being.

They are logically consistent when they oppose genetic cell replication. They are also logically opposed to abortion, to in vitro fertilization as it is generally practiced, and to some methods of family planning.

I don't question their sincerity, but I sincerely do not agree with them. And I do not believe that the Congress should prohibit potentially lifesaving research on genetic cell replication because it accords a cell, a special cell, but only a cell, the same rights and protections as a person.

I look forward to hearing from the witnesses today. Thank you very much for holding these hearings.

Mr. BILIRAKIS. And I thank the gentleman. Mr. Greenwood for an opening statement?

Mr. GREENWOOD. Thank you, Mr. Chairman, and I do particularly appreciate your holding this hearing. The humorist and social critic H.L. Mencken once wryly observed that, "For every complex problem, there is a solution that is simple, neat, and wrong."

Today, this committee has before it two competing bills to outlaw the cloning of human beings. Mr. Weldon's bill, H.R. 1644, while commendable in its intent, suffers from the weight of Mr. Menschen's observation.

It is a simple and straightforward solution to a very complex matter of science, but it is, unfortunately, wrong. It seeks to ban all forms of cloning which involve the use of the cells of human beings.

The measure which Mr. Deutsch and I—the measure which Mr. Deutsch and I have introduced, however, while perhaps failing the simplicity test, does confront the need to provide a sophisticated solution to a complex problem.

The admonition we try to follow is the one which Einstein recommended: "Everything should be made as simple as possible, but not simpler."

Esentially, our bill would seek to outlaw all attempts at reproductive human cloning, while permitting further and very carefully circumscribed research in the areas of somatic cell nuclear transfer,

a process that holds out a very real promise of a new kind of therapy known as regenerative medicine.

Briefly, this promising therapy would replace damaged or dead cells with healthy, and vigorous, new, and transplantable cells, thereby enabling physicians to treat millions of those who now suffer from chronic diseases, such as diabetes, stroke, heart disease, Parkinson's disease, and spinal cord injury.

This is about allowing people who are in coma to open their eyes, and stand up, and return to their family. This is about allowing people who are paralyzed, quadriplegics, to walk again. That is what is at stake here.

I have had an opportunity to review the written testimony of our distinguished panel of witnesses here today, and I believe it is fair to say that while all of them oppose reproductive cloning, not all are convinced that cloning research is without merit.

Indeed, two of our scholars will testify that their support of Mr. Weldon's bill is more a matter of public policy; one might even say politics, rather than good science. Simply stated, it would appear that they do not think that reproductive cloning can be effectively banned once the research genie has been let out of the bottle.

But that approach still begs the question I asked in my opening remarks at our first hearing on cloning earlier this year. The question this generation must ask is this: what should we do with this science? 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 illnesses that may be lost. Should we entirely ban this technology?

And I 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.

We owe it to ourselves and our posterity to have more faith in our ability to guide and direct human conduct than this cramped approach would allow.

One of our witnesses, though not himself a scientist, asserts that any form of research into therapeutic cloning is, "as morally abhorrent as it is medically questionable."

His objection is that embryonic cells are, in actuality, "new, living human beings." Even if we were to accept this premise, which I do not, what are we to make of in vitro fertilization? Each year, thousands, if not hundreds of thousands, of human embryos are discarded. Should this process, too, be outlawed? Shouldn't this practice also be construed as morally repugnant given the witness's definition?

And make no mistake; in vitro fertilization is not free of very complex and difficult, moral, ethical, and legal controversies. Issues of third-party donations of sperm or eggs, surrogate mothers, embryo division, sex selection of children, genetic testing, and potential genetic engineering, even rights of ownership, all are present in this practice.

But here, as one of our other witnesses recently pointed out, dogma is overcome by human desire. For while some clergy may condemn in vitro fertilization, 75 percent of the American people favor the practice as a means for a loving couple to bring a child into the world.

Then, there is the reality of the old-fashioned method of reproduction that we call sex. It is simply not true in the human body that every time an egg and sperm are joined human life begins.

On the contrary, quite frequently the embryo fails to attach to the uterine wall and is flushed out of a woman's body. What are we to make of this, when the largest loss of embryos is a result of the natural order of things human?

Mr. BILIRAKIS. Would the gentleman please finish up? The time is——

Mr. GREENWOOD. Mr. Chairman, I would ask unanimous consent for an additional 1 minute to complete my opening statement?

Mr. BILIRAKIS. We are getting away from that 3-minute thing that I asked——

Mr. GREENWOOD. Well, Mr. Chairman, since it is my bill, I wondered if I could just have this indulgence?

Mr. BILIRAKIS. Without objection, it will——

Mr. GREENWOOD. Thank you.

Mr. BILIRAKIS. [continuing] be the case.

Mr. GREENWOOD. In making this observation, I do not mean to be glib. On the contrary, I wish to admonish all of us that we should exercise great care when we make pronouncements about a mystery as deep as the creation of human life. The question about when life begins is too profound to be settled here today.

And in any case, this is not what this hearing is about. And if we cannot all agree on when life begins, we can all of us: Christian, Muslin, and Jew agree to this, I think, that every child is a new idea in the mind of God, and that this is now, and will be forever, the essence of humanity.

Using this definition, human clones would be replicates, the human equivalent of an epilogue. This is where I choose to draw the line. I oppose it; it must be outlawed.

And where there is a risk of some morally bankrupt charlatan pursuing reproductive cloning, we must make it abundantly clear that that man or woman is a pariah, even as we embrace the child who may be born of such an effort.

But make no mistake; the wistful hope of some of today's witnesses that in outlawing every aspect of cloning, we will somehow eliminate attempts to accomplish human cloning is a little more than whistling in the dark.

And I hope that they will forgive me when I observe that by embracing a universal ban on cloning, it is they who would be guilty of throwing the baby out with the bath.

The philosopher Arthur Schopenhaeur observed that, "All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident."

I believe that this is precisely what occurred in the case of in vitro fertilization, and I believe we will look back upon this hearing today and recall that the same was true of the remarkable medical breakthroughs made possible by therapeutic cloning.

In 1846 when the Scottish physician, James Simpson, urged the use of chloroform to reduce the——

Mr. BILIRAKIS. Mr. Greenwood, I am sorry, but you are 2 minutes over, sir.

Mr. GREENWOOD. Very well.

Mr. BILIRAKIS. Mr. Deutsch for an opening statement?

Mr. DEUTSCH. Thank you, Mr. Chairman. I would ask the members of the that they would accept my written statement in full into the record.

Mr. BILIRAKIS. Without objection, that will be the case for every member of the subcommittee.

Mr. DEUTSCH. I would like the chairman and ranking member for holding a second hearing on this important and complex subject. I understand that this is a powerful issue with many points of view to be heard and discussed.

I hope that members listen carefully to the testimony of our witnesses, and use this opportunity to better understand the scientific and ethical issues surrounding human cloning.

Our actions today when proceed with these bills will have a profound effect on the future of scientific discovery and the health and welfare of our constituents. We have a responsibility to proceed in a thoughtful and considerate manner that acknowledges the future benefits of scientific research, while accepting and protecting against the current flaws in the cloning process.

Mr. Chairman, I believe it is fair to say that no one sitting on this stage thinks we should allow reproductive cloning at this point in time. The process has clearly been shown to be imprecise and dangerous. Of the animals that have been cloned to date, none have been free of abnormalities.

The great majority of cloned animals die at birth or soon after. Those that survive often suffer from kidney, brain, or immune system abnormalities. Even Dolly the sheep, successfully cloned only after more than 270 attempts, suffered some severe obesity.

With these apparent risks, though highly prevalent in animals, it is imperative that we ban reproductive cloning and that we devote appropriate resources to upholding this ban.

That being said, it is clear there are significant benefits to be derived from therapeutic cloning, as several of our witnesses will testify. Since our last hearing on the subject in March, I have worked closely with Congressman Greenwood to develop legislation that we believe protects the public from the precarious and uncertain nature of reproductive cloning, while preserving promising biomedical research.

Specifically, the Greenwood-Deutsch legislation bans the use of human somatic cell and nuclear transfer with the intent to initiate a pregnancy, and imposes severe criminal and civil sanctions on any person or company that breaks this law. This language is the guts and substance of our legislation.

However, we have purposefully drawn a bright line in the bill between reproductive cloning and therapeutic cloning. Our legislation specifically protects the use of human somatic cell nuclear transfer to clone molecules, DNA, cells, or tissues.

This is one of the most promising areas of research for diseases like Alzheimers, Parkinson's, and diabetics—diabetes, just to name a few.

To ban therapeutic cloning, as the Weldon-Stupak legislation does, would be a travesty for the millions of people in our country whose lives are affected on a daily basis by these devastating conditions.

I won't go into detail of the myriad of cures and treatments that therapeutic cloning could provide, as Dr. Okarma and Mr. Perry will more than adequately make this point with their testimony.

I only emphasize the importance of understanding the clear distinction between reproductive cloning, which we need to unequivocally ban, and therapeutic—therapeutic cloning, which we unequivocally need to protect.

As we have moved toward this hearing, there have been questions raised by supporters of the Weldon-Stupak bill about the ability of our bill to effectively eliminate reproductive cloning without banning the creation of cloned embryos.

Let me state now that I am committing to working to tighten and amend the legislation to ensure it fits our intended policy objectives. However, I believe there are inherent flaws in the logic of some of these issues that were raised with the Greenwood-Deutsch legislation.

For instance, a recent "Dear Colleague" issued by Dr. Weldon implies there is no way to enforce a ban on transferring a cloned embryo to a woman's uterus if there is no ban on creating those embryos. My response to Dr. Weldon's concern is, how will you enforce your ban on creating cloned embryos?

One benefit of the Greenwood-Deutsch legislation is that it prospectively addressees the enforcement issue by requiring all entities that plan on performing human somatic cell nuclear transfer to register with the FDA.

That registration will contain an attestment they are aware of the prohibition on reproductive cloning and will not engage in any violation of that prohibition.

Additionally, by specifically stating in the legislation that it is a crime to intend to use human somatic cell nuclear transfer to initiate a pregnancy, our bill allows the FDA to intervene in a potential reproductive cloning scenario even prior to the creation of a cloned embryo. The Weldon-Stupak legislation forces the FDA to delay intervention until an embryo has been cloned.

I would like to address one final issue before I wrap up my statement. One of those issues that neither bill addresses is that—the products derived from therapeutic cloning.

If the Weldon-Stupak legislation passes and therapeutic cloning is banned in the United States, there is no doubt that bio-tech companies will simply move off-shore and continue their research elsewhere.

The question we are then faced with is, will we also ban the potential lifesaving product as the result of this off-shore—off-shore therapeutic cloning? Will we deny our constituents access to these phenomenal products?

If we deem therapeutic cloning to be unethical, how can we possibly reverse course and reap the benefits of off-shore research? This is a question for another time, but it is one that I think members should be aware of as they contemplate the effects of our actions on future discoveries.

In closing, I would like to again caution members against making a quick decision on this issue. There are obviously many points of view to be considered, and our witnesses today will add significant substance to this debate.

However, we are essentially debating a single tradeoff: it is more important to enact a broad ban——

Mr. BILIRAKIS. Please finish up.

Mr. DEUTSCH. [continuing] that would prohibit research, or should we spend a little extra enforcement to narrow a ban on reproductive cloning while allowing lifesaving research to continue? I ask the members to keep that in mind as we proceed. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Dr. Ganske for an opening statement.

Mr. GANSKE. Thanks, Mr. Chairman. I will be brief. Cloning a human being is immoral, period. I believe there is wide-spread, bipartisan agreement on that. Some people sort of shrug their shoulders and say, "Well, somebody is going to clone a human being. What can you do about it?"

I say we rise up in moral outrage and that we pass laws, both in this country and internationally, to prevent the cloning of a human being.

We need to look carefully at the total issue. There are some who would say we should not allow stem-cell research. There are some that would say we shouldn't allow any "cloning" at all.

And Mr. Chairman, I remember years ago, when I was taking care of a little boy who had a 95 percent burn over his entire body, and it was one of the first uses of cell lines that were grown from that little boy.

Now, under some definitions, that could be termed a cloning, a product to create those sheet of epithelium that were used.

As we look at this issue, let us agree, no cloning of human beings, and let us also look very closely at the language of any legislation so that we do not prevent the ability to effectively treat certain disease conditions. And with that, I yield back.

Mr. BILIRAKIS. Thank you, gentleman. Mr. Stupak?

Mr. STUPAK. Thank you, Mr. Chairman, and thank you for holding this very important and timely hearing. I think it is obvious which bill I support, H.R. 1644, the Weldon-Stupak Human Cloning Prohibition Act of 2001.

H.R. 1644 amends the U.S. Criminal Code to ban the creation of cloned human embryos for research or reproductive purposes. What our bill would do is to prohibit performing, or attempting to perform, human cloning; participating in an attempt to perform human cloning; shipping or receiving the product of human cloning for any purpose; and importing the product of human cloning for any purpose.

It draws a very bright line as to what activities are specifically prohibited. Many people have attempted to paint this bill as handcuffing the bio-technology and bio-research efforts currently underway.

The truth is, there is no cloned human embryo testing going on. And so, the arguments we will hear against this bill today will be conjecture at best; as in, we think this may happen, but we are not sure. Well, Mr. Chairman, I would like the researchers to be a bit more sure before they begin creating human clones.

The Weldon-Stupak bill intentionally steers clear of issues such as animal cloning, in vitro fertilization or IVF, and allows cloning

techniques to produce DNA, cells other than human embryos, tissues, and plants.

It also stays clear from stem cell research because, and I want to make this point very clear, stem cell research is being done on existing embryos at IVF clinics. The Weldon-Stupak bill does not prohibit this type of research on existing human embryos that are already slated for destruction. Therefore, stem cell research can and will go on.

This is not a Republic versus Democrat issue. H.R. 1644 reflects that. Currently, we have 105 co-sponsors, 19 of which are Democrats, much more bipartisan than any other cloning bill.

Some people have painted this bill as a pro-life vehicle. This is not true. I would like to point out the United Methodist Church has endorsed the Weldon-Stupak bill, as well as our witness today, pro-choice advocate, Judy Norsigian.

H.R. 1644 is an ethical bill about an ethical, moral, and legal problem. And I am proud that is able to reach across the divisive pro-life/pro-choice lines.

Another point that will be brought up in today's hearings by pro-cloning advocates will be what is called therapeutic research. Briefly, these advocates say that cloning of human embryos is essential for organ transplant.

To explain, let us say I have a faulty heart. Pro-cloning researchers will say, "Let me clone myself, using an embryo, exact my own stem cells within to grow new heart cells to replace the damaged. Then, implant these cells."

This will, so the theory goes, cut down on transplant rejection and cut down on the brutal immuno-suppressive drugs. My question is, why not clone my heart cells and cut out on the uncertain step of directing embryonic stem cells to become heart cells?

Finally, some have mentioned their concern with the lack of a sunset date, thus forever ruling out human embryo cloning. This is not true.

The Weldon-Stupak bill has a provision that directs scientists to come back to us when they feel that can make an—when they feel they can make a strong case for human embryo cloning. This puts the burden of proof on the researchers, which is where it should be.

One last distinction between our bill and the other human cloning bills: our bill bans a specific act. The Greenwood-Deutsch bill, for example, bans intent, a much more blurred standard.

Thank you, Mr. Chairman. I look forward to the testimony of our witnesses, and I welcome Mr. Allen, the Deputy Secretary of HHS.

Mr. BILIRAKIS. The Chair thanks the gentleman. Dr. Norwood for an opening statement?

Mr. NORWOOD. Thank you very much, Mr. Chairman, and I will try to get you back on schedule. I will be brief. Let me say to Mr. Allen, we are delighted you are here. And I thank you very much, Mr. Chairman, for holding this hearing.

I am really here today to listen. What was once considered science fiction now has become a reality, human cloning. And with that reality comes the ability to discover new treatments and treatments for conditions and diseases, perhaps even ways of preventing them from occurring at all.

I believe that we should move cautiously in considering any legislation that would arbitrarily close the door on important avenues of research.

Now, we have two bills before us, and I am a co-sponsor of the Weldon-Stupak bill. But I admit, I am also very interested in the approach Mr. Greenwood has taken. I believe that we need to give these bills great scrutiny to make sure that we understand all the potential consequences of both bills.

Again, Mr. Chairman, I thank you for holding this hearing. I commend you for your efforts to further examine this issue of cloning, and I look forward to hearing from our witnesses today, and would gladly yield back the balance of my time.

Mr. BILIRAKIS. And I thank the gentleman for that. Mr. Strickland for an opening statement?

Mr. STRICKLAND. Thank you, Mr. Chairman. Mr. Chairman, I woke up this morning, thinking about a young man in my district who is in his late 20's who, in his early 20's, had a serious car accident, and is unable to even breathe on his own. He has 24-hour care. He has back-up power in case the electricity would fail so that he could continue to breathe.

That young man, I hope someday, will have hope that he, and others like him, will no longer be required to spend his entire life in bed, being cared for by others.

I was thinking of him because I knew I was coming to this hearing, and I knew that what we were going to be talking about this morning was very important. I absolutely agree with what Dr. Norwood just said. We should be very careful that we not close the door, at least at this stage of our knowledge, on efforts to advance science and medicine.

We are opposed to the cloning of human beings. But we need to be very careful; and I hope we, as a committee, will be very, very careful, that we not allow theology or philosophy or politics to interfere with the decisions that we make here, but that we make sure that the decisions we make are based upon sound science.

I am a United Methodist. My friend, Mr. Stupak, is a Roman Catholic. But I think neither of us can allow our churches to tell us how to respond to this issue. I am not—I am not implying that that is true of either of us, but I do believe that there is a danger with this issue of allowing it to get caught up in matters which are apart from science and our responsibilities as Representatives to support sound science.

I haven't made up my mind on which bill I am going to support, but I am convinced that what we are doing today is important and vital, and it will ultimately affect huge numbers of the American people. And for that reason, we ought to approach it with the utmost seriousness of purpose.

Thank you, and I yield back my time.

Mr. BILIRAKIS. And I thank the gentleman. Mr. Bryant for an opening statement?

Mr. BRYANT. Thank you, Mr. Chairman. I have been sitting over here, making notes and deciding whether I want to give an opening statement or not, and trying to move things along. And I thought I could echo and join in my—my good colleague from Michigan's statement, Mr. Stupak.

And I certainly agree with him 100 percent, and I thought I could end it right there. But as I continue to hear some of the statements about—being made about this research and the need for it, which I don't quarrel with that, and I don't quarrel with these many, many difficult circumstances, these terrible cases where people have been hurt or—or have diseases; and certainly somewhere down the road, perhaps research can discover a cure or something to help them.

And we all support that. Those are terrible cases. But we do look at things like theology, and philosophy, and even politics, up here on everything we do. We operate in a world not purely humanistic, not just on science. We draw lines all the time out there.

We don't let prisoners sell their organs, or anybody, for that matter, sell their organs. We don't require prisoners to give up organs because they are in prison. We don't grow people. We don't create people for organ harvesting and things like that, and other body parts. We don't kill seniors, at least yet, for lack of a quality of life and things like that.

So, I think we operate in a bigger world than simply sound science. There is no question sound science plays a role in so many things. But yet, when you are dealing with such deep, moral issues, for many of us who do have a clear definition of where we think life begins, I think you could find people that could say anything about that.

Some say at the beginning, when the sperm meets the egg, perhaps now survivability and with the technology that we have got to keep these little premature babies alive, you know, when is that? The law in my State, in Tennessee, in civil cases is viability. And some might even say, you can argue through partial-birth abortion, is it doesn't begin until the baby is actually born.

You have got people that will say all kinds of definitions there. And if I am going to make a mistake on when that life begins, I am going to try and err on the side of life, and give the benefit, the most generous benefit.

Even in our criminal courts today and our law system, people who are sentenced to death have layers of appeal because we give them the benefit of the doubt. And yet, in situations like this where perhaps we are creating lives there and then destroying those lives, there is no—no one advocating for them.

So, I think there are difficult issues here. Unquestionably, there are terrible cases that we have to deal with. We have to have this research. And I am just optimistic, and hopeful, and encouraged that there are other ways we can get to this research through the tissue replication, as I understand it—I am not a doctor—something short of having to create, in my—in my belief, a life, and then destroy that life to help these very difficult circumstances.

And again, I just—I hope there is another way to do this. And I am encouraged, and I am glad to have all of the different opinions here today. I want to listen as much as I can. We have got schedules for—we are in and out a lot.

But I do—I did feel it necessary to at least respond in part to some of the statements that are being made in—in this regard. And for that, Mr. Chairman, I thank you again for holding this very important hearing, and I would yield back my time.

Mr. BILIRAKIS. The Chair certainly thanks him. Mr. Green for an opening statement?

Mr. GREEN. Thank you, Mr. Chairman, and thank you for holding the hearing on these two bills which address the controversial issue of human cloning. Cloning was once the subject of science fiction novels. Many of us associate cloning with the disturbing notion of designer babies or a human race that is void of individuality or spirit.

And we remember Huxley's "Brave New World" and the frightful images it conjured up of genetically manipulated and cloned individuals. What was once science fiction could become a reality.

In 1997, the cloning of Dolly the sheep opened up all our eyes to the possibility of human cloning. Human cloning either for therapeutic or reproductive purposes raises a number of ethical concerns that this committee and our Nation must consider.

If animal cloning has taught us anything, it is that cloning has significant risk. Miscarriages, birth defects, and genetic problems are the norm when it comes to cloning. Less than 3 to 5 percent of cloned animal embryos survive. In fact, it took more than 270 tries before scientists were able to clone Dolly.

Despite these risks, a March 28 Oversight and Investigations Subcommittee hearing demonstrated that there are fringe groups who intend to clone human beings without regard to the consequence of such activities.

I think that most people on this panel would agree that the risk associated with human reproductive cloning far outweigh any potential benefits, and that this kind of activity should be banned. That much is evident as both of the bills we're considering ban human cloning for reproductive purposes.

However, there is another side to cloning, therapeutic cloning, which holds great promise for the treatment of a range of diseases such as diabetes, heart disease, organ failure, spinal cord injury, and Parkinson's disease.

Many members of the scientific community believe that in order to unlock these mysteries, we must perform research on cloned human embryos. That is where these two bills depart.

Mr. Chairman, no one in this room knows any degree of certainty whether cloning research will achieve the goals it has promised, but we will never know the full potential of this technology if we stop it in its tracks.

Rather than throwing up an arbitrary roadblock on these scientific avenues, as one of these bills does, we should proceed with caution. And I hope the committee will consider all of the elements before we pass legislation which could have a chilling effect on research for treatments of some of our most dreaded diseases. Thank you, and I yield back my time.

Mr. BILIRAKIS. The Chair thanks the gentleman and will ask for the statement of Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman, and thank you for convening this important hearing today on the issue of human cloning. As science rapidly advances in our Nation and our world, we, as legislators, are faced with ethical dilemmas as we attempt to make sure that our world doesn't begin to resemble Huxley's "Brave New World."

While we want to encourage lifesaving, scientific advances, we must not let science advance in a moral vacuum. Americans agree. In fact, in a poll by Time/CNN in March of this year, 90 percent of those polled opposed human cloning.

While there is agreement that we must ban cloning, there is disagreement on the best way to do this. And today, we will hear testimony on two, radically different approaches to banning cloning.

The Greenwood bill would place a 10-year moratorium on implanting a cloned embryo in a woman's uterus. The Weldon bill would ban both the creation of a cloned embryo and the implantation of a cloned embryo.

Regardless of whether members are pro-choice or pro-life, it can be argued that the only effective way to ban cloning is the way it is done in the Weldon bill.

For example, if there were only a ban on implanting a cloned embryo, what happens when one of the cloned embryos is implanted in a woman's uterus, which we know could occur at some point? Would the woman be taken into custody and forced to have an abortion?

Regardless of the moral issues that some of us have with the Greenwood approach of creating life for the explicit purpose of research and then destroying it, I simply believe that this approach of only banning implantation is completely unenforceable.

Roe v. Wade, the Supreme Court decision, guarantees women the right to choose. I can't imagine that supporters of Roe, or anyone else for that matter, would force a woman who has had a cloned embryo implanted in her uterus to have an abortion. This is not China.

Another determination that needs to be made when we consider these young, living, human embryos is do they have the quality of people or property? If they are property, then we can do with them what we wish, including research, experimentation, destruction.

If they have the quality of people, although very tiny, very young, live human beings, they should not be created for experimentation and destruction and harvesting, no matter how sophisticated or therapeutic or regenerative.

As someone has said previously, human cloning is immoral. Are we going to permit the creation of a whole new class of human beings just for research, experimentation, harvesting, and destruction?

So, I fear the outcome of anything less than a complete ban on cloning, both embryonic and reproductive, would result in cloned human beings in America actually being implanted and being born.

I look forward to hearing the testimony from our distinguished panel of witnesses today.

Mr. BILIRAKIS. The Chair thanks the gentleman. Mr. Barrett for an opening statement?

Mr. BARRETT. Thank you very much, Mr Chairman. I will be brief. I want to thank you for convening this hearing. I think that previous members from both sides of the aisle and both sides of this issue have pointed to the thorny nature of the debate that we face today.

And I—rather than expounding on what may or may not happen, I am frankly looking forward to hearing from the—from the dif-

ferent witnesses to see what the administration's viewpoint is, and what the various other members of the panel have to offer. So, I would yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentleman. Let the record show that Ms. Wilson and Mr. Buyer are present, and have waived an opening statement. And even though she is not a member of this subcommittee, Ms. DeGette has requested the opportunity to make a brief opening statement, and the Chair now recognizes her.

Ms. DEGETTE. Thank you, Mr. Chairman. And it is really good to be back with my colleagues, even just for a brief moment. At the Oversight and Investigations hearing we held in March, all of us were horrified, collectively, at the testimony of experts in animal cloning who talked about the results that we don't hear about in the media with Dolly and so on, but the failed results and the grotesque results that came from animal cloning.

And we agreed, collectively, that cloning—human cloning was immoral, and that human cloning was impractical and should not occur. What is—we were also equally horrified at the cavalier attitude of some of the proponents of human cloning who testified at that hearing.

And we were all shocked about their complete lack of understanding about the moral, ethical, and physical implications of attempting human cloning.

And so, I welcome legislation to ban cloning. But at the same time, we need to understand what so many of my colleagues have talked about today here.

Increased understanding about the human genome, as well as the rapid advancement of technology, have prompted significant controversy about the possible application of cloning techniques of humans and whether there are appropriate applications.

The Greenwood-Deutsch bill prevents the abuses of human cloning while, at the same time, allowing for appropriate continued research in an area of science that holds answers, answers which could affect the lives of millions of Americans who are affected by so many diseases, as we have heard, from diabetes to Alzheimers to Parkinson's to different kinds of paralysis, and on, and on.

Therapeutic cloning, if appropriately done and if it is matched with appropriate safeguards, can hold so many of the keys that it would be irresponsible for Congress to pass legislation which would not allow this very targeted type of research to continue.

And so, Mr. Chairman, I thank you for having this hearing, and I also would caution my colleagues; we must be very careful. We cannot pass a bill simply because it seems politically expedient.

Too many lives of Americans are at risk. And we need to be very careful that while we are banning human cloning, we also don't stop research that will benefit so many millions of Americans. With that, I yield back the balance of my time.

Mr. BILIRAKIS. I think the gentlelady. That completes opening statements. As I had said earlier, the opening statements of all members of the subcommittee are made a part of the record.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KENTUCKY

Thank you Mr. Chairman. The debate on human cloning represents one of the most controversial and important issues facing our nation and society today. Rapid advances in biotechnology have transformed what was only recently an abstract hypothetical question into a very tangible and pressing legislative problem.

The American people look to their representatives in Washington for leadership and careful deliberation on the subject of human cloning. As a Committee, we are charged to reach a conclusion that will preserve the sanctity and uniqueness of human life without impeding important biomedical research that promises to improve the health of millions of Americans.

While both the Weldon-Stupak and Greenwood-Deutsch bills explicitly ban the cloning of human beings, their differing approaches attempt to resolve the predicament using varying degrees of restriction. H.R. 1644 enjoins all research utilizing somatic cell nuclear transfer, prohibiting both reproductive and therapeutic cloning procedures. In H.R. 2172, however, Reps. Greenwood and Deutsch limit the ban to include only human embryonic cells intended for developing human clones. Any use of the nuclear transfer technology for purposes other than developing a human clone would remain lawful.

Our challenge is to carefully consider the potential benefits and dangers of human cloning technologies, avoiding any unintended consequences of permitting or banning cloning research. I look forward to listening to the testimonies of our panel of witnesses and the opinions of my colleagues in order to reach a satisfactory answer to this most difficult question.

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WYOMING

We are fortunate today in that we have many powerful incentives to drive innovation; incentives that on the surface seem less than admirable: money, power, glory, prestige.

I say fortunate however because without the many innovations we have seen over the past decade—in medicine, technology, energy, aerospace and so on, we would not be living as comfortably as we are today.

In fact, some of us might not even be here without the many breakthroughs in medical science. For that, we should be very grateful.

There is however another aspect to innovative research, one of which we should be particularly mindful.

At what point does research go too far? At what point does research lead us to a place where maybe we shouldn't be? It is herein that lies the controversy.

It seems like we are in a race to understand the great mysteries of life, death, birth, disease, race, time—and the many other unknowns that we face.

In so many ways, discovery has been a blessing to us, especially when it comes to medical science, but sometimes we are in such a hurry to see what we can do that we don't stop long enough to decide whether we should.

One prime example of that is the cloning of human beings. This process comes dangerously close to wielding one of the most awesome forces in nature.

We haven't the slightest idea what to expect in the aftermath of cloning humans and, quite frankly, I think it is a dangerous proposition with which to play.

I want us to stop and think carefully about what we do in the name of research. It can be a wonderful thing, but it also demands great responsibility and humility.

As I consider this issue in the grand scheme of things, I cannot support cloning human embryos, and am very concerned about the possibility of cloning these embryos solely for research purposes, only to destroy them later. That just doesn't hold true to my idea of the spirit and intent of medical research.

I look forward to hearing from our witnesses today, and appreciate the chairman indulging me on this issue.

Mr. BILIRAKIS. And the Chair now welcomes Mr. Allen, with apologies for your sitting there all of this time listening to us talk. But you are probably relatively accustomed to that.

Mr. Allen is the Deputy Secretary of the Department of Health and Human Services. Sir, your written statement, of course, is already a part of the record. We will set the clock at 10 minutes. And

I would hope that you would supplement and compliment that written statement. Please proceed.

STATEMENT OF HON. CLAUDE A. ALLEN, DEPUTY SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. ALLEN. Thank you, Mr. Chairman and members of the committee I am Claude Allen, Deputy Secretary of the Department of Health and Human Services. And while it is true that having sat through all of the opening statements, it has been very enlightening.

This is, indeed, my first appearance before this committee in this capacity, as I have been on the job all of 2 weeks now.

I do want to say that I appreciate this opportunity to discuss the position of the administration regarding the cloning of human beings. Secretary Thompson is working this week at the Health Resources and Services Administration, and regrets that he could not personally be here to give this testimony.

The moral and ethical issues posed by the prospect of cloning human beings are profound and demand our unflagging attention. And I know the members have given much of your attention in that very way.

Secretary Thompson and President Bush make it very clear that they oppose any and all attempts to clone a human being. We oppose the use of human somatic cell nuclear transfer cloning techniques either to assist human reproduction or to develop cell or tissue-based therapies.

At the same time, the Secretary and the President strongly support other approaches to development of these therapies, such as research with genes, cells, or tissues from humans or animals consistent with current law.

Current biomedical science is riddled with vast areas of uncertainty about somatic cell nuclear transfer techniques and the consequences of their use. We, therefore, believe that any attempt to clone a human being, not only would present a grave risk to the mother and the child, but also would pose deeply troubling moral and ethical issues for humankind.

Further, we support both the Presidential directive already in place that prohibits the use of Federal—of government funds for cloning human beings and the current restrictions on HHS appropriations that bar the use of Federal Government funds to create human embryos for research purposes.

The American Medical Association Policy Statement E2.147 issued in 1999 stated further—that further investigation and discussion of the harms and benefits of human cloning is needed, and the potential for unknown physical and psychological harm, including violations of privacy and autonomy, are significant.

Ian Wilmont, as many have already noted, the scientist who cloned Dolly the sheep, has come out publicly against human cloning, stating that the risks inherent in cloning mammals are so great that it is "criminally irresponsible" to experiment with humans.

After 4 years of experience in animal cloning techniques, the failure rate is 98 percent. Animals that survive have problems with abnormal—abnormally high birth weight, extra large organs, heart

troubles, even poor immune systems. These animals are often euthanized to end their suffering.

It is clear that this administration has a moral imperative to prohibit the use of cloning technology for the purposes of creating a human being for reproduction or for research.

At the same time, we look forward to working with the committee and the members on your—and the colleagues in Congress in sustaining life-giving research into cell and tissue-based therapy to combat disease.

On behalf of Secretary Thompson and the President, let me thank you all for holding this hearing. It does address very critical issues that we must confront.

I will end by saying that I think Mr. Pitts, Congressman Pitts, really stated it the best when he said that we must not let science advance in a moral vacuum. The times in society when we have done that have resulted in great disasters, times when we have turned our back on our fellow men and women in this country and around the world.

We believe, at the Department of Health and Human Services, that the committee's work should be applauded in carefully considering and carefully reviewing these matters that have such critical importance to the future of not only those who may benefit from therapy, but also for society itself.

With that, I will stop and entertain any questions. There are many other issues that I think have been addressed in my written statement. Mr. Chairman, if I may also, at the very beginning, I meant to apologize for the committee receiving my testimony late last evening.

It is not designed to prevent you from having an opportunity to review it. It was simply late in the night that we were able to get it finally worked out and get it up here to you. So, please accept my apologies for that, as well as the Department's.

[The prepared statement of Claude A. Allen follows:]

PREPARED STATEMENT OF CLAUDE A. ALLEN, DEPUTY SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Committee, I am Claude Allen, Deputy Secretary of the Department of Health and Human Services. I appreciate this opportunity to discuss the position of the Administration regarding the cloning of human beings.

BACKGROUND

The moral and ethical issues posed by the prospect of cloning human beings are profound and demand our unflagging attention. Secretary Thompson and President Bush oppose any and all attempts to clone a human being. We oppose the use of human somatic cell nuclear transfer cloning techniques either to assist human reproduction or to develop cell- or tissue-based therapies. At the same time, we strongly support other approaches to development of these therapies, such as research with genes, cells, or tissues from humans or animals, consistent with current law.

Any attempt to clone a human being not only would present a grave risk to the mother and the child but also would pose deeply troubling moral and ethical issues for humankind. Further, we support both the Presidential directive already in place that prohibits the use of federal funds for cloning human beings and the current restrictions on HHS appropriations that bar the use of federal funds to create human embryos for research.

These matters are of special interest to the Department of Health and Human Services because attempts to use cloning technology to clone a human being are subject to both the biologics provisions of the Public Health Service Act and the drug

and device provisions of the Federal Food, Drug, and Cosmetic Act. On March 28, an FDA representative testified on this subject before the House Energy and Commerce, Subcommittee on Oversight and Investigations. As indicated then, because of unresolved safety questions on the use of cloning technology to clone a human being, FDA will not permit such attempts. In 1998, FDA described its position in a widely circulated "Dear Colleague" letter.

In keeping with the provisions of its statutory responsibilities, FDA's role in these matters is limited to scientific, technical and regulatory considerations. However, as noted by the President as well as by the National Bioethics Advisory Commission, additional concerns beyond the scope of FDA's role remain to be resolved (especially the broad social and ethical implications of cloning human beings, such as whether the use of human somatic cell nuclear transfer is morally acceptable under any circumstance.

COMMENTS ON PENDING LEGISLATIVE PROPOSALS

The Administration favors the passage of specific legislation to prohibit the cloning of a human being, including cloning techniques either to assist human reproduction or to develop cell- or tissue-based therapies. We look forward to working with the Congress to achieve this goal. For today, I present our comments on the Cloning Prohibition Act of 2001 (H.R. 2172, introduced by Mr. Greenwood) and the Human Cloning Prohibition Act of 2001 (H.R. 1644, introduced by Mr. Weldon), respectively.

H.R. 2172

H.R. 2172 focuses on preventing (a) the use of human somatic cell nuclear transfer (SCNT) technology to initiate a pregnancy or (b) the shipment or transportation of the product resulting from such technology if the product is intended to initiate a pregnancy. The bill does not restrict any other uses of human SCNT, such as creating human embryos for research purposes. This is a major concern to the Administration.

To foster enforcement of its provisions, the bill requires that an individual who intends to perform human SCNT register his/her name and place of business. This registration must include a statement or attestation, signed by the individual, declaring that he/she is aware of the prohibitions specified in the bill and will not engage in any activity that violates them. The registration requirement could cover a substantial number of academic and industrial laboratories.

The bill amends the Federal Food, Drug and Cosmetic Act to provide for criminal and civil penalties for any of the bill's prohibited activities. Moreover, to protect the confidentiality of the information that will be collected as a result of the registration process, the bill requires that the Secretary not disclose any of this information unless the registrant has provided authorization in writing or the disclosure does not identify either the individual or his/her place of business.

H.R. 1644

H.R 1644 amends Title 18 of the U.S. Code to prohibit (a) performing or attempting to perform human cloning, (b) participating in an attempt to perform such activity, or (c) shipping, receiving, or importing the product of human cloning. To achieve these ends, the bill defines "human cloning" as follows:

> "The term 'human cloning' means human asexual reproduction, accomplished by introducing the nuclear material of a human somatic cell into a fertilized or unfertilized oocyte whose nucleus has been removed or inactivated to produce a living organism (at any stage of development) with a human or predominantly human genetic constitution."

As we interpret the bill, it prohibits not only the use of human somatic cell nuclear transfer to initiate a pregnancy but also all other applications of somatic cell nuclear transfer with human somatic cells, such as cloning to produce cell- and tissue-based therapies. This is consistent with Secretary Thompson's and the President's views.

Scientific research that is not specifically prohibited in the bill is unrestricted by it. Examples of research that are not prohibited are the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans. Penalties for violation of the bill's prohibitions include at least $1 million in civil penalties and/or up to 10 years in prison.

We support this bill's intent of banning human cloning, but believe that it warrants further review to resolve some technical issues.

CONCLUSION

HHS applauds the Committee for addressing the issues associated with cloning human beings and welcomes the initiative of Representatives Greenwood and Weldon in offering specific legislative proposals. We look forward to working with the Congress to prohibit morally offensive uses of cloning technology without stifling the development of important cell- and tissue-based therapies to combat human diseases.

Mr. BILIRAKIS. The Chair, on behalf of the committee, accepts your apology. Obviously, it is certainly helpful if we can get it on time.

Mr. ALLEN. Certainly.

Mr. BILIRAKIS. The staff—I know the staff was here until, what, 11:30 last night waiting for the testimony. They didn't have anything else to do, just sat waiting.

Mr. ALLEN. Indeed, thank you.

Mr. BILIRAKIS. The Chair recognizes himself for questions. Mr. Allen, given the administration's opposition to the creation of cloned human embryos, what uses of cloning technology does the administration support? Would it be anything that doesn't give rise to a human embryo?

Mr. ALLEN. Mr. Chairman, I believe in my written statement, on page 6—and I will highlight that for you—we believe that there is already areas that can and should continue to see the research advance that are not prohibited by the use of somatic cell nuclear transfer, techniques such as using—that produce molecules, DNA, cells other than human embryos, tissues, organs, plants, and animals.

And we believe that both of those areas are wide open. What we are focusing on is a very narrow area, and that is the use of the human cell, the somatic cell, for the purpose of cloning, whether that be for reproductive purposes or whether that be for what we have heard earlier described as therapeutic or research-based work.

Mr. BILIRAKIS. You and I both have just used the word "human" a couple of times. Let me ask you the question; what is human? If legislation were passed banning the creation of cloned human embryos, how would the administration interpret the word "human"?

Before you go into that, I sould share with you that there was a news story a while back that scientists created a monkey that contained a strand of DNA from a jellyfish, which served as a fluorescent marker for the embryonic-embryonic monkey.

If this were done to a cloned human embryo, would this act render a human embryo into a chimera and therefore, not protected under the act? Would it be a loophole? Would the administration interpret anything that is predominantly human in origin in its genetic make-up to be considered human for enforcement purposes?

Mr. ALLEN. Mr. Chairman, let me first say the administration has not taken a position on the findings that you——

Mr. BILIRAKIS. Yes, that was going to be the next question.

Mr. ALLEN. [continuing] and I just want to make that very clear. I think the fact that we would have to even go down that track to try to guess or define what "human" is raises some serious implications that go back to question both of the moral, legal, and ethical implications.

However, I think your point of addressing the question, the word "in origin" certainly gives us some parameters to begin to look at, as we look to try to define that.

We are human because—not simply because of our genetic make-up because, indeed, we do share 98 percent of our make-up with, for example, monkeys. But it is those characteristics that make us distinct from other mammals, even primates that make us distinct, such as our ability to reason, our moral conscience. These are things that make us human.

So, I think to try to simply isolate it to a scientific definition, I think we are defeating the purpose of who we are as people, as individuals, as a species, that is distinct from all others. And that is not simply limited to our genetic make-up.

Mr. BILIRAKIS. Well, even though the administration has not taken a position on the Weldon bill—and I think we are all sort of curious about that—would you feel that maybe there should be a more succinct definition of the word "human" in any legislation that might progress through the committee?

Mr. ALLEN. We certainly think that the reason we have withheld from endorsing either bill in this circumstance is because we believe there is room for a lot of technical improvement. And that certainly could serve as one of those areas that probably would need to be spelled out.

Again, we know that, as a lawyer, that lawyers can certainly slice and dice words if you are not very careful about how you define. We would hope that that would not be the case.

But certainly, that is an area that, should the committee—and we will go back and look at that. We believe that we have opportunities to offer some technical advice in that area to clarify.

Mr. BILIRAKIS. All right. I do believe that others will probably raise the question of why you have not chosen to endorse the bills. So, I will just go ahead and yield. Mr. Waxman to inquire?

Mr. WAXMAN. Thank you very much, Mr. Chairman. Now, Mr. Allen, you say the administration opposes genetic cell replication and research, cloning that uses human egg cells to create genetically identical cells, but is not intended to lead to reproductive cloning to create a human being.

In your statement, you explain why the administration opposes creation of a human being, but you don't explain why you oppose research that is not intended to create a human being. Why?

Mr. ALLEN. Mr. Waxman, thank you for the question, and I do want to clarify it and make that very clear why we believe that. I think that the comments that have been made by the committee thus far really encapsulate much of that; and that is, that these are areas that go far beyond just simply science.

They go to the heart of the moral, legal, and ethical questions that need to be raised about this area of research that we are going into.

With regards to why we have not endorsed one of the bills versus the other, but we strongly believe that we need to ban both research and reproductive cloning is because leading down the track of research cloning, it is a very small step to have an embryo that was created for a clone for research purposes to be simply implanted into a woman that ultimately leads to——

Mr. WAXMAN. But don't you draw any distinction between research that leads toward a human version of Dolly, the sheep, and research that uses egg cells to develop tissues for organ repair?

Mr. ALLEN. Sir, I think you——

Mr. WAXMAN. Don't you draw those distinctions in your mind?

Mr. ALLEN. I think you can draw a distinction, but I think the question, once again, comes back to intent. It gets us to a place where we would have to interpret the intent of the individual or company or individuals who are creating for the purposes of research.

A very simple example: a kid in a candy store. I own a candy store. My son works in that candy store, has access to everything; he is passionate about candy. It is a very small step for him to go from me telling him what is prohibited, "You may not have that," to simply taking one off the shelf and using it for that purpose.

Mr. WAXMAN. Yes.

Mr. ALLEN. I believe that, and the administration believes that, it is the best interest that, at this time, that we ban both research, as well as reproductive, cloning because of the easy step to take that moves us across that line that we all agree is reprehensible.

Mr. WAXMAN. But can't you deal with intent? We deal with intent all the time in the criminal law.

Mr. ALLEN. The issue of intent is—and the way that the language is written, and the bill focuses on the intent. But what we cannot deal with is we cannot stop once that process has taken place, once a human embryo that has been cloned has gone from the research laboratory, has been implanted into a woman, that area, then, we have gone down that path; we have made that step.

And that is one that raises serious questions about what do you do at that point? I think there has been questions already raised about do you—you can punish the person for implanting it. Do you punish the researcher who did not know the intent of the person who would ultimately implant that in the——

Mr. WAXMAN. Well, we are talking about, I gather, the intent of the researchers. But do you oppose this research because you think an egg cell with implanted core genetic material is the same as a human being?

Mr. ALLEN. I am sorry; I missed——

Mr. WAXMAN. Do you oppose this research because you think that an egg cell with implanted core genetic material is the same as a human being?

Mr. ALLEN. That is not the basis upon which we are making this objection and opposition. We are basing it upon, again, the fear and the concern, the real fear and real concern——

Mr. WAXMAN. That it will be misused?

Mr. ALLEN. That is correct.

Mr. WAXMAN. Okay. Does the administration oppose in vitro fertilization or research on in vitro fertilization?

Mr. ALLEN. We do not oppose in vitro fertilization because there is a very significant distinction. In vitro fertilization involves the union of an egg cell, that is one set of chromosomes, with a sperm cell, a second set of chromosomes.

And that is to produce a fertilized egg that has two sets of chromosomes. The distinction here when we are talking about the

cloning is that the somatic cell nuclear transfer cloning involves the removal of the egg from a single cell, and the implantation, or the fusion, with a nuclear material to create one set that is identical to the source that it came from.

So, there is a fundamental distinction between in vitro fertilization and what we are talking about here in banning, and that is to that cell nuclear transfer cloning.

Mr. WAXMAN. Okay. Well, thank you. Your answers are very helpful, and we will think them through, and work with you on this. Thank you, Mr. Chair.

Mr. BILIRAKIS. I thank the gentleman. Mr. Greenwood to inquire?

Mr. GREENWOOD. Thank you, Mr. Chairman, and thank you for your testimony, sir. If I calculate right, this administration has been in office about 5 months?

Mr. ALLEN. That is correct.

Mr. GREENWOOD. That is right. This is a momentous—you would agree, I think, that this is a momentous issue for our future.

Mr. ALLEN. Absolutely.

Mr. GREENWOOD. Okay. Could you share with us, with this committee, with whom did this administration consult in order to arrive at its position which, as you stated, is that we oppose the use of human somatic cell nuclear transfer of cloning techniques either to assist human reproduction, which we all do, but—or to develop cell or tissue-based therapies.

Now, with whom did you consult? With whom did this administration consult in order to arrive at that conclusion?

Mr. ALLEN. Mr. Greenwood, the administration certainly has expertise within the Department itself, at HHS, whether it be NIH, the FDA, scientists within the administration. Outside, we also——

Mr. GREENWOOD. Did this administration consult with the NIH and the FDA prior to coming to this conclusion?

Mr. ALLEN. Certainly, we would have worked with them, and their input has gone into this decision. At a different level, however, I will say that it is very clear that, as has been indicated, that this involves significant policy issues that bear also on the views of the President and the Secretary as based upon the science that we have worked with, within the Department and outside of the Department as well.

Mr. GREENWOOD. Very complex. For instance, did you bring BIO, the organization that represents the bio-technology group—did the administration bring BIO and the scientists who are involved in this kind of research to consult with them prior to formulating its views?

Mr. ALLEN. Certainly throughout the time that this issue has been around, we have certainly consulted with and worked with representatives from all communities, the bio-tech community, the faith community, the legal community. We have worked with all because this issue does have implications for all.

And for that reason—I cannot document for you at this point who everyone has met with within the administration. But certainly, there has been consultation and work with—as we have developed these positions.

Mr. GREENWOOD. Now, Mr. Allen, when you—when you responded to Mr. Waxman's question on the—and you described the technical difference between a nuclear transferred embryo, if you will, and one that is produced by the union of the male and female reproductive cells—so, you correctly described why—the technical difference between in vitro fertilization and somatic and nuclear cell transfer.

Now, what is the ethical distinction that you are making—that this administration is making here?

Mr. ALLEN. The administration has not made an ethical distinction between those two in this regard. What we are focusing on is—and I think the distinction, with all due respect, the Greenwood bill, is the distinction that is made there, that it is appropriate for banning it as far as reproductive purposes, but allow the research purposes to go forward.

What we are concerned about, as I have stated earlier, is the fact that that is a very, very thin line to divide upon because it is too easy, too simple to cross that line.

Mr. GREENWOOD. So, if I understand you, sir, what you are saying is that it is—that this administration's policy is based on not an ethical decision whether it is good for humanity to use this regenerative, therapeutic medicine to save the lives of potentially millions of people, but it is making a distinction on the basis—basis of that notion that the egg, that the cloned egg, once that process has occurred, could be diverted to break the law that I am trying to write, that it could be diverted for that purpose and go—become used as—for reproductive cloning.

Is that the administration's position?

Mr. ALLEN. If I understand your question, Mr. Greenwood, the administration's position would be that we believe that—that both reproductive and research purposes of cloning, using somatic cell nuclear transfer cloning, would be what we support in prohibiting for the mere reason that it is a very easy leap from one to the other.

Beyond that, I think it is important to recognize that is not simply based upon science. It is not simply based upon moral or ethical considerations. It is based upon the combination thereof.

And as a policy decision, we believe that, at this time, that it is important that we send a very strong message that human—that the production or the creation of a human being by the means of cloning, whether accidental or intentional, should be banned.

Mr. GREENWOOD. Well, we all agree on that. But what I am—what I am trying to hone in on here is this administration is not taking the position that something unethical or immoral has happened at the moment of the somatic cell transfer, but rather it is the potentiality of that cell then being implanted in the uterus that is the danger?

Even though we outlaw that in our bill, it is the potentiality that that could be transferred——

Mr. BILIRAKIS. Very, very brief response to that.

Mr. ALLEN. I think that is a fair——

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. ALLEN. Yes, I think that is a fair summation of the position.

Mr. GREENWOOD. Thank you.

Mr. BILIRAKIS. Mr. Deutsch?

Mr. DEUTSCH. Thank you, Mr. Chairman. You indicated that the administration supports legislation to ban therapeutic and reproductive cloning. Can you indicate how this ban that you endorse will be enforced?

Mr. ALLEN. Well, I believe, at this point, what we are looking at is the enforcement mechanisms that are cited in the bills before us. Certainly, the FDA plays a role in that as it regulates both the biological and other aspects, both under the products bill as well as the FDA's other statutory authority to do so.

It has enforcement mechanisms, and we currently do that in other areas. And we believe this would be similar to that as well.

Mr. DEUTSCH. All right. Again, just from an enforcement standpoint, would you wait until you hear a tip or require some information indicating that someone wants to clone, or will you act perspectively by doing random site visits and interviews?

Mr. ALLEN. I believe the FDA does both at this time. We receive tips, and we do act upon random site visits consistent with the authority that the FDA already has in both of these areas.

Mr. DEUTSCH. All right. The administration budget recites the grim statistics on the lower number of site inspections on foreign and domestic facilities under FDA jurisdiction. The FDA cannot even identify all the facilities that make prescription drug ingredients that are introduced into commerce in this country.

FDA and Customs inspect less than 1 percent of imports of food, drugs, and other items under FDA jurisdiction. NIH says that it lacks expertise on the subject of cloning. What assurance can you give that the administration is serious about enforcing a ban on human cloning?

Mr. ALLEN. We would work with—in this area, certainly there are a number of options available to the administration. Certainly, we can re-deploy existing resources within the Department to try to begin to address these issues, as well as seek additional appropriation should that be necessary to do so.

But the FDA currently believes that it is able to enforce, and does enforce, the laws as they currently exist. And this would be simply a further area for——

Mr. DEUTSCH. Is the deterrent effect of the Weldon bill sufficient prevention for the cloning of humans?

Mr. ALLEN. Could you resay——

Mr. DEUTSCH. The Weldon bill, the prohibitions that it has, do you believe that is a sufficient deterrent?

Mr. ALLEN. We believe that the Weldon bill does suggest, and leads in the right direction, of what we believe is a policy statement that should be enforced. And that is a total ban on human cloning. We believe there are some technical adjustments to the bill that probably could improve upon, and that is what we are willing to work with the committee and the Congress on to try to accomplish.

Mr. DEUTSCH. Earlier this year, the Oversight and Investigations Subcommittee held a hearing on the subject of human cloning. At that hearing, and the media events approximate to it, various individuals, some claiming to be aliens, made statements to the effect

that they intended to clone a human being in the United States in the near future.

The FDA testified that they were aware of these claims and were investigating the matter. Can you tell us, in detail, what steps the administration has taken since then to investigate these matters and, if necessary, to stop human cloning.

Mr. ALLEN. I know that the administration—the FDA is currently looking into these assertions of the possible existence of a human cloning laboratory here in the United States. And it is FDA policy not to discuss publicly investigation techniques or strategy.

However, Dr. Zahn is here from the FDA, has testified on these areas in the past, and I believe she would be prepared to give you some more detail on that at the appropriate time.

Mr. DEUTSCH. So, it is fair to say that there is an ongoing investigation then?

Mr. ALLEN. It is fair to say that we are aware of it and are investigating, yes.

Mr. DEUTSCH. Okay, let me ask you a question regarding the administration's position. You know, obviously, there is this—the issue that—in terms of what we call therapeutic cloning, that the research potential is incredibly dramatic. And the administration's proposal, as I understand it at this point, is to ban those.

And I understand the policy reasons why you are suggesting to ban those. I think what is clear from my opening statement, I mentioned that it is clear that this research is going to go on whether or not the United States bans it.

It is going to go on in other countries because other countries do not consider it the same as the administration's position. Would that then be the administration's position to ban the importation of drugs that were—that were basically researched or, in fact, substances that were the benefits of human—of stem cell research?

What would the administration's position be in that area?

Mr. ALLEN. The administration has not taken a position on that at this point. What we are focusing on are the two bills. Of course, the Weldon bill does—I am sorry, the Weldon-Stupak bill does focus on importation and banning that.

And for that reason, we believe that that is an appropriate response under the legislation to do so. But the administration has not formulated a position as to——

Mr. DEUTSCH. Again, I really—I am going to ask that question again and try to hear a clear answer because, to me, it is—it is, you know, really almost shocking what you have just said, that in a case of the research—because this is not—I mean, it is hypothetical at this point, but some of the potential seems incredible, as Mr. Strickland mentioned.

And I think talking about the reality, talking to families, talking to real people who are suffering from incredibly debilitating illnesses where it is clear that the potential to make, you know, absolutely miraculous recoveries, that, in fact, your position would be that if those drugs existed to cure paralysis, to cure cancer, that your position would be that those drugs would not be able to be imported into the United States of America.

Mr. BILIRAKIS. Let us finish up here.

Mr. ALLEN. Certainly. Congressman Deutsch——

Mr. BILIRAKIS. The time has expired.

Mr. ALLEN. [continuing] it should not be remarkable that we are not outright saying that we would allow the importation of that. The FDA does that every day. There are many drug therapies and other techniques that may have been developed elsewhere, but we have a responsibility to protect the health and safety of Americans.

And absent a review of that and consideration of the impact that that may have on human life, it would not be irresponsible to say we would ban it at this point. But we leave open the possibility and the prospect that should there be developed, and should there by, hypothetically, therapies that could benefit American people, it will go through the same process by which we would allow that to take place and to be imported into this country.

Mr. BILIRAKIS. Dr. Ganske to inquire?

Mr. GANSKE. Thank you, Mr. Chairman, and thank you, Mr. Allen, for being with us today. Up until just a few days ago, Secretary of Health and Human Services, Tommy Thompson, was saying that he, "wasn't sure what the President's position was."

Now, we have your statement today, and this is the President's position. Is that right?

Mr. ALLEN. That is correct.

Mr. GANSKE. And this is the Secretary's position?

Mr. ALLEN. That is correct also.

Mr. GANSKE. All right. Well, let us—I just want to be absolutely clear on this. On page 5, you say, "As we interpret the bill, it prohibits not on the use of human somatic cell nuclear transfer to initiate a pregnancy, but also all," underline that, "all other applications of somatic cell nuclear transfer with human somatic cells, such as cloning to produce cell or tissue-based therapies."

That is consistent with Secretary Thompson's and the President's views? Let us just be absolutely clear.

Mr. ALLEN. That is correct.

Mr. GANSKE. Okay. So, now, are you saying that it is the administration's position that it should be illegal for anyone to do somatic cell nuclear transfer?

Mr. ALLEN. Within the context of the jurisdiction of the United States, that is correct. That is what we have the authority to control.

Mr. GANSKE. So, the ongoing work in that area you would make illegal?

Mr. ALLEN. At this point, what the administration's position is, as stated there, is indeed the use of somatic stem cell nuclear transfer cloning techniques are what we are focusing on here. And that is the administration's position.

Mr. GANSKE. How does the administration answer the groups like Juvenile Diabetes, and the groups that are concerned with spinal cord injury, the groups that are looking—that the—the kidney failure groups that are looking to potentially be—we have a tremendous shortage of kidneys. They are looking for an opportunity to be able to develop a kidney. I am kind of interested in an answer.

Mr. ALLEN. The position. It is focusing solely on the use of a technique of somatic cell nuclear transfer for cloning purposes. We are not saying that other techniques that are currently proven to

be efficacious for the very issues that you have raised could not be continued. That research is untouched.

Mr. GANSKE. Is the administration aware that there are a number of very pro-life United States Senators who have expressed an opinion on this, such as former Senator Connie Mack and others who would probably vehemently disagree with the—this administration's position?

Mr. ALLEN. We are aware that the position the administration has taken is based upon the concern for—as the bills presented here today point out, and that is, is that there are no therapies that have been developed in the area that rely upon embryonic—rely upon pre-natal cloned cells.

That point has not been taken, and it does not take away all the other therapies, all the other research that is ongoing to provide for the cures that you are talking about. We believe that there is no boundaries that have been established for the vacuum that is created.

And if we allow and say that we support the use of cloned cells for that purpose, if we say that we support that, that opens up the——

Mr. GANSKE. Is it this administration's position that the FDA currently has the authority, then, to stop this procedure?

Mr. ALLEN. While we believe that that is not necessary for this discussion, that position to address this, because under the legislation, particularly the Weldon-Stupak bill, it alleviates the need to arrive at that position because it bans both reproductive and research in those areas.

Mr. GANSKE. Do you think—but do you think the FDA has the authority to stop this now?

Mr. ALLEN. I cannot give you a personal opinion on that. The administration, certainly the FDA, can speak to that specifically. Dr. Koon has spoken to that in the past, and I believe she is prepared to do so if——

Mr. GANSKE. Is the FDA making plans, then, to go into private laboratories to stop this type of research?

Mr. ALLEN. Those plans are not underway at this time. That is not the——

Mr. GANSKE. But consistent with the administration's statement here that that would be—I mean, that would be consistent with this administration's statement.

Mr. ALLEN. Upon the passage of the legislation, this administration would be prepared to work with the committee to implement the law to the full effect, according to the regulations that are provided.

And any other—any further clarifications of all that would be necessary, we would be willing to seek that from the Congress.

Mr. GANSKE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Stupak to inquire?

Mr. STUPAK. Thank you, Mr. Chairman. Mr. Allen, I would like you to clarify a statement you made regarding tissue-based therapies. You and the administration only object to tissue-based therapies derived from cloned human embryos. Is that correct?

Mr. ALLEN. I am sorry, I could not hear.

Mr. STUPAK. Sure. The administration, and you representing the administration, only object to tissue-based therapies derived from cloned human embryos, correct?

Mr. ALLEN. That is correct.

Mr. STUPAK. In fact, our bill specifically says, is it your understanding, that we do not restrict areas of scientific research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells, other than human embryos, tissues, organs, plants, or animals, other than human beings. Is that correct?

Mr. ALLEN. That is correct.

Mr. STUPAK. And so, some of the questions like the statement Mr. Strickland made, and even the question Mr. Deutsch asked, what if, our bill also, in this last part sentence of the Congress, also says if further therapies or research becomes available, they could always come back before the legislative body and say we need some relief in this area as we are doing this research.

We leave it to the scientists to tell us when to come back, and not just a prohibition. Is that your understanding?

Mr. ALLEN. That is our understanding. In fact, for those two reasons, the section—subsection (d), the scientific research, where it makes very clear what this—this bill not forescribe, make it a reason why we believe that those therapies can continue, those efforts of research continue, and why the administration believes that it is appropriate to speak very strongly on what we do prohibit and support.

Furthermore, we believe that the—the ability here for science does change. And if the science demonstrates that embryonic cloning is ethicacious, safe, and effective, there is an opportunity again, a safety clause here, that allows for review.

And we believe that that also is an appropriate way to address the issue.

Mr. STUPAK. And the administration, it does not object to other forms of tissue replication or cell-based therapies, do they?

Mr. ALLEN. No.

Mr. STUPAK. Pardon?

Mr. ALLEN. No, we don't.

Mr. STUPAK. Okay. Are there any therapies, medical uses from cloning, even stem cells, in existence right now?

Mr. ALLEN. We are not aware of any, no.

Mr. STUPAK. Okay. Thank you, Mr. Chairman, and I yield back.

Mr. BILIRAKIS. I thank the gentleman. Dr. Norwood?

Mr. NORWOOD. Mr. Allen, I am going to basically ask you to repeat yourself. I am only going to ask you two questions, and I want you to take plenty of time and give us a lengthy, clear-cut answer. Does the administration support the Greenwood bill?

Mr. ALLEN. We do not support the Greenwood bill because it does allow for research cloning. So, we do not support the Greenwood bill.

Mr. NORWOOD. And is that the only reason?

Mr. ALLEN. That is principally a reason. There are other reasons that we would want to look at—again, there are technical issues that we would need to address. I could highlight a couple of those: one, just the impact that it has on inconsistency among the States.

It was stated earlier that a number of States have already acted in this area. The Greenwood bill preempts much of what those—what other States may do in those areas. And so, that would cause for some concerns.

Some States that have varying degrees of how these address these issues—by preempting some and not others, it does create for some interpretation issues, as well as enforcement issues for the Department.

Those would be principally some of the areas that we would have concerns about.

Mr. NORWOOD. All right. To your knowledge—and the Congressman can speak for himself; but to your knowledge, has Congressman Greenwood worked with the administration to see if he could—if the two of you could work this out?

Mr. ALLEN. To my knowledge—again, personally, I have only been on-board for a very short while. So, therefore, I am not aware of—and we would be certainly willing to sit down with Congressman Greenwood to talk about that and address many of these issues.

But I think on the policy issue, the policy decision about—which the administration is very clear on, is the prohibition against all forms of cloning.

Mr. NORWOOD. I will yield.

Mr. GREENWOOD. Thank you, gentleman, for yielding. Here is a problem we have, Mr. Allen. We all agree, the administration, everybody in this room, everybody probably—practically everyone in the Congress, we need to ban human reproductive cloning.

And if we don't do something legislatively, we may very well, very soon, be in a position where people are actually trying to do something that we all agree is very unsafe and very unethical, and that is to try to create human beings through cloning.

There is huge disagreement on the second part of this, the therapeutic part. And I would predict, I think accurately, that we are never going to get a Weldon-style bill through the U.S. Senate.

There was precedent for that when the Republicans were in control, and you are certainly not going to get a Weldon-type bill that bans the therapeutic cloning through the Senate.

So, now we are in a position that we are going to fail, as a Nation, to ban reproductive cloning because we can't get past this issue of therapeutic cloning. And what I have been trying to argue is, if we want to prohibit therapeutic—the reproductive cloning, let us do it, which is what our bill does, and leave to another day the debate about he therapeutic cloning. And I guess my question——

Mr. NORWOOD. Excuse me, I have got to reclaim my time to get to the next question.

Mr. GREENWOOD. Okay, all right. Well, let me——

Mr. NORWOOD. But you——

Mr. GREENWOOD. I thank the gentleman for yielding.

Mr. NORWOOD. Mr. Allen, does the administration support the Weldon-Stupak bill?

Mr. ALLEN. The administration does not actively endorse the Weldon-Stupak bill for the reasons I have cited. Also, there are some areas that we believe that are technical questions that——

Mr. NORWOOD. Well, speak up. What are those areas?

Mr. NORWOOD. A couple of those areas, for example, is in the bill itself—one of the concerns is within the definition section, define of the term "asexual reproduction." There were some concerns about the ability to maneuver around the word of what—without defining specifically what asexual reproduction is would be one area that we would certainly want to work with and clarify.

The issue of importation, banning of the importation of—I believe—I am not sure exactly—Congressman Waxman raised the question about that. What would actually be banned? Will we be banning—if a child was born that was the product of cloning, would we be ban that?

Also, the meaning of "nuclear material" is another question. I know that—what we think the intent of the bill is, but we would want to seek clarification of what nuclear material would be. Those are just a few areas that——

Mr. NORWOOD. And well, I am in the cautionary, so just quickly and last, does the White House believe we need to legislate this year on this issue?

Mr. ALLEN. The White House has not taken a position as far as legislating. We do believe that there is significant concern and significant harm based upon statements that have been made, whether real or fictitious, however close they may be.

But we do believe that there is a significant concern that if we do not legislate in this area, that we could move very quickly down this track, whether it is for research purposes that could ultimately lead to reproductive purposes for cloning. So, we would say yes, we believe that there needs to be some action in this area this year.

Mr. NORWOOD. I suspect we all agree with that. So, I hope you will encourage the White House crew to work with Mr. Weldon, and Mr. Stupak, and Mr. Greenwood, because we need to get this done.

Mr. ALLEN. We will do that.

Mr. BILIRAKIS. Mr. Pitts to inquire?

Mr. PITTS. Thank you, Mr. Chairman. Secretary Allen, to my knowledge, three people: a Dr. Bosalier, Dr. Okarma, and Dr. Zabos have informed the committee that they all intend to clone human embryos.

How has the FDA, or has the FDA, used their authority to monitor and regulate the activities of these researchers who intend to clone human embryos, two of whom, we are told, intend to implant?

Mr. ALLEN. Without discussion—discussing or disclosing the FDA's techniques for investigation, we will say that we have taken these claims very seriously. And in some instances, contact has been made with the principals who said that they intend to do this.

And we have discussed very carefully with them the requirements for such—beginning of such research. For example, the FDA requires that an investigational new drug application be filed by anyone or any entity that seeks to begin moving down this track. None have been filed.

And thereby, we would notify and work with any of these individuals to let them know that that is a requirement, and that FDA would seek to enforce in that area.

Mr. PITTS. I have an enforcement question. The FDA says they have the power to regulate the entire cloning process if the intent is to implant the cloned embryo into a surrogate mother.

If FDA officials showed up at a laboratory, how could they distinguish between those cloned embryos destined for destruction by experimentation and those destined for implantation?

Mr. ALLEN. That is an excellent question. And that is the reason why we believe that you must ban all, because you cannot make the distinction based upon intent. And whose intent are we referring to? Is it the intent of the one who created the clone through the process, or is it the intent of that individual who seeks to implant?

Those are questions that must be worked out. And the FDA does not have the ability to make that discern—to discern that.

Mr. PITTS. And one final question: on the bottom of page 2 of your written testimony, you state, "Additional concerns beyond the scope of FDA's role remain to be resolved, especially the broad social and ethical implications of cloning human beings, such as whether the use of human somatic cell nuclear transfer is morally acceptable under any circumstance."

Yet, your written testimony also states that, "The administration opposes the use of human somatic cell nuclear transfer cloning techniques either to assist human reproduction or develop cell or tissue-based therapies."

That sounds to me as if that additional concern has been resolved by the administration. Am I correct?

Mr. ALLEN. If I understand your question, the answer will be yes.

Mr. PITTS. Okay, thank you, Mr. Chairman.

Mr. GREENWOOD. Would the gentleman yield? Would the gentleman yield?

Mr. PITTS. I will be happy to yield.

Mr. GREENWOOD. Mr. Allen, if you came into a laboratory where this kind of research with somatic transfer was taking place, and you find on that laboratory table an egg that has had its genetic material transferred and a gun, how do you know—how do you—isn't the question of what the intent is the same for—in both instances?

In other words, why not confiscate the gun and the cells because we don't know what the intent is of the user, whether the user intends to commit a crime with either one of those?

It seems to me to be a very strikingly absurd position to say that in most instances, we respect the freedom of individuals to say that they have not committed a crime until they commit one. But in this instance, we want to stop them before because we do not understand what their intent is. What is the distinction there?

Mr. ALLEN. Mr. Greenwood, I think it really raises the question about the intent language in your bill, specifically. And I think that that—I would turn that back to you and say that that is the concern that we have with your bill, is that it requires us to figure that out.

And we have no way of doing that, top figure out whether a set of embryos are set for research purposes as opposed to being shipped and ultimately used for reproductive purposes.

And the way to deal with it at this point is to ban both.

Mr. GREENWOOD. Thank you, gentleman, for yielding.

Mr. BILIRAKIS. I thank the gentleman, as a courtesy to a member of the full committee—well, no, I see that Mr. Green has now appeared. Mr. Green to inquire?

Mr. GREEN. Yes, Mr. Chair. And I know we have a vote on, so I will be as quick as I can.

Mr. BILIRAKIS. No, it is a recess.

Mr. GREEN. Oh, okay, that is even better.

Mr. BILIRAKIS. You still can be brief though.

Mr. GREEN. Oh, okay, I will try and be brief, then, Mr. Chairman.

Mr. Allen, your statement that the administration opposes somatic cell nuclear transfer for both therapeutic and reproductive purposes, but that it supports other approaches to development of these therapies such as research of genes, cells, or tissues from humans or animals consistent with current law—can you elaborate on the phrase "consistent with current law"?

Current law, for example, provides that Federal funding is available for research that uses embryonic stem cells. Are we to take from your statement the administration has now settled on its position on the matter? I guess current law is a——

Mr. ALLEN. If I understand your question referring to stem cell research, the President will make a statement. He will make a decision as to the administration's position on stem cell research, embryonic stem cell research.

That is not my place to do that. And he will make that statement, and it will be a very clear statement about that. What we are focusing on here is solely on the issue of cloning and using cloned human embryos for the purpose, whether it be for stem cell research or for reproductive purposes as well.

So, it is a very narrow review. The issue of stem cell research will be discussed at a later date by the President, himself.

Mr. GREEN. Okay, but does the administration—the administration does not support the use of any kind of research into human cloning for stem cell research, or is that something we are going to wait for the Secretary?

Mr. ALLEN. The answer would be—if it uses human cloning, then the answer would be no.

Mr. GREEN. Okay. You indicate that the concerns of scope of the FDA role remain to be resolved, such as whether the use of human somatic cell nuclear transfer is morally acceptable in any circumstances.

Elsewhere in your statement, you clearly support a total ban on SCNT. Yet, this argued statement I just quoted implied that you are not sure, that the administration's position could change.

Under what circumstance, if any, would the administration support therapeutic use of human somatic cell nuclear transfer?

Mr. ALLEN. We believe that it is a very responsible position to say that we should ban this entire area at this point. Science may advance. There may be therapies that can be developed based first upon animal cloning techniques to see whether they are ethicacious in humans.

Thereby, one of the reasons why the Weldon-Stupak bill, we believe, has some advantages to it is that it does allow for a review period after a scientific panel has looked at this entire area.

And for that reason, we believe that—that it is important that we remain flexible on what might be without being absolute in that position.

Mr. GREEN. I don't think I have anything else. Thank you, Mr. Chairman; I yield back.

Mr. BILIRAKIS. I thank the gentleman. Ms. Cubin to inquire?

Ms. CUBIN. I don't have anything.

Mr. BILIRAKIS. Thank you. Mr. Brown, do you have——

Mr. BROWN. No, I am not ready yet.

Mr. BILIRAKIS. We are all finished up with the exception of extending courtesy to a member of the full committee, Ms. DeGette.

Ms. DEGETTE. Thank you so much, Mr. Chairman. And again, I appreciate your courtesy. Mr. Allen, you had testified, I believe in response to Mr. Greenwood's question, that the way the administration developed its position on this issue was you have experts internally, and you also consulted the NIH. Is that correct?

Mr. ALLEN. The NIH would be considered internally as well. Our position is——

Ms. DEGETTE. Okay, but you did consult the NIH?

Mr. ALLEN. The NIH would certainly be a part of the Department——

Ms. DEGETTE. And were——

Mr. ALLEN. [continuing] and their opinions would be——

Ms. DEGETTE. [continuing] they consulted here, sir?

Mr. ALLEN. Their opinions would certainly have weighed into where we are, yes.

Ms. DEGETTE. Okay, because the reason I ask is on March 26, we received a letter from Ruth Kirchstein, who is the acting Director of the NIH, who said, "NIH, itself, lacks experience in this area of cloning research," and they declined to testify in the March hearing we had in the Oversight and Investigations Subcommittee because they didn't have any experience.

Mr. Chairman, I would ask unanimous consent to submit that letter for the record.

Mr. ALLEN. And I appreciate that, but that is not inconsistent with what I have——

Ms. DEGETTE. Okay, thank you——

Mr. ALLEN. [continuing] said in that we are working with——

Ms. DEGETTE. [continuing] sir, I just—I just want——

Mr. ALLEN. [continuing] the NIH.

Ms. DEGETTE. [continuing] the record to be clear the NIH does not feel it has expertise in this area. Now, let me ask you, Mr. Allen, you had testified, I believe in response to Mr. Pitts' questioning, that you go into these labs, you see these cells sitting here, and you can't really tell what they are for. So then, all this research might as well be banned.

Is it the administration's position that in vitro fertilization should be banned as well since, when we walk into labs, if we see fertilized eggs, we don't know what is going to happen with those?

Mr. ALLEN. The answer would be no.

Ms. DEGETTE. Why not?

Mr. ALLEN. Because in vitro fertilization—there is a distinction between the two, and I think I explained a little earlier——

Ms. DEGETTE. Well, I know the distinction between the two, but here is my concern. If you walk into a research lab, and you see a bunch of fertilized eggs, how are you going to know what the purpose is? Is the purpose going to be to take the—to take the DNA out and to clone cells, or is the purpose going to be to go in and implant those for in vitro fertilization?

How are you going to know the difference when you see that matter in a research lab?

Mr. ALLEN. Well, we don't know the difference when we see that matter in——

Ms. DEGETTE. Okay.

Mr. ALLEN. [continuing] the research lab.

Ms. DEGETTE. So, how—how is it that you are going to allow one but not the other?

Mr. ALLEN. In vitro fertilization is something that is already regulated under FDA. And therefore, the protocols, the processes, and procedures would have already been considered by FDA, and have been reviewed. And this certainly——

Ms. DEGETTE. Well, but the—I don't suppose it has been reviewed by FDA under the Weldon-Stupak bill or the Greenwood bill, right?

Mr. ALLEN. That is correct. And in both of those circumstances, that protocol would be developed upon passage——

Ms. DEGETTE. Well, how—do the——

Mr. ALLEN. [continuing] of the legislation.

Ms. DEGETTE. [continuing] little cells have nametags? I mean, how are you going to know? I don't—I am not meaning to be flip here, but you walk into a research lab; how are you going to know the purpose of those fertilized eggs?

Mr. ALLEN. All the more reason why, in this area of cloning, when we are talking about cloning cells—one point that I think is important to make, what this legislation again does not prohibit, it does not prohibit in vitro fertilization. It does not prohibit twinning of cells for the purpose of implantation.

Ms. DEGETTE. Okay, but those——

Mr. ALLEN. But those are issues that we——

Ms. DEGETTE. But they can't be—the difference cannot be visually determined. Would that be correct?

Mr. ALLEN. I am not the scientist here. I would imagine that you are correct, that it is not—that is correct.

Ms. DEGETTE. Okay, thank you. Now, I have another question. I am sorry, they only give us 5 minutes, and I am already pushing my——

Mr. ALLEN. But I assume you want me to give you full answers and complete answers so that it is not incorrect for the record. So, if you would——

Ms. DEGETTE. Let me ask you one more question, which is that in the Weldon-Stupak bill, and you just talked about this for a moment when Mr. Green was questioning you, that bill says that the scientific community can come back if they feel like cloning research would be necessary for some non-human reproductive purpose, correct?

I think it says the scientific community can come back and request——

Mr. ALLEN. No, actually, it requires the scientific—it requires a report to be issued to the Secretary and the President that will already affirmatively address that in a 5-year period.

Ms. DEGETTE. Okay.

Mr. ALLEN. Prior to that time——

Ms. DEGETTE. Okay, what——

Mr. ALLEN. Prior to that time——

Ms. DEGETTE. Uh-huh.

Mr. ALLEN. [continuing] if there is—if there are advances that are made known, certainly the Department would be looking at that as we are ongoing in this area.

Ms. DEGETTE. Right. Here is my question to you: if we ban the research, how are they going to be able to make a report? If they can't do the research, how are they going to be able to tell you what the benefits of this type of research would be?

Mr. ALLEN. Very simply, in that they can do the research in other mammals.

Ms. DEGETTE. But that is not——

Mr. ALLEN. They can do the research——

Ms. DEGETTE. But that is not this exact type of research, right?

Mr. ALLEN. Correct, it is not because——

Ms. DEGETTE. Okay.

Mr. ALLEN. [continuing] this is an area that we are talking about banning.

Ms. DEGETTE. So, you are saying they——

Mr. ALLEN. Can I actually——

Ms. DEGETTE. [continuing] can transfer animals——

Mr. ALLEN. [continuing] just finish an answer—complete the question because I want to——

Ms. DEGETTE. Go ahead.

Mr. ALLEN. [continuing] give you a complete answer. And I think that—that the record is entitled to see that——

Ms. DEGETTE. Go ahead, finish.

Mr. ALLEN. [continuing] very clear. Is the answer is very clear; the research, the language of the Weldon-Stupak bill allows for ongoing research and consideration of the scientific ethicacy of all of these areas that we are talking about.

Currently, what we are talking about is that you can do this in every other area, but there is no indication that there are therapies that have been developed, nor should—the position of the administration is nor should they be at this point, absent an indication that they would be both safe, ethicacious, and that there are moral, legal boundaries that are put around that research.

Ms. DEGETTE. Thank you.

Mr. BILIRAKIS. The gentlelady's time has expired. Mr. Allen, the in vitro fertilization would ordinarily take place in a research lab?

Mr. ALLEN. Not likely.

Mr. BILIRAKIS. Ordinarily, not likely?

Mr. ALLEN. Usually, it takes place in a fertility clinic.

Mr. BILIRAKIS. Right. So, ordinarily, they wouldn't be side by side on a table, or a group of tables in a laboratory?

Mr. ALLEN. That is correct, Mr. Chairman.

Mr. BILIRAKIS. Mr. Burr to inquire.
Mr. BURR. Am I the last, Mr. Chairman?
Mr. BILIRAKIS. You are not the last; Mr. Brown will be the last.
Mr. BURR. Could I pass to Mr. Brown and come back to me?
Mr. BILIRAKIS. If Mr. Brown is willing to——
Mr. BURR. I am still trying to get caught up on the——
Mr. BILIRAKIS. [continuing] accept that pass.
Mr. BROWN. Mr. Burr, I probably could.
Mr. BILIRAKIS. No, no——
Mr. BURR. I will say some nice things about Mr. Brown.
Mr. BILIRAKIS. [continuing] discussion on tax cuts now.
Mr. BROWN. Well, Mr. Chairman, since you brought up the tax cut and you always seem to need to do that——
Those of you that don't come to this hearing, don't get that. It is really rather a stupid inside joke, but nonetheless. I yield my 5 minutes actually to Ms. DeGette. Thanks.
Ms. DEGETTE. Thank you, Mr. Chairman. Just a couple more questions.
Mr. ALLEN. Certainly.
Ms. DEGETTE. You had, I think, testified in response to someone's question that we have not yet seen any kind of scientific—direct scientific result from human stem cell research, which is accurate, I believe, right?
Mr. ALLEN. I don't think I—that is not correct.
Ms. DEGETTE. Okay.
Mr. ALLEN. We do know that there were use of human stem cell research in some of the Parkinson's and Alzheimers cases that were absolutely disastrous. So, we do have some evidence of their use.
Ms. DEGETTE. But we also have some evidence from Canada, don't we, about the use of stem cell research in Type-1 diabetes?
Mr. ALLEN. I will have to defer to you on that. I have not seen that.
Ms. DEGETTE. Okay, well, I will let you know because I am the co-chair of the Congressional Diabetes Caucus, that we have seen some promising——
Mr. ALLEN. Oh, I wasn't——
Ms. DEGETTE. [continuing] stem cell research in Canada. And also, in April, scientists at the National Institutes of Health used mouse embryonic stem cells to generate insulin-producing organs resembling the islets of the pancreas. Were you aware of that research?
Mr. ALLEN. I was aware of that.
Ms. DEGETTE. So, I think you would agree with me we are seeing some very promising stem cell research coming out, would you not?
Mr. ALLEN. Actually, I think the two examples you posited, it demonstrates that use in other mammals, that it is been very promising. But in use of humans, it has not been.
Ms. DEGETTE. Well, actually, there has been some use in humans in other countries and——
Mr. ALLEN. Those two examples you have posited that are—that is what I am going on.
Ms. DEGETTE. Yeah.
Mr. ALLEN. I am not the scientist.

Ms. DEGETTE. And actually, I think you were the one that testified that mammal research is often transferrable to humans, which is why we do research on mammals.

Mr. ALLEN. Which is why we should perfect mammal research prior to experimentation on humans.

Ms. DEGETTE. I don't think anybody would disagree with that, certainly with cloning. Let me ask you another question, which is, as I—what is the administration's position on products which may be developed by use of this type of cloning process, perhaps developed overseas?

Let us say, for example, some kind of products that dramatically, positively impact Parkinson's patients are developed, would it be the administration's position that those products should be banned in the United States?

Mr. ALLEN. They would be subjected to the same protocol that other products would be subjected to by the FDA before they are allowed to be—allowed to be utilized in the United States. We do that with other areas. We have done it in the area of——

Ms. DEGETTE. Sure.

Mr. ALLEN. [continuing] cancer, so it would be the similar——

Ms. DEGETTE. Well, as I understand the Weldon-Stupak bill, products developed with this type of cloned material would banned. So, would the administration support that part of the—that bill?

Mr. ALLEN. That is one of the areas that I said that we would need to work out with technical assistance with the bill patrons to consider and see what impact it has on other areas of what we do approve of and support.

Ms. DEGETTE. Now, getting back to your point about FDA approval, is—I know safety and ethicacy are two of the criteria used by the FDA in deciding whether or not to approve a drug.

For example, if we had a Parkinson's drug that was developed overseas with use of these cloned techniques, would—I would assume the FDA will use those same standards in deciding whether to approve the drug, unless it was banned, right?

Mr. ALLEN. I would—if I understand your question correctly, I would say that is correct. And it goes back to your prior question. That is why we believe that having a period—an absolute ban on that is imperative.

However, the administration is not saying that we are not willing to look at—look at what has been done. And that is not——

Ms. DEGETTE. I am sorry——

Mr. ALLEN. [continuing] inconsistent.

Ms. DEGETTE. [continuing] I am kind of confused because you are—on the one hand, you are saying that we should have a ban on these products. But then, you are saying, well, we need to look at it. I don't know what you mean by that.

Mr. ALLEN. What I mean by that is very clear. I think it is very imperative, and the administration believes it is imperative, that we take a position, a very clear position, on what we believe is——

Ms. DEGETTE. Yeah, I get that, but what is that——

Mr. ALLEN. You got that part.

Ms. DEGETTE. [continuing] clear position? That is not what I get.

Mr. ALLEN. Okay, the clear position is that the administration is opposed to the use of stem cell nuclear transfer cloning for research or reproductive purposes.

Ms. DEGETTE. Well, obviously, the reproductive purposes, we all——

Mr. ALLEN. Research or——

Ms. DEGETTE. [continuing] agree on that.

Mr. ALLEN. [continuing] reproductive.

Ms. DEGETTE. Now, on the research, let us say a drug is developed——

Mr. BILIRAKIS. The gentlelady's time, or I should say the gentleman's time, is expired.

Ms. DEGETTE. Thank you.

Mr. BILIRAKIS. Mr. Burr to inquire?

Mr. BURR. I thank the Chair's indulgence. Mr. Allen, tell me what the administration says to those folks around this country that potentially might be waiting for a breakthrough into the current research that is out there.

Mr. ALLEN. Well, the administration's position would be that there are ample existing therapies and treatments, and very promising areas to address many of these areas—many of these concerns, whether it is for cancer, organ, bone marrow transplants. I saw an article in the paper this morning.

And we believe that we should be very aggressive in pursuing, and very aggressive in supporting, that research.

Mr. BURR. Is the research that is currently being done, are the scientists that are currently working on somatic cell nuclear transfer, are they wrong? Is there something there that HHS and this administration sees that says they won't be successful?

Mr. ALLEN. We believe that there is something that the research, thus far—I think the discussion earlier was in the area of where we have seen some of this occur is in the stem cell research area where there was use of embryonic stem cells for Parkinson's and Alzheimers that had very deleterious effects on the individuals that the therapies were used on.

In this area, we believe also that we need to be very careful, extremely careful, of going down that road because of the impact not only on the mother and child that may be produced as a result of cloning, but also the impact that it has on society. There are psychological; there are also moral——

Mr. BURR. Is this a policy decision or is this a scientific decision?

Mr. ALLEN. We believe that it is a policy decision that is based on the science. And that is why I think, contrary to the——

Mr. BURR. Who made this decision?

Mr. ALLEN. This is the decision of the President and the Secretary of Health——

Mr. BURR. And they made——

Mr. ALLEN. [continuing] and Human Services.

Mr. BURR. [continuing] that decision, when?

Mr. ALLEN. I am here providing that position.

Mr. BURR. I know you are here delivering the message today. When did they make the decision? When did you and the Secretary have a conversation relative to this decision?

Mr. ALLEN. My conversation—again, I have been on-board all of 2 weeks, so I will have—I would have talked with the——

Mr. BURR. Well, clearly, it must have——

Mr. ALLEN. —Secretary during that time.

Mr. BURR. [continuing] happened sometime in that period.

Mr. ALLEN. So, it happened within that period. I cannot speak specifically for when the President made his mind up about this issue. I do know that——

Mr. BURR. Do we condone——

Mr. ALLEN. [continuing] when the——

Mr. BURR. Do we condone the research that is currently going on in the U.K. as it relates to stem cell research?

Mr. ALLEN. I am not here to comment on the efforts of the work that is done in other countries. We have a responsibility——

Mr. BURR. Do we condone——

Mr. ALLEN. [continuing] for what takes place in——

Mr. BURR. If they were to—if they were to——

Mr. ALLEN. If I may——

Mr. BURR. [continuing] make legal——

Mr. ALLEN. [continuing] Finish my——

Mr. BURR. [continuing] human cloning, would we come out against that policy?

Mr. ALLEN. Again, that is something that is left for the British Government and its citizens to decide what is in their best interest and what is——

Mr. BURR. So, if they——

Mr. ALLEN. [continuing] appropriate for them. It is not for us to decide.

Mr. BURR. If they passed a law that made legal human cloning, we would not come out in this country in opposition to human cloning in the U.K.?

Mr. ALLEN. Again, I see no reason why I should provide a position to comment on what the U.K. has done or is doing. I think it is imperative that, from our perspective, we look at what the United States does.

The United States is a leader in the world, both morally—serving as a moral force, as well as looking at science and the advancement of it. And we believe, at this time, that this the wrong-headed to——

Mr. BURR. Would one conclude that the administration sees no scientific value out of additional research in stem cell nuclear transfer?

Mr. ALLEN. That is incorrect.

Mr. BURR. They do see promise?

Mr. ALLEN. The administration believes that it is inappropriate at this time for us to proceed forward with research in this area.

Mr. BURR. Do they see promise in this area, or do they see no promise?

Mr. ALLEN. I am not sure that I can give you an either/or. I think that certainly——

Mr. BURR. Well, it is a scientific question.

Mr. ALLEN. [continuing] we believe that there is promise——

Mr. BURR. [continuing] and I think you alluded to the fact——

Mr. ALLEN. [continuing] we believe that there is scientific evidence——

Mr. BURR. [continuing] that if cancer was——

Mr. ALLEN. [continuing] that there is promise as we work within mammals and see the ethicacy there. The application to humans at that point is something that we would certainly need to look at and consider.

That is, again, the reason why we believe that the Weldon-Stupak bill provides for the vehicle through which further analysis, further review, and further comments to be made on that area.

Mr. BURR. Mr. Chairman, I am sorry that I wasn't here for the full discussion. And I am sure I will have follow-up questions. I would ask unanimous consent that we be allowed to send those directly to the Agency?

Mr. BILIRAKIS. Without objection, that is the case. I think that ends this portion of the hearing, Mr. Allen. We appreciate your being here. Obviously, there will be questions that will be forwarded to you. We would request timely responses.

It is a tough issue, and I am not sure that anybody has really counted votes in terms of either piece of legislation as they may be re-molded. But I would like to think that we are intent on moving, at some point, on this issue.

So, please take a little bit of leadership on it, and work with the principals.

Mr. ALLEN. Certainly, we—and we look forward to working with the members. Thank you.

Mr. BILIRAKIS. Thank you. Thank you very much, sir. The second panel consists of Mr. Thomas Okarma, President of the Geron Corporation, here on behalf of the bio-tech industry; Dr. Leon Kass, Addie Clark Harding Professor of Social Thought and the College from the University of Chicago; Mr. Louis Guenin, lecturer on ethics and science with the Department of Microbiology and Molecular Genetics, Harvard Medical School; Dr. Stuart Newman, Professor of Cell Biology and Anatomy for the Department of Cell Biology and Anatomy, New York Medical College; Mr. Dan Perry, Executive Director of Alliance—with the Alliance for Aging Research; Ms. Judy Norsigian, Executive Director of the Boston Women's Health Book Collective-Collective, associated with Boston University, Boston University School of Public Health; Mr. Richard Doerflinger, Associate Director for Policy Development with the National Conference of Catholic Bishops; and Mr. Francis Fukuyama, Omer L. and Nancy Hirst Professor of Public Policy for the School of Public Policy at George Mason University.

Lady and—where is Ms. Norsigian? Ms. Norsigian and gentlemen, welcome. Thank you so much for being here. You have had to sit through 2 hours of this. But believe me, that is not really a long period of time when you take into consideration how we function up here and the usual interruptions we have running in for votes.

But we do have a little bit of a break in the sense that there is a recess on the floor. So, hopefully, we can go uninterrupted, for a short period of time anyhow, and maybe complete it.

Your written statement is a part of the record. We will set the clock at 5 minutes. Hopefully, you can complete your statement

within that period of time. If you go over for a short period of time, I won't call you on it. But I would appreciate it if you would compliment and supplement your written statement.

We will start off with Mr. Okarma. Please proceed, sir.

STATEMENTS OF THOMAS OKARMA, PRESIDENT, GERON CORPORATION, ON BEHALF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION; LEON R. KASS, ADDIE CLARK HARDING PROFESSOR OF SOCIAL THOUGHT AND THE COLLEGE, UNIVERSITY OF CHICAGO; LOUIS M. GUENIN, LECTURER ON ETHICS IN SCIENCE, DEPARTMENT OF MICROBIOLOGY AND MOLECULAR GENETICS, HARVARD MEDICAL SCHOOL; STUART A. NEWMAN, PROFESSOR OF CELL BIOLOGY AND ANATOMY, DEPARTMENT OF CELL BIOLOGY AND ANATOMY, NEW YORK MEDICAL COLLEGE; DANIEL PERRY, EXECUTIVE DIRECTOR, ALLIANCE FOR AGING RESEARCH; JUDY NORSIGIAN, EXECUTIVE DIRECTOR, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH; RICHARD M. DOERFLINGER, ASSOCIATE DIRECTOR FOR POLICY DEVELOPMENT, NATIONAL CONFERENCE OF CATHOLIC BISHOPS; AND FRANCIS FUKUYAMA, OMER L. AND NANCY HIRST PROFESSOR OF PUBLIC POLICY, THE SCHOOL OF PUBLIC POLICY, GEORGE MASON UNIVERSITY

Mr. OKARMA. Good afternoon. I am Tom Okarma, President and CEO of Geron Corporation in Menlo Park, California. Geron is a biopharmaceutical company focusing on discovering, developing, and commercializing therapeutic and diagnostic products in oncology, drug discovery and regenerative medicine.

Today, I am testifying on behalf of my company and the Biotechnology Industry Organization. BIO represents more than 950 biotechnology companies, academic institutions, State bio-tech centers, and related organizations in all 50 U.S. States and 33 other nations.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to testify today at this important meeting on cloning. In my testimony today, I would like to make three points.

First, Geron Corporation, BIO, and the overwhelming portion of scientists and physicians oppose human reproductive cloning of human beings.

Second, however in our shared zeal to prevent reproductive cloning, we must not prevent research on tissue cloning, which is fundamental to enable the development of safe and effective cellular transplant patient therapies that could, and we predict will, revolutionize medicine.

Third, the objective of the research is to develop a scalable process to enable the direct conversion of a somatic or body cell into a pluripotent cell without consuming oocytes and without generating embryos.

Such a process would allow the generation of transplantable replacement cells that would not be rejected by the immune system. First, ban reproductive cloning. It would be extremely dangerous to attempt human reproductive cloning. It took over 270 attempts before Dolly was successfully cloned.

In fact, in most animals, reproductive cloning is no better than a three to 5 percent success rate; that is, very few of the cloned animal embryos implanted in a surrogate mother animal survive.

The others either die in utero, sometimes at very late stages of pregnancy, or die soon after birth. It is simply unacceptable to subject humans to those risks.

To allow human reproductive cloning would be irresponsible. Worse yet, it could lead to a back-lash that would stifle the numerous beneficial applications of therapeutic cloning technology, some of which I will now describe.

It is critical, therefore, to distinguish the use of cloning technology to create a new human beings from other appropriate and important uses of the technology, such as cloning specific human cells, genes, and tissues that do not and cannot lead to a cloned human being.

The full potential of this technology comes from its use in regenerative medicine. Many diseases result in the disruption of cellular function or the destruction of tissue. Heart attacks, stroke, diabetes, are all examples of common conditions in which critical cells are lost to disease.

Today's medicine is completely unable to restore this loss of function. Regenerative medicine is a new therapeutic paradigm that holds the potential to cause an individual's currently malfunctioning cells to begin to function properly again, or even to replace dead or irreparably damaged cells with fresh, healthy ones, thereby restoring organ function.

The goal of the research is to produce transplantable cells that provide these benefits without triggering immune rejection of the transplanted cells. This could be used to treat numerous diseases such as diabetes, heart disease, stroke, Parkinson's disease, and spinal cord injury.

For example, today, we have learned how to turn undifferentiated human pluripotent stem cells into human neurons, human liver cells, and human heart muscle cells. These human replacement cells function normally in vitro, raising the possibility for their application in the treatment of devastating diseases affecting these tissue types.

This would, for example, allow patients with heart disease to receive new heart muscle cells that would improve heart function. Cellular cloning techniques are a critical and necessary step in the production of sufficient quantities of vigorous replacement cells for the clinical treatment of patients.

Somatic cell nuclear transfer research is essential if we are to achieve our goals in regenerative medicine. We must understand the biological properties of the egg cell and the transferred nucleus that cause a differentiated cell to turn into a pluripotent one.

This process is called "reprogramming," and we are still not sure how it works, which is why we need to perform the research.

At Geron, our aim is to harness and therapeutically apply the power of this biology. Once we fully understand reprogramming, we will be able to develop specific cells for transplantation without immune rejection.

We will do that by taking a differentiated cell from a particular patient, reprogramming it back to form a pluripotent cell from

which we can produce the differentiated cells we need for transplantation back into that individual.

By using the patient's own cells as starting material, we will avoid complications due to immune response rejection.

However, this is precisely the research that would be banned by the Weldon bill. Because the Weldon bill does not distinguish between reproductive cloning and the use of cloning for research purposes, it will cutoff this work and prevent its therapeutic applications from reaching patients.

In contrast, the bipartisan bill introduced by Representatives Greenwood and Deutsch and others bans reproductive cloning appropriately, but allows the continuation of research.

BIO supports Greenwood-Deutsch because it strikes the appropriate balance between prohibiting acts that are unsafe and unethical, while promoting vital medical research.

Last, it is critical to emphasize that once we understand the molecular biology of reprogramming, we will no longer need to use egg cells or to create blastocysts. The commercial process envisioned would transform a somatic cell, such as a skin cell, into a pluripotent cell directly, without the use of oocytes or the creation of blastocysts.

Moreover, understanding the biology of reprogramming is a critical step to improve the usefulness of so-called adult stem cells. Ironically, the Weldon bill will also be a set-back for adult stem cell research.

In conclusion, Mr. Chairman, human reproductive cloning remains unsafe, and the ethical issues it raises have not been reasonably resolved. It should be prohibited.

However, as Congress seeks to outlaw reproductive cloning, it must not write legislation that will stop research using cloning technology.

Unfortunately, the Weldon bill fails that test. Simply put, enactment of the Weldon bill will stop critical therapeutic research in its tracks. Only Greenwood-Deutsch strikes the right balance. Thank you.

[The prepared statement of Thomas Okarma follows:]

PREPARED STATEMENT OF THOMAS OKARMA, PRESIDENT AND CEO, GERON CORPORATION ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

Good afternoon. My name is Thomas Okarma. I am the President and CEO of Geron Corporation in Menlo Park, California. Geron is a biopharmaceutical company focused on discovering, developing, and commercializing therapeutic and diagnostic products for applications in oncology, drug discovery and regenerative medicine. Geron's product development programs are based upon three patented core technologies: telomerase, human pluripotent stem cells, and nuclear transfer.

I am testifying today on behalf of my company and the Biotechnology Industry Organization (BIO). BIO represents more than 950 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

Mr. Chairman, and members of the Subcommittee, thank you for the opportunity to testify today at this important hearing on cloning. Let me start by making our position perfectly clear: BIO opposes human reproductive cloning. It is simply too dangerous technically and raises far too many ethical and social questions.

That's why BIO wrote to President Bush earlier this year and urged him to extend the voluntary moratorium on human reproductive cloning which was instituted in 1997. I would respectfully ask for this letter to be included in the hearing record.

It would be extremely dangerous to attempt human reproductive cloning. It took over 270 attempts before Dolly was successfully cloned. In fact, in most animals, reproductive cloning has no better than a 3-5% success rate. That is, very few of the cloned animal embryos implanted in a surrogate mother animal survive. The others either die in utero—sometimes at very late stages of pregnancy—or die soon after birth. Only in cattle have we begun to achieve some improvements in efficiency. However, scientists have been attempting to clone many other species for the past 15 years with no success at all. Thus, we cannot extrapolate the data from the handful of species in which reproductive cloning is now possible to humans. This underlines that this would be an extremely dangerous procedure.

It is simply unacceptable to subject humans to those risks. Rogue and grandstanding so-called scientists who claim they can—and will—clone humans for reproductive purposes insult the hundreds of thousands of responsible, reputable scientists who are working hard to find new therapies and cures for millions of individuals suffering from a wide range of genetic diseases and conditions.

The Food and Drug Administration (FDA) has publicly stated that it has jurisdiction over human reproductive cloning experiments and that it will not approve them. BIO supports that view and hopes that the next FDA commissioner—whoever that might be—will assert FDA's current statutory authority forcefully.

There are also many ethical concerns raised by the specter of cloning. As noted in BIO's letter to the President, "Cloning humans challenges some of our most fundamental concepts about ourselves as social and spiritual beings. These concepts include what it means to be a parent, a brother, a sister and a family.

"While in our daily lives we may know identical twins, we have never experienced identical twins different in age or, indeed, different in generation. As parents, we watch with wonder and awe as our children develop into unique adults. Cloning humans could create different expectations. Children undoubtedly would be evaluated based on the life, health, character and accomplishments of the donor who provides the genetic materials to be duplicated. Indeed, these factors may be the very reasons for someone wanting to clone a human being."

As you can see, Mr. Chairman, many of these issues strike at the heart of beliefs and values that are inherent in the human condition. What does it mean to be an individual? How should we view our parents, brothers, sisters, and children? How does the world around us influence our intellectual, physical and spiritual development? These are just a few of the questions raised by human cloning. In my view, reproductive cloning would devalue human beings by depriving them of their own uniqueness.

To allow human reproductive cloning would be irresponsible. Worse yet, it could lead to a backlash that would stifle the numerous beneficial applications of therapeutic cloning technology—some of which I will describe today—that could lead to cures and treatments for some of our most deadly and disabling diseases.

BENEFICIAL USES OF CLONING TECHNOLOGY

It is critical to distinguish use of cloning technology to create a new human being (reproductive cloning) from other appropriate and important uses of the technology such as cloning specific human cells, genes and other tissues that do not and cannot lead to a cloned human being (therapeutic cloning). These techniques are integral to the production of breakthrough medicines, diagnostics and vaccines to treat many diseases. They could also produce replacement skin, cartilage and bone tissue for burn and accident victims, and result in ways to regenerate retinal and spinal cord tissue.

Let me briefly explaining a cloning technology—somatic cell nuclear transfer—and how it is used for research purposes. First, the nucleus of an egg cell is removed. In its place, we insert the nucleus of an already differentiated cell (a cell that performs a specific function in the body). Chemicals are added to stimulate the egg to start dividing. At about 3-5 days, a blastocyst is formed which contains an inner cell mass comprised of undifferentiated, pluripotent cells. These cells are removed and used for research. The research value of these cells is enormous. These stem cells have the potential to form any cell in the body and can replicate indefinitely. Studies in animals demonstrate that this could lead to cures and treatments for millions of Americans who suffer from diseases and disabilities such as diabetes, stroke, Parkinson's Disease, heart disease, and spinal cord injury.

As exciting as that is—it's only a part of the story. The full potential of this technology comes from its use in regenerative medicine.

REGENERATIVE MEDICINE

Many diseases result in the disruption of cellular function or destruction of tissue. Heart attacks, strokes, and diabetes are examples of common conditions in which critical cells are lost to disease. Today's medicine is unable to completely restore this loss of function. Regenerative medicine, a new therapeutic paradigm, holds the potential to cause an individual's currently malfunctioning cells to begin to function properly again or even to replace dead or irreparably damaged cells with fresh healthy ones, thereby restoring organ function.

The goal of Geron's regenerative medicine program is to produce transplantable cells that provide these therapeutic benefits without triggering immune rejection of the transplanted cells. This could be used to treat numerous chronic diseases such as diabetes, heart disease, stroke, Parkinson's Disease and spinal cord injury.

At Geron, therapeutic cloning technology is one of the techniques we use to create pure populations of functional new cells that can replace damaged cells in the body. For example, we are learning how to turn undifferentiated human pluripotent stem cells into neurons, liver cells and heart muscle cells. Thus far, these human replacement cells appear to function normally in vitro, raising the possibility for their application in the treatment of devastating chronic diseases affecting these tissue types. This would, for instance, allow patients with heart disease to receive new heart muscle cells that would improve cardiac function. Cellular cloning techniques are a critical and necessary step in the production of sufficient quantities of vigorous replacement cells for the clinical treatment of patients.

Somatic cell nuclear transfer research is essential if we are to achieve our goals in regenerative medicine. We must understand the biological properties of the egg cell (and the transferred nucleus) that cause a differentiated cell to turn into a pluripotent cell. This process is called "re-programming"—and we're still not sure how it works. That's why we need to continue to perform research.

At Geron, our aim is to harness and therapeutically apply the power of this biology. Once we fully understand re-programming we will be able to develop specific cells for transplantation without immune rejection. We'll do that by taking a differentiated cell from a particular individual and re-programming it to form a pluripotent cell from which we can produce the differentiated cells we need for transplantation back into that individual. By using the patient's own cells as starting material, we will avoid complications due to immune response rejection.

However, this is precisely the research that would be banned by the Weldon bill. Because the Weldon bill does not distinguish between reproductive cloning and use of cloning for research purposes, it will cut off this work and prevent its therapeutic applications from reaching patients. In contrast, the bi-partisan bill introduced by Reps. Greenwood, Deutsch, and others bans reproductive cloning but allows the continuation of research. BIO supports Greenwood/Deutsch because it strikes the appropriate balance between prohibiting acts that are unsafe and unethical, while promoting vital medical research.

It is important to emphasize that *once we understand the molecular biology of re-programming, we will no longer need to use egg cells or create blastocysts.* Therefore, this technology is likely to be used only for a short, finite period of time. Moreover, understanding the biology re-programming is a critical step to improve the usefulness of adult stem cells. Ironically, therefore, the Weldon bill will also be a setback to adult stem cell research.

CONCLUSION

As the current Congress pursues legislative prohibitions on human reproductive cloning, we urge caution and a distinction between reproductive and therapeutic cloning. We all agree that given the current safety and social factors, human reproductive cloning is repugnant. However, it is critical that in our enthusiasm to prevent reproductive cloning, we not ban vital research, turning wholly legitimate biomedical researchers into outlaws, and thus squelching the hope of relief for millions of suffering individuals.

Our nation is on the cusp of reaping the long dreamed of rewards from our significant investment in biomedical research. The U.S. biotech industry is the envy of much of the world, especially our ability to turn basic research at NIH and universities into applied research at biotech companies and in turn, into new therapies and cures for individual patients. Using somatic cell nuclear transfer and other cloning technologies, biotech researchers will continue to learn about cell differentiation, re-programming, and other areas of cell and molecular biology. Armed with this information, they can eventually crack the codes of diseases and conditions that have plagued us for hundreds of years, indeed, for millennia.

In conclusion, Mr. Chairman, human reproductive cloning remains unsafe, and the ethical issues it raises have not been reasonably resolved. It should be prohibited. However, as Congress seeks to outlaw reproductive cloning, it must not write legislation that will stop research using cloning technology. Unfortunately, the Weldon bill fails that test. Simply put, enactment of the Weldon bill will stop critical therapeutic research in its tracks. Only Greenwood/Deutsch strikes the right balance.

Thank you for the opportunity to testify. I'll be happy to answer any questions.

Mr. BILIRAKIS. Thank you. Dr. Kass, please proceed, sir.

STATEMENT OF LEON R. KASS

Mr. KASS. Thank you, Mr. Chairman, for the opportunity to testify before the subcommittee. I am Leon Kass. I am a professor at the University of Chicago. I have been professionally concerned for over 30 years with the ethical implications of biomedical technologies.

These technologies have now brought us to a crucial fork in the road where we are compelled to decide whether we wish to travel down the path that leads to the brave, new world. That, and nothing less, is what is at stake in your current deliberations about whether we should tolerate the practice of human cloning.

And if I may say so, I have heard Members of Congress say that we should be very careful not to jeopardize the health benefits that are available from research cloning. I think we should be very careful before we take any step that might lead us in an accelerated path down this road toward the brave, new world. Care has to be exercised on both sides.

I am here to testify in favor of a national ban on human cloning, and in particular, in favor of H.R. 1644, the Human Cloning Prohibition Act 2001, for two reasons.

First, I believe that cloning human beings is unethical, both in itself and, importantly, in what it will surely lead to. And second, I believe that this bill offers us the best, indeed the only, reasonable chance of preventing human reproductive cloning from happening.

In the written testimony, I give the ethical arguments as to why we should object to human reproductive cloning. Having heard no dissent on that, I will simply skip over that and take it for granted that we agree on that, and speak only about the legislative approaches.

But I do want to say one thing here. There is more at stake in this question than the simple question of cloning, because what we would be establishing if we say yes to cloning, is that we will be establishing, as a dangerous principle, the right that we have to determine in advance the genetic make-up of our children.

If we won't—don't want to travel down that road, we want to make sure that we have an effective ban on human cloning now, before we are overtaken by events. It is important that we do something now.

Two legislative approaches have been proposed. One would ban only so-called reproductive cloning by prohibiting the transfer of a cloned embryo to a woman to initiate a pregnancy. The other would ban all cloning by prohibiting the creation even of the embryonic clones.

I had, once upon a time, looked for a third way, but I am now convinced that an effective ban on reproductive cloning requires a ban on all cloning, on all cloning, including the creation of the embryonic clones, and here is why.

Once the cloned embryos are produced and available in the laboratories and assisted reproduction centers, it will be virtually impossible to control what is done with them.

Stockpiles of cloned human embryos could be produced, bought and sold without anyone's knowing it. Efforts at clonal reproduction would take place out of sight, within the privacy of the doctor/patient relationship. And moreover, a ban on only reproductive cloning will turn out to be unenforceable.

Should illicit cloning be discovered, governmental attempts to enforce the reproductive ban would run into a swarm of legal and practical challenges. And the practice at that stage, I submit, would be impossible to police or regulate.

Therefore, if you are serious—anyone who is really serious about trying to prevent human reproductive cloning must seek to stop this process at the start.

Now, I believe H.R. 1644 is precisely suited to accomplish this goal, no more and no less. It explicitly and precisely defines the specific deed that is outlawed, human somatic cell nuclear transfer to an egg, and it does not entangle us in difficult determinations of the perpetrator's intent or knowledge.

It is extremely carefully drafted and limited in its scope, and it makes it clear that there is to be no interference with scientifically and medically useful practices of animal cloning or equally valuable cloning of human DNA fragments, duplication of cells, stem cells or somatic cells, in culture.

And if enacted, this bill would bring the United States into line with the already and soon-to-be-enacted practices of many other nations. And we should take the lead, rather than be an outlaw nation in this regard.

People who prefer the other approach, namely a ban only on the transfer of a human clone to initiate a pregnancy, will probably look with favor on the other bill before you, H.R. 2172.

But please observe; in my opinion, I think a careful consideration of the specifics of this bill shows that it does not effectively provide the ban on reproductive cloning that everyone wants.

Indeed, it does not explicitly ban reproductive cloning at all. It prohibits only two things. First, it prohibits the creation of the embryonic clones by people whose intent it is to begin a pregnancy; and second, it prevents people from shipping or transporting the "cellular product resulting from this transfer," but only if they know that the product is intended to be used to initiate a pregnancy. Those are the only two acts that are prohibited.

Put those two prohibitions taken together; they fail to outlaw a pregnancy initiating transfer of a cloned embryo to a woman by someone other than its manufacturer. Indeed, nowhere in this bill, nowhere in this bill, does it specifically ban the act of reproductive transfer to a woman by anyone.

And if this bill really, seriously intended to outlaw reproductive cloning, it should have read that, "It shall be unlawful to use the cellular product of somatic cell nuclear transfer to initiate a preg-

nancy." It nowhere says anything that clear. This bill fails to outlaw the attempts to create a live, born human-cloned individual.

Consider this possible scenario. It is very clear. I create the embryos by somatic cell nuclear transfer. You buy them from me, and you tell me that you want them for research. And I ship them to you, taking you at your word.

Your company changes management, or you change your mind, and they decide it is profitable to use the purchased embryos for reproductive cloning. Under the terms of this bill, I have done nothing illegal; you have done nothing illegal, and the cloned child is born.

In brief, with all due respect, as I read the present text of the Greenwood bill, it seems to be less the Cloning Prohibition Act of 2001 and more the Human Embryo Cloning Registry and Industry Protection Act of 2001.

It is not the reproductive cloning ban the American people are looking for. And I have some other things, some——

Mr. BILIRAKIS. Please summarize, Dr. Kass.

Mr. KASS. [continuing] details. I will just wind up. It seems to me, as the composition of this panel of witnesses will make clear, the issue of human cloning is not an issue of pro-life or pro-choice. It is not mainly about death and destruction. It is not about a woman's right to choose. It is not about stem cell research. It is not even about the basic freedom of scientists to inquire.

It is most emphatically about baby design and manufacture. And it is the opening skirmish in a long battle against eugenics and the post-human future.

Once the embryonic clones are produced in the laboratories, this eugenic revolution will have begun, and we will have lost our best chance to do something about it.

[The prepared statement of Leon R. Kass follows:]

PREPARED STATEMENT OF LEON R. KASS, ADDIE CLARK HARDING PROFESSOR, COMMITTEE ON SOCIAL THOUGHT AND THE COLLEGE, THE UNIVERSITY OF CHICAGO

Thank you, Mr. Chairman, for the opportunity to testify before the subcommittee. I am Leon R. Kass, Addie Clark Harding Professor in the Committee on Social Thought and the College, The University of Chicago. I have been professionally concerned, for over 30 years, with the ethical implications of biomedical advance. Originally trained in both medicine and biochemistry, I remain enthusiastic about biomedical research and its promise to cure disease and relieve suffering. Yet, as has been obvious for some time, new biotechnologies are also providing powers to intervene in human bodies and minds in ways that go beyond the traditional goals of healing the sick, to threaten fundamental changes in human nature and the meaning of our humanity. These technologies have now brought us to a crucial fork in the road, where we are compelled to decide whether we wish to travel down the path that leads to the Brave New World. That, and nothing less, is what is at stake in your current deliberations about whether we should tolerate the practice of human cloning.

I am here to testify in favor of a national ban on human cloning and, in particular, in favor of HR 1644, "The Human Cloning Prohibition Act of 2001," for two reasons. First, I believe that human cloning is unethical, both in itself and in what it surely leads to. Second, I believe that this bill offers us the best—indeed, the only—reasonable chance at preventing human reproductive cloning from happening. (The full version of my argument is contained in a recent essay, "Preventing a Brave New World: Why We Should Ban Human Cloning Now," written precisely to gain support for such a bill and published in the May 21, 2001 issue of *The New Republic.* I submit it as an appendix to this statement.)

The vast majority of Americans object to human cloning, and on multiple moral grounds, among them the following. It constitutes unethical experimentation on the

child-to-be, subjecting him or her to enormous risks of bodily and developmental abnormalities. It threatens individuality, by deliberately saddling the clone with a genotype that has already lived and to whose previous life its life will always be compared. It confuses identity by denying the clone two biological parents and by making it the twin of its older copy. It represents a giant step toward turning procreation into manufacture (especially when understood as the harbinger of nontherapeutic genetic manipulations to come). And it is a radical form of parental despotism and child abuse—even when practiced freely and on a small scale. Permitting human cloning means saying yes to the dangerous principle that we are entitled to determine and design the genetic make-up of our children. If we do not wish to travel down this eugenic road, an effective ban on cloning human beings is needed, and needed now before we are overtaken by events.

A majority of members of Congress, I believe, are, like most Americans, opposed to human cloning. But opposition is not enough. For if Congress does nothing about it, we shall have human cloning, and we shall have it soon. Congress' failure to try to stop human cloning—and by the most effective means—will in fact constitute its tacit approval.

What, then, is the most effective way to stop reproductive human cloning? Two legislative approaches competed with each other the last time Congress took up this issue. One bill would have banned only so-called reproductive cloning by prohibiting the transfer of a cloned embryo to a woman to initiate a pregnancy. The other bill would have banned all cloning by prohibiting the creation even of the embryonic human clones. Both sides opposed reproductive cloning, but because of the divide over the question of embryo research we got no ban at all. It would be tragic if we again failed to produce an effective ban on cloning human beings, especially now that certain people are going ahead with it and defying us to try to stop them.

A few years ago, I was looking for a middle way between the two alternatives that failed last time, but I am now convinced that an *effective* ban on reproductive cloning requires a ban on *all* human cloning, including the creation of the embryonic clones. Anyone truly serious about preventing human reproductive cloning must seek to stop the process from the beginning, at the stage where the human somatic cell nucleus is introduced into the egg. Here is why.

Once cloned human embryos are produced and available in laboratories and assisted-reproductive centers, it will be virtually impossible to control what is done with them. Biotechnical procedures and experiments take place in laboratories, hidden from public view, and for good commercial reasons these doings are concealed from the competition and everyone else. Huge stockpiles of cloned human embryos could thus be produced and bought and sold in the private sector without anyone knowing it. As we have seen with in vitro embryos created to treat infertility, embryos produced for one reason can be used for another reason: today "spare embryos" once created to begin a pregnancy are now used—by someone else—in research, and tomorrow clones created for research will be used—by someone else—to begin a pregnancy. Efforts at clonal baby-making (like other forms of assisted-reproduction) would take place out of sight, within the privacy of a doctor-patient relationship, making outside scrutiny extremely difficult. Moreover, the transfer of embryos to begin a pregnancy is a simple procedure (especially compared with manufacturing the embryo in the first place), simple enough that its final steps could be self-administered by the woman, who would thus absolve the doctor of blame for having "caused" the illegal transfer.

Worst of all, a ban on only reproductive cloning will turn out to be unenforceable. Should the illegal practice be detected, governmental attempts to enforce the reproductive ban would run into a swarm of practical and legal challenges, both to efforts aimed at preventing embryo transfer to the woman and—even worse—to efforts seeking to prevent birth after the transfer has occurred. Should an "illicit clonal pregnancy" be discovered, no government agency is going to compel a woman to abort the clone, and there would be an understandable swarm of protest should she be fined or jailed before or after she gives birth.

For all these reasons, the only practically effective and legally sound approach is to block human cloning at the start, at the production of the embryonic clone. Such a ban is rightly characterized not as interference with reproductive freedom, nor even as unprecedented or dangerous interference with scientific inquiry, but as an attempt to prevent the unhealthy, unsavory, and unwelcome manufacture of and traffic in human clones. It would do what the American people want done: stop human cloning before it starts.

H.R. 1644, introduced by Dr. Weldon and joined now by more than 100 cosponsors, is just what the doctor ordered, precisely suited to accomplish this goal, no more and no less. It explicitly and precisely describes the specific deed that is outlawed (human somatic cell nuclear transfer to an egg), and it does not entangle us

in difficult determinations of the perpetrator's intent or knowledge. Its substantial criminal and monetary penalties will almost certainly shift the incentives for renegades who are tempted to proceed. Extremely carefully drafted and limited in its scope, the bill makes very clear that there is to be no interference with the scientifically and medically useful practices of animal cloning or the equally valuable cloning of human DNA fragments, the duplication of somatic cells, or stem cells in tissue culture. Moreover, if enacted this bill would bring the United States into line with the already and soon-to-be-enacted practices of other nations, and, in collaboration with these efforts, offers us the best and, I think, the only realistic chance we have of keeping human cloning from happening, or happening much.

People who prefer the other approach to stopping human cloning, namely, a ban only on transfer of an embryonic clone to initiate a pregnancy, will oppose H.R. 1644 and will probably look with favor on the other bill before this Committee, H.R. 2172, introduced last week by Reps. Greenwood and Deutsch. But, in my opinion, a careful consideration of the specifics of this bill (as now written) shows that it does not effectively provide the ban on reproductive cloning that everyone wants. Indeed, it does not *explicitly* ban reproductive cloning *at all.* This bill permits the use of human somatic cell nuclear transfer technology (HSCNTT [1]), the act that creates an embryonic human clone. It prohibits (only) two things. First, it prohibits this act by people *whose intent is to begin a pregnancy.* Second, it prohibits people from shipping or transporting "the cellular product resulting from HSCNTT," but only if they *know* that "the product is intended to be used to initiate a pregnancy." These two prohibitions, even taken together, fail to outlaw a pregnancy-initiating transfer of a cloned embryo to a woman—by someone *other* than its manufacturer. (Indeed, *nowhere does the bill specifically ban the act of reproductive transfer to a woman by anyone.*[2]) As a result, this bill fails to outlaw efforts to create a live-born human cloned individual.

The Greenwood-Deutsch bill places virtually no restrictions on the *use* of licitly produced "cellular products" of the technology (i.e., the embryonic clones), *once they are created.* Strikingly, there is no prohibition on *receiving* the "cellular product" of HSCNTT (i.e., the embryos) with an intent to initiate a pregnancy; indeed, there is no restriction whatsoever on what the purchaser of such embryos may do with them. Consider this possible scenario: I create embryo clones by HSCNTT. You buy them from me, telling me that you want them for research, and I ship them to you, taking you at your word. You change your mind (say, because your company's new management sees the prospect of gain from reproductive cloning), and you then use the purchased embryo (that you did not yourself create) to initiate a pregnancy. Under the terms of this bill, I have done nothing illegal and neither have you, and in the meantime, the cloned child is born.

There are two further difficulties with this bill. The two banned acts turn entirely either on intent or on foreknowledge of someone else's intent—hard matters to discern and verify. Also, because the cloned embryo is treated like an ordinary drug whose registration with the FDA is (for obvious reasons) kept confidential, the public will be completely in the dark even about who is producing the embryo clones, much less where they are being bought and sold and who is doing what with them. With all due respect, as I read the present text of this bill, it seems to me to be less the "Cloning Prohibition Act of 2001" and more the "Human Embryo Cloning Registration and Industry Protection Act of 2001." It is not the reproductive cloning ban the American people are looking for.

I understand fully that some scientists and biotechnologists hope that the practice of embryo cloning would someday yield autologous tissues (and even organs) for transplantation, derivable for each person from his own embryonic twin clone, tissues useful for the treatment of serious chronic disease (so-called therapeutic cloning). Perhaps they are right. But we now have promising alternate routes to the same therapeutic possibilities—not only non-embryonic (so called adult) stem cells,

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[1] HSCNTT is defined as the act of "transferring the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or rendered inert."

[2] Readers of the bill may see this for themselves, by substituting the statutory definition of HSCNTT [provided in SEC. 1001. (a) (2)] into the first prohibition [SEC. 1001. (a) (1) (A): "It shall be unlawful to transfer or to attempt to transfer the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or rendered inert with the intent to initiate a pregnancy." That this is the correct meaning of what is prohibited can be confirmed by the appearance, in the description of the second prohibited act [SEC. 1001. (a) (1) (B)], of the phrase "cellular product resulting from HSCNTT," that is, the embryonic human clone. *If the bill wanted explicitly to ban the act of so-called reproductive human cloning, the first prohibition could and should have read: "It shall be unlawful to use the cellular product of HSCNTT to initiate a pregnancy."* Furthermore, such a proscription would have made the prohibition of shipping and transporting unnecessary.

but also *non-cloned* embryonic stem cell lines—that do not run the risk of opening the door to human clonal reproduction (and that, it should be added, will not require commodifying women's reproductive tissues in order to provide the enormous numbers of eggs that will be needed to create the cloned embryos). Should these other alternatives fail, and should animal cloning experiments demonstrate the unique therapeutic potential of stem cells derived from embryo cloning, Congress could later revisit this issue and consider lifting the ban on the cloning of embryos. H.R. 1644, in fact, provides for just such a review of the relevant scientific and therapeutic possibilities, as does H.R. 2172 (the Greenwood-Deutsch bill).

As the composition of the panel of witnesses before you today makes clear, the issue of human cloning is most emphatically not an issue of pro-life versus pro-choice. It is not mainly about death and destruction, and it is not about a woman's right to choose. It is only and emphatically about baby design and manufacture, the opening skirmish of a long battle against eugenics and against the post-human future. Once embryonic clones are produced in laboratories, the eugenic revolution will have begun, and we will have lost our best chance to do anything about it.

The present danger posed by human cloning is, paradoxically, also a golden opportunity. The prospect of cloning, so repulsive to contemplate, is the occasion for deciding whether we shall be slaves of unregulated innovation and, ultimately, its artifacts, or whether we shall remain free human beings who guide our medical powers toward the enhancement of human dignity. The preservation of the humanity of the human future is now in our hands.

Mr. BILIRAKIS. Thank you very much, sir.

Mr. Guenin—is that correct?

Mr. GUENIN. Guenin.

Mr. BILIRAKIS. Mr. Guenin. Thank you, you may proceed.

STATEMENT OF LOUIS M. GUENIN

Mr. GUENIN. Mr. Chairman and members of the subcommittee, I am Louis Guenin of the Department of Microbiology and Molecular Genetics at Harvard Medical School where my field of work is ethics.

In order to assist the subcommittee, the talk that I should like to set for myself is to unmask the compelling, but sometimes overlooked grounds for moral approval of non-reproductive somatic cell nuclear transfer.

I shall emphasize that we should insist for every moral view on an analysis faithful to that view's fundamental commitments; and that from such an analysis, we find that moral views that are sometimes invoked against this research, in fact, pronounce it not only permissible, but virtuous.

So, I shall be speaking about the instrumental use of embryos; that is the use of embryos as means, not ends in themselves. We may distinguish two sets of embryos for this purpose. The first consists of embryos that are produced by in vitro fertilization for the purpose of pregnancy. And the second consists of those produced by in vitro fertilization or somatic cell nuclear transfer solely for the purpose of medical treatment or research.

We may say that the elements of that first set are created by reproductive embryo creation, and that making elements of the second set is an instance of non-reproductive embryo creation.

I use that expression instead of the word "cloning," because in this instance, although the genome of the supposed donor is, in fact, copied, the nuclear donor is not, himself or herself, copied. There is never an offspring.

So, the question is whether it is moral to use an embryo as means. Some readers of the philosopher Kant would believe that that question answers itself because Kant teaches us to "use hu-

manity . . . always at the same time as an end, never simply as a means."

But for Kant, "humanity" includes only rational beings. And the subject of current scientific interest consists of microscopic embryos that do not have brains and are not rational.

What we may do with them, according to Kantian morality, would follow from the command that we—that we, as universal beings, act on universal laws, that we can will without contradicting ourselves.

One such law, holds Kant, states a duty to aid others. There is no contradiction in willing that scientists should relieve suffering, and that the rest of us should join in supporting him by using donated, unenabled embryos.

The developmental potential of an embryo becomes "enabled," as I use that expression, if and only if the embryo enters a woman's reproductive system. The boundary of the human body separates enabled from unenabled embryos.

I would like to identify a set of unenabled embryos that is permissible to use as means. Suppose that Mary wants to help others by donating—donating to research or therapy an embryo created in an earlier attempt at pregnancy, or an egg designed to be used in somatic cell nuclear transfer.

She, thereupon, issues instructions that prohibit the—prohibit reproduction; that is, she prohibits the embryo be implanted in a uterus. And she also prohibits nurture of the embryo for more than 14 days. That period of time is important because until the 14th day, an embryo can split, forming twins, and any twins can recombine.

So, in view of that, there is not the individuation of a person. In the words of the late Harvard philosopher W.V. Quine, "No entity without identity."

Consider also the case of Michael, who suffers from Parkinson's disease. He contributes a somatic cell for the purpose of enabling a autologous transplant; that is, a transplant to him of cells bearing his own genome. And he imposes the same restrictions as does Mary.

For an unenabled and unindividuated embryo donated by someone like Mary or Michael, whether from a fertility clinic or created solely for research or therapy, I use the term "epidosembryo". This comes from the Green "epidosis" for a beneficence to the common weal.

The donation of such an embryo is a generous act, but we have to ask still whether it is permissible for scientists to use it. Enablement of an embryo, as I have described it, is an entirely discretionary act.

No woman is obliged to undergo intrauterine transfer of an embryo. The instructions that are issued by donors of epidosembryos conclusively foreclose any chance that the embryos will become babies. They will never be enabled.

The instructions allow research or therapy and nothing else. And that is a decision that the donors make, not the recipients. Therefore, there is no possible person that corresponds to such an embryo.

Moreover, an early stage embryo, so small that it is invisible to the naked eye, lacks the sensory apparatus to feel pleasure or pain.

Because the use of such an embryo cannot thwart the actualization of any possible person, because an embryo cannot suffer any discomfort, it is permissible to use the embryo in aid of others.

Some witnesses will be objecting that it is wrong to create an embryo for some purpose other than procreation. According to a previously influential teleological view that trances to Aristotle, in every creature, every cell has a purpose. And we, today, even think that, in many cases, we know what the purpose is.

It is a short step, then, to say that this notion of a mapping of cells to purposes is not purely of human origin, but perhaps of divine. And thereupon, some would object to highjacking cells to be used for some purpose other than their ordained purpose.

But we mortals formerly thought that bone marrow was used only to nurture bone. And now, we know that it is the factory for the manufacture of blood.

We used to think that kidneys exist only for benefit of those that enclose them. And now, we think it virtuous to donate one's kidney.

We know that oocytes, when they are fertilized, develop into children, or at least some of them do. But who of us can say that sexual reproduction is the sole end that an oocyte may permissibly serve.

Even assuming that the biological function of an oocyte were singular and known, it does not follow that it is immoral to deploy it for some other purpose. Nor is it obvious that a moral wrong occurs if an embryo dies without implanting in the uterus.

Embryos die in that manner, in vivo, all the time. And we do not treat their passing as the death of a person.

Now, to take an explicitly religious point of view, suppose that we could have a conversation with God about this. We tell him that we have discovered stem cells and, furthermore, we have discovered somatic cell nuclear therapy.

I suspect his first reaction might be gently to tease us that it took a few thousand years to get here. But to be serious about it, I think he would commend us for an attempt to help others.

In view of what is known as the second greatest of the Commandments, I suspect he would praise epidosembryo donors. I doubt that he would stand on metaphysics about early stage microscopic embryos, but rather wish us——

Mr. BILIRAKIS. If you could summarize, Mr. Guenin?

Mr. GUENIN. Yes, Mr. Chairman—rather wish us to use our abilities to relieve suffering. The burden of my testimony, I would therefore conclude, is that it would disserve the cause of morality, disserve our fulfillment of our duty to aid those who suffer if any government action were to thwart non-reproductive somatic cell nuclear transfer.

When I speak of morality, I refer to the intersection of the leading moral views of our time on this kernel, that it is virtuous to relieve suffering in actual lives when we may do so at no cost in potential lives.

In my written statement, I would just mention that I make the following further points: that Catholicism should be counted as an

ally of this research, not an opponent. This relates to its fundamental belief in the duty to relieve suffering.

And the fact that the thesis of zygotic personhood draws Catholicism into contradiction not only of its 18th Century-long belief otherwise, but of its fundamental belief in soul, I suggest that it is misleading to conflate the abortion of an enabled conceptus with experiment on an unenabled conceptus.

And I make some points of Constitutional and drafting about the pending legislation. I suggest——

Mr. BILIRAKIS. In your written statement?

Mr. GUENIN. Pardon me?

Mr. BILIRAKIS. In your written statement, you make——

Mr. GUENIN. Yes.

Mr. BILIRAKIS. [continuing] those points?

Mr. GUENIN. Yes. If I may just close with this, final——

Mr. BILIRAKIS. Please close.

Mr. GUENIN. [continuing] sentence, Mr. Chairman? I suggest there that a sensible prescription would prohibit "transfer to a uterus of an embryo created by somatic cell nuclear transfer." That would paint, without using too broad a brush. Thank you, Mr. Chairman.

[The prepared statement of Louis M. Guenin follows:]

PREPARED STATEMENT OF LOUIS M. GUENIN, DEPARTMENT OF MICROBIOLOGY AND MOLECULAR GENETICS, HARVARD MEDICAL SCHOOL

Mr. Chairman and Members of the Subcommittee, the task that I should like to set for myself, in order to assist the Subcommittee in its consideration of legislation against human cloning, is to unmask the compelling grounds for moral approval of nonreproductive somatic cell nuclear transfer ("SCNT"). The method leading to the conclusions that I shall offer is simple to describe though somewhat difficult to execute. It consists first in probing moral views until we have passed beyond phrases and aspirations to the most fundamental commitments of each. It then requires us to construct a moral analysis faithful to each view. I shall emphasize that if we insist on this regimen, we shall find that even moral views thus far invoked against nonreproductive SCNT commend it as not only permissible but virtuous.

1. EMBRYO SUBJECTS

I shall be speaking about the instrumental treatment of embryos, the use of embryos as means rather than as ends in themselves. An embryo treated instrumentally is an "embryo subject." We may distinguish two sets of embryo subjects:

(a) a set A each element of which is an embryo created by *in vitro* fertilization ("IVF") for the purpose of pregnancy, and

(b) a set *B* each element of which is an embryo created by IVF or SCNT solely for the purpose of medical treatment or research.

We may say that elements of *A* are created by "reproductive embryo creation," and those of *B* by "nonreproductive embryo creation," the latter standing for any process of embryo creation for a purpose other than producing a baby. I do not use the term "cloning" for nonreproductive embryo creation by SCNT ("nonreproductive SCNT") because in that process, no copy of the nucleus donor ever develops. No infant is born. Only the donor's nuclear genome is copied. Nonreproductive embryo creation does not risk deformed or socially anomalous offspring or like problems that may trouble us about reproductive use of SCNT in humans ("reproductive cloning").

2. KANT'S MORALITY AS PROPONENT, NOT OPPONENT, OF EMBRYO USE

In considering elements of *A* or *B* as research subjects, we encounter a different problem. Is it moral to use an embryo as a means? Some readers of Kant have thought that this question answers itself. The second form of Kant's categorical imperative, embraced by many religious traditions, bids us to "use humanity . . . always at the same time as an end, never simply as a means." But as I have explained elsewhere ("Morals and Primordials," *Science* 292: 1659-1660 [2001], copy attached), by "humanity" Kant understands only rational beings. The early stage embryo sub-

jects of current scientific interest are microscopic. They do not have brains, they are not rational. For Kantian guidance on how we must act with respect to any nonrational being, we must look to a more general principle. That is the command that we as rational beings act only on those maxims that, without contradicting ourselves, we can will as universal laws. One such law, Kant holds, states a duty of mutual aid. When we imagine that we stand seriatim in the shoes of our fellows who suffer from diseases that we might cure, we do not contradict ourselves in willing that we collectively support biomedical scientists in the relief of suffering by use of donated *unenabled* embryos.

3. THE EPIDOSEMBRYO SUBJECT, AN UNENABLED UNINDIVIDUATED EMBRYO TO WHICH NO POSSIBLE PERSON CORRESPONDS

Let me explain enablement, the key concept that I have introduced here. I say that the developmental potential of an embryo becomes enabled if and only if the embryo enters a woman's reproductive system (either fallopian tubes or uterus). The boundary of the human body separates enabled embryos from unenabled embryos. I shall describe, if I may, a set of unenabled embryos that one may permissibly use as means. Suppose that Mary wants to help others by donating to research or therapy (a) an embryo produced from one of her eggs in an earlier fertility procedure or (b) an unfertilized egg for use in SCNT. In her donative instructions, given to the physician who recovered the egg from her, she prohibits reproduction. She forbids intrauterine embryo transfer and she also prohibits ex utero embryo nurture for more than fourteen days. The fourteen day constraint assures that neither research nor therapy will use a person as means. How is that so? Until day 14, any embryo can split, forming twins, and until day 14, twins can recombine, neither mother nor physician being the wiser. Thus until the end of the first fortnight, identity of an individual is not established, and hence it does not make sense to say that there exists a new person. "No entity," said the late philosopher W.V. Quine, "without identity."

Consider also the case of Michael, a victim of Parkinson's disease. Michael arranges with his physician for a somatic cell to be removed from Michael's body so that via SCNT, that cell's nucleus may be used to generate embryonic stem cells of Michael's own genome, thereby enabling an autologous transplant. Michael imposes the same embryo restrictions as does Mary.

For an unenabled unindividuated embryo donated by someone like Mary or Michael, I use the term *epidosembryo*. I derive this word from the Greek epidosis for a beneficence to the common weal. In the relief of suffering, epidosembryos enable the bounteous possibilities of stem cell research and cellular reprogramming. (Here I describe the general concept of an epidosembryo, whether of set *A* or *B*. The discussion in "Morals and Primordials" principally concerns epidosembryos from *A*.) For the following reasons, it is morally permissible to use an epidosembryo. Enablement is an entirely discretionary act. No woman is obligated to undergo intrauterine transfer of an embryo. Instructions issued by epidosembryo donors conclusively foreclose any chance of enabling the embryos. The instructions specify research or therapy, and nothing else. Hence there exists no chance that an epidosembryo will become an infant. Therefore no possible person corresponds to such an embryo. To this we add that any early stage embryo—each so small as to be invisible to the naked eye—lacks the sensory apparatus to feel pleasure or pain. Because use of an epidosembryo cannot thwart the actualization of any possible person—no possible person corresponds to the embryo—and because the embryo cannot experience frustration or discomfort, it is permissible to use an epidosembryo in aid of others.

Because we owe profound respect to any human life form, especially embryos, we cannot use embryos for frivolous means. But the hopes of scientists for embryo research are far from frivolous. First, from work on stem cells science may be able to overcome juvenile-onset diabetes, Parkinson's, Alzheimer's, muscular dystrophy, and other diseases, and to accelerate drug development by supplying for testing normal human cells in lieu of abnormal and animal tissues. Second, in SCNT we anticipate a stem cell possibility that embryos donated from fertility clinics cannot provide. In SCNT we have an ingenious means for obtaining transplantable cells of the patient's own nuclear genome. Such an autologous, histocompatible transplant is the holy grail of cell replacement therapy. For efficiency's sake, instead of creating cells of each patient's genome whenever needed, SCNT might be used in the project of creating a bank of embryonic stem cell lines. Scientists would culture one line for each of the more common alleles of the major histocompatibility complex (the set of genes that code for antigens, the structures that signal whether a cell is self or nonself). Or into cells from an embryonic stem cell line, scientists might by

transgenesis insert a given patient's own version of the complex. Each of these strategies in principle could issue in transplantable cells that surmount the vexing problem that a patient's immune system rejects anything that it does not recognize as self. Third, SCNT also constitutes our hope for knowledge of how a cell's reprogramming can occur. If we can find out how reprogramming occurs in an egg following SCNT—we know that it does occur, but do not know the details—clinicians might learn how to induce reprogramming of adult patients' cells. In such case we have the exciting prospect of inducing specialized cells in the adult to differentiate into developmentally much earlier cells that patients desperately need. Even neurons might be regenerated.

4. REPLY TO OBJECTIONS CONCERNING USE OF EPIDOSEMBRYOS

Let me address two likely objections to what I have said about unenabled embryos.

(a) It might be argued that an embryo outside the body possesses a potential to become an infant and that we just happen to observe it at a preimplantation stage, a stage through which passes every embryo that becomes a neonate. But embryos passing through that stage inside a woman's body have a nontrivial chance of implanting in the uterus. Epidosembryos have no such chance. That is to say that they have less chance of becoming babies than do the gametes of a man and woman who have never met. Most of us would approve experiments on gametes—even though each contains half the genome of a possible person. For moral purposes, some cells and cell masses are possible persons, others are not.

(b) Still it will be objected that the reason that embryos created by SCNT have a zero chance of becoming babies is that someone created them with precisely that fate in mind, and that it is wrong to create an embryo with no thought of procreation. (This is the moral objection peculiar to nonreproductive embryo creation in contrast with use of epidosembryos from fertility clinics.) Here I think that one can put one's finger on the view that may explain much of the reluctance understandably voiced concerning the challenged use of embryos. According to a previously influential teleology originating with Aristotle, some purpose obtains for every cell type, every structure. At various times in history, it has been thought that for many a cell and structure in the human, we humans know what the purpose is. It is a short step from there to the notion that the mapping of cells to purposes is not an accident but a divine design. Whereupon some would object to hijacking cells for purposes other than those ordained.

Who can know the mind of God on this? We mortals formerly thought that the sole purpose of bone marrow is to nurture bone. Now we look upon the marrow as the factory where blood cells are manufactured. We used to think that kidneys exist solely for benefit of those enclosing them, and now we recognize the virtuousness of donating one's kidney to another. We know that oocytes when fertilized develop into children, but who is to say that sexual reproduction is the sole end that oocytes may permissibly serve? Even assuming that the natural function of a cell were both singular and known, it does not follow that it would be immoral to deploy it for another purpose. Nor it is obvious that a moral wrong occurs if embryos die without implanting in a uterus. The majority of embryos do die in such manner. We do not treat their passing as the deaths of persons.

Let me take up a religious point of view. If we could have a conversation with God, is it plausible that He would tell us never to fertilize an egg except for purposes of creating a baby? If we informed Him that we had discovered stem cells, and had invented SCNT, He might first gently tease us that it took us a few thousand years to discover these things. As for what we should make of them, we may recall what Christianity teaches as the second greatest of the commandments, and the Golden Rule as embraced by virtually all religions. I suspect that God would commend epidosembryo donors. I suspect that He would not stand on metaphysics about microscopic embryos, but would wish us to use our humble abilities to relieve suffering—an effort that expresses esteem for life—when we have happened upon a way to do so in which we do not prevent the existence of any possible person who would otherwise become actual. He would know that children will not result from the use of epidosembryos as sources of stem cells or subjects of study.

From a religious perspective, SCNT may even be said to offer one advantage over the use of embryos created with pregnancy in view. Nonreproductive embryo creation does not bring to an end any divine-human procreative collaboration.

5. BREADTH OF MORAL SUPPORT FOR NONREPRODUCTIVE EMBRYO CREATION

The use of unenabled embryos as means for helping others, even as we are reminded of how carefully we must proceed, enjoys the support of a wide range of reli-

gious traditions. That support is even broader than commonly supposed. To see this, let us consider what is ostensibly the principal opposition. I refer to the view of the Congregation for the Doctrine of the Faith of the Roman Catholic Church, as joined by fundamentalist Christians, which asserts two doctrines: (a) that human life is a sacred gift of God that we must respect, and (b) zygotic personhood, the thesis that fertilization suffices to create a new person.

[a] *We Respect Life by Relieving Suffering at No Cost in Potential Lives*

The Congregation has declared that IVF, cloning, and other technological innovations in reproduction are inconsistent with the sanctity of human life. The reason that the Congregation rejects these procedures is twofold: it categorizes the procedures as nonconjugal reproduction, and thus as a departure from God's manner of giving life, and it expresses fear that they might lead to eugenics. But note that these two objections do not apply to procedures, such as nonreproductive embryo creation, that do not produce babies. What respect for life requires therefore remains an open question. I suggest, with ample support in religious traditions, including Catholicism, that relieving widespread human suffering when one may do so at no cost in potential lives—this in fulfillment of the wishes of generous cell donors—virtuously affirms respect for human life.

[b] *Zygotic Personhood Untenable*

I have explained in my recent paper in Science that (i) zygotic personhood contradicts the Catholic church's more plausible teaching, maintained during the church's first nineteen centuries, that at fertilization a conceptus cannot, for lack of structures corresponding to the intellectual faculty that makes us human, constitute a person, and that (ii) zygotic personhood is refuted by the fact that embryos do not individuate until day 14, as Catholic theologians have recognized. The church, having recently conceded that personhood is a philosophical question, offers only one argument for zygotic personhood. That argument consists in identifying a new person with the genome formed at each conception. But the church cannot maintain this embrace of genetic reductionism. To do so contradicts the church's fundamental belief in mind and soul.

We must first plumb the depths of any moral view before we can ascertain its verdict on a question at hand. When we include in our analysis of Catholicism its bedrock—including the second greatest of the commandments and the consequence that we are obliged to come to the aid of our neighbors and to answer the call to charity—we find a compelling case for epidosembryo research and therapy.

It would be misleading to conflate the use of *unenabled* embryos with abortion. An abortion kills a conceptus developing in the womb, an *enabled* conceptus. An enabled conceptus will follow a course of gestation requiring only that the mother stay healthy. Whereas absent a voluntary act to which no one is obliged, an unenabled embryo will never implant, will never mature even to the fetal stage. Fewer abortions mean more babies. Were society to refrain from nonreproductive embryo creation, not one more baby would likely be born.

6. WISHFUL THINKING ABOUT ADULT CELLS WILL NOT OBVIATE STUDY OF EMBRYONIC

Opponents of embryo use have recently urged that we forego use of embryos and instead use cells that they characterize as functionally equivalent and less morally problematic, namely, adult cells. This line of wishful thinking, embraced in H. R. 1644, § 2, finding (7), begins with the notion that we might confine stem cell research to adult stem cells. Clinging to this idea, some nonscientist opponents of embryo research are wont to trumpet every report about the plasticity of adult stem cells. Meanwhile these advocates will exaggerate every qualification or condition that they hear mentioned by cautious scientists careful not to overstate present knowledge about embryonic stem cells. The refutation of this wishful thinking is immediate. Embryonic stem cells are pluripotent, which is to say that they are capable of issuing in every cell type save for the placenta. Adult stem cells are only multipotent, each capable of issuing in no more than a few cell types. When pluripotency is the goal, the earlier the better. For some cell types, among them cardiac and pancreatic islet, no adult stem cells have been found. Where adult stem cells are known to exist, often they can be found only in small quantities and obtained only by intrusive means. For instance, to obtain adult stem cells useful in the brain, as one would wish to do for Parkinson's disease, one must drill a hole in the cranium. Adult stem cells may also embody the effects of aging and contain genetic abnormalities accumulated over the course of a life. If, painlessly for both donor and recipient, one could rejuvenate one's skin with a transplant from a family member, who would prefer their grandmother's skin to that of a newborn niece? We must also recognize that stems cell vary in the extent to which clinicians will be able to direct

differentiation. Embryonic stem cells may prove easier to direct. For all these reasons, it is simply implausible that adult stem cells are functional substitutes for embryonic stem cells. Nor can one assume that embryonic germ cells, derived from abortuses five or more weeks old, are functionally equivalent to embryonic stem cells.

It does not advance understanding to interject, as have opponents of embryo research, that no therapies by means of embryonic stem cells have yet been confirmed. For both adult and embryonic stem cells, the present agenda is basic research. In the U. S. there has been scant little research on embryonic stem cells and SCNT. Both lines of inquiry are stymied by law. No funds dispensed by the National Institutes of Health may be used for research in which embryos are destroyed (Pub. L. 106-554, Title V, § 510). It is unrealistic to expect confirmed therapies from research not yet performed.

Frequently in the history of science when the prospect has appeared of beneficial results from several alternative avenues of inquiry, and when it has not been known which avenue would be the most productive, the practice has been to follow all paths simultaneously. Sundry mathematicians traveled down numerous paths, developing whole new fields of mathematics in the process, before Andrew Wiles combined insights from multiple fields into the proof of Fermat's Last Theorem. And then there is serendipity. Often great advances occur in one direction while scientists believe that they are working in another. Roentgen discovered x-rays without looking for them. Sometimes multiple avenues all bear fruit. Biomedical research could reveal a clinical need for all varieties of stem cells, one type for one disease, another type for another disease. When delay and inefficiency are measured in lives lost, it would be a shame to bet everything on one horse.

The overwhelming majority of biomedical scientists prize embryonic stem cell research as one of the most promising frontiers for the relief of human suffering in our lifetime. The ability to generate specialized cells of all types renders the use of embryonic stem cells, through SCNT and otherwise, that rare strategy that can yield therapies in virtually all fields of medicine. If biomedical scientists imagined that adult cells would suffice instead, they would be the first to tell us so. Research on adult cells does offer some promise, should be pursued, and is being pursued. But the overwhelming majority of biomedical scientists urge that embryonic research possesses singular advantages and is yet more promising. On the question of which avenues of investigation are relatively more promising, the judgment of these scientists should serve as our guide, just as it does in budgetary decisions. We have learned from encounters with such ventures as "creation science," which purportedly refutes the theory of evolution, that we must be sceptical when nonscientist advocates offer purported analyses of scientific data to reinforce conclusions that they have already reached on nonscientific grounds. The current incarnation of data advocacy would have us believe that we have little to gain scientifically from the alternative that the advocates disfavor on moral grounds. To object to embryo research explicitly on moral grounds is of course quintessentially pertinent here. (Though, according to my analysis, morality bids us support, not oppose, that research.) But whatever our moral theory, if we think that the moral permissibility of an action depends on that action's probable success in achieving a scientific result, we ought to take counsel about that probability from science's mainstream. The voice of science's mainstream is resounding. We could fail to apprehend the scientific consensus on the singular promise of embryonic stem cell research only by putting our heads in the sand.

The rationale for SCNT is even more compelling than that for embryonic stem cells in general, this by virtue of two advantages to which I have alluded—and perhaps others not yet glimpsed. First, SCNT affords a means of producing stem cells that are (a) ample in quantity and pluripotent and (b) of the patient's own genome. Adult cells do not allow us to achieve (a); an unrelated embryo from a fertility clinic will not achieve (b). Second, eggs developing after SCNT furnish the optimal opportunity for observing the full scale reprogramming of gene expression and the cell's other regulatory mechanisms, the likes of which either does not naturally occur in specialized cells of the adult, or occurs on a scale too small to allow us to learn much if we could observe it. By studying reprogramming in embryos, scientists hope to learn what steps to take in order to induce reprogramming in specialized cells of adult patients, which in turn could obviate the need to obtain embryonic stem cells for therapy. Scientists would not urge this research, would not predict the loss of useful therapies if we forgo it, if they could gain that knowledge without using embryos created by SCNT.

In short, if Congress defies the advice of science's mainstream and excludes unenabled unindividuated embryos from research, it will handcuff research for no moral gain.

7. PRESERVING THE LEGALITY OF NONREPRODUCTIVE SCNT

As the Members well know, there obtains a scientific and, if I may say, a public consensus that because reproductive cloning in animals so often issues in deformed offspring, and because cloning in *homo sapiens* poses further technical challenges and questions that have not been met, we ought not presently to attempt the cloning of a human. That is not the whole of the moral discussion, since we can imagine a day when present problems have been overcome to the extent that the procedure has become relatively reliable. Thereupon we would return to the morality of "replacing" a lost child with a clone and of using SCNT to conceive a child who could be available as a histocompatible donor to a sick child. Consider again a religious perspective. We, none of us, can confidently say that, if we could have a conversation with God, He would tell us to shun reproductive cloning in all instances. But insofar as reproductive cloning is not presently reliable, and I therefore cannot defend it on moral grounds, I confine myself here to the case for preserving nonreproductive embryo creation. We may further narrow the discussion to nonreproductive SCNT rather than nonreproductive embryo creation in general. For the proposed legislation would forbid SCNT but not restrain the use of IVF in research.

Thus far I have discussed morality, the only cited rationale for making nonreproductive SCNT a crime. I have argued that a close analysis of leading moral views reveals moral approval and praise for nonreproductive SCNT. This issues even from quarters that might be thought settled otherwise. I now turn to two pragmatic arguments. These have been advanced for the proposition that, even if nonreproductive SCNT is moral for the reasons that I have offered, the procedure should be prohibited anyway. The first of these arguments emanates from concern for enforceability of a ban on cloning, the second from fear of a slippery slope. I shall show that neither argument sustains the prohibition of nonreproductive SCNT.

[a] *Difficulty of Enforcement: Inherent for Any Proscription of Reproductive Conduct, Not Grounds for an Overly Broad Proscription*

The first argument is broached in H. R. 1644, § 2, finding (8), which asserts that "it will be nearly impossible to prevent attempts at 'reproductive cloning' once cloned human embryos are available in the laboratory." Fully stated, the argument starts with the premise that for satisfactory enforcement of a statute that prohibits *x*, law enforcement officials must be able to detect most instances of *x*. Next it is asserted that officials will not reliably be able to detect reproductive cloning if and when it is perpetrated by someone legally permitted to perform SCNT for research and therapy. It is then concluded that, by dint of such undetected violations, a statute prohibiting only reproductive cloning cannot be enforced to a satisfactory extent.

I contend that the enforcement problem envisioned here is a red herring. As the foregoing argument itself implies, the question that we must ask, when urged to forbid all SCNT so as to tighten the noose around reproductive cloning, is as follows. If SCNT in research and therapy were permitted, what would be the *probable incidence* of surreptitious reproductive cloning by persons performing SCNT in research and therapy? The probable incidence, so I shall suggest, is negligible. The foregoing argument leaps from the observation that undetected violations can occur to the conclusion that *significantly many* undetected violations *will* occur.

We must understand the laboratory environment. Cell biology laboratories—where studies of stem cells and cellular reprogramming would occur—do not serve patients. Such laboratories contain no examining rooms, no surgical suites, no equipment for the invasive procedures of removing an egg from an ovary or transferring an embryo to a uterus. Most of the scientists who work in such laboratories are Ph.D.s, not physicians. Eggs and somatic cells used by such laboratories in research will have been shipped there as donations. If cell donors impose the condition by which I earlier defined an epidosembryo, the laboratories will have use of the cells on condition that any resultant embryo not be transferred to a uterus. A federal law forbidding reproductive cloning would effectively impose this condition in all cases. So if a rogue scientist seeks to clone a human, that scientist must be surreptitious indeed. The rogue must remove an embryo from a laboratory's inventory and arrange an intrauterine embryo transfer in such fashion that the rogue and the woman receiving the embryo manage to keep the whole thing secret. Where can the rogue arrange an intrauterine transfer? He cannot engage a reputable physician, hospital, or clinical laboratory. If reproductive cloning is a federal crime, reputable providers will not perform the procedure—just as, comporting with a nonpenal statute (Pub. L. 106-554), NIH-supported scientists now abstain from SCNT for any purpose. Hence the rogue must collaborate with a woman willing to undergo an assisted reproduction procedure without the usual circumstances of medical care. And she must be willing to risk punishment by a minimum fine of $1,000,000 and up

to ten years" imprisonment. By proposed 18 U.S.C. § 302(a)(2) of H. R. 1644, she and the rogue would both be guilty of the crime.

A step earlier in the analysis, consider also what it would take for a woman to *want* an embryo produced in a research laboratory. As a solution to infertility, SCNT is inferior to IVF: IVF produces offspring that combine the genomes of the parents, and does not, like cloning, make a deformed neonate more probable than not. Therefore a woman interested in a baby by SCNT—if we can imagine that desire amid public awareness of how likely is a deformed child—will most likely not be infertile but instead someone seeking a clone of a previously or presently living human identified by her. That is the imagined primary motivation for cloning. Only by a highly improbable accident would an embryo created in a research or clinical laboratory serve a cloning purpose of someone other than the person who chose the somatic cell donor. A woman considering cloning will not want any of a laboratory's already extant embryos. She will want only an embryo created to order, an embryo bearing a genome chosen by her. We observe what follows from this. For the vast majority of embryos produced by SCNT in research and for therapy—in a reputable laboratory, for all of the embryos—there will be no women wishing to bear them. And in the ordinary course, the embryos will be consumed in research and therapy.

So regardless how many embryos are produced by SCNT in laboratories across the country, for a rogue to produce an embryo acceptable to a given woman, the rogue must arrange yet another surreptitious procedure, namely, removal of a somatic cell from a corpse or living human chosen by her. She would also likely prefer that any embryo transferred to her be made of one of her eggs so that the clone will bear her mitochondrial DNA, not a stranger's. In order to furnish one of her eggs to the rogue scientist, she would have to undergo an oocyte recovery procedure that punctures her ovarian wall. For this she would need to seek out a fertility clinician, and, after the procedure, ask the physician to give her an egg to take home. That would immediately seem suspicious to the clinician because in the usual practice of IVF, all recovered eggs are fertilized in hopes of obtaining a few transferable embryos.

From these circumstances we can see why the risk of surreptitious cloning via research and medical care is negligible. Talk of large numbers of embryos sitting around ready to make clones makes for good rhetoric, but we must insist on analysis. Consider further that penal legislation against reproductive cloning will thwart any large scale efforts to attempt the procedure, and in consequence its success rate on transferred embryos—i.e., the ratio of healthy infants to embryos transferred—will doubtless remain dismal. As proponents of a ban on reproductive cloning have observed, the public keenly understands the high risk of deformities through reproductive cloning and strongly opposes the practice. Opposition may harden if we learn that, in addition to the high incidence of deformities at birth, ostensibly healthy infant clones are found to develop serious health problems later in life. We do not yet know how even Dolly's life will go. All of which suggests that scant few women would be willing to tackle both the high risk of a deformed offspring and a jail sentence, fewer still if only a rogue will assist. Despite recent announcements by a handful of providers who say that they intend to produce clones, conspicuous by its absence is any sign that a significant number of women are willing to enlist. Even if, by virtue of research in other countries, the day arrives at which cloning has so greatly improved that the risk of deformities is deemed tolerable, a woman would do better to procure the procedure legally in a foreign country—assisted reproduction already serves the affluent—than to commit a crime without benefit of customary medical care.

In view of all these circumstances, the notion that SCNT in research and therapy will to any significant extent form a conduit to illegal reproductive cloning seems manifestly improbable.

Of course I do not purport to say that never will it happen that a researcher or provider attempts illegal reproductive cloning. Some illegal reproductive cloning may occur, without detection, even if federal law forbids *all* SCNT. Not only might a rare disreputable health care provider stray, but in theory women and cooperating cell donors who do not care whose eggs were used could, acting without medical assistance, buy oocytes through advertisements in campus newspapers, learn somatic cell nuclear transfer from the literature, and perform intrauterine embryo transfers entirely in private. A person who is clever and determined enough can violate any law. That does not alter my fundamental point. By virtue of the circumstances that I have described, research and clinical laboratories are not a probable back door route to illegal cloning.

Upon recognizing that airtight enforcement of any law seems unattainable, we ought not lash out and broaden a cloning prohibition to sweep nonreproductive SCNT within its maw. Instead we should understand that enforceability depends on the chosen territory. The territory chosen here should give us pause. Within the pe-

numbra of the Bill of Rights, as interpreted in the Supreme Court's decision in *Griswold v. Connecticut* (1965), the right of privacy extends to reproduction. The Court has also made clear that each person's zone of privacy encompasses reproduction under the care of a physician. Hence if H. R. 1644 declared it a crime to perform or attempt contraception, or *in vitro* fertilization, it would be said that such prohibition unconstitutionally infringes the right of privacy. Can the conclusion be different when the proscribed act is reproductive cloning? H. R. 1644 itself states in § 2, finding (8)(A), that "cloning would take place within the privacy of the doctor-patient relationship." A measure of the intrusiveness of an anticloning statute is what would be adduced as evidence of the crime. When a mother as defendant denies bearing a clone, a prosecutor may seek a "genetic audit" comparing her child's DNA to that of the person allegedly cloned. In facilitating patents on DNA sequences, as in the Biotechnology Patent Protection Act of 1995, Congress has already opened the door to legal claims predicated on DNA audits. But now we are talking about incarceration of parents on the basis of such evidence. The fate of a criminal statute about reproduction lies in the courts. We ought not worsen its chances by overbreadth. Apart from this constitutional problem, as a matter of policy overbreadth here would foreclose such a negligible increment in illegal cloning as to make unreasonable an opportunity cost measured in relief of human suffering.

What can wisely be done to tighten enforceability of an anticloning statute includes four provisions that I shall mention in a moment. First I must discuss the second argument for making nonreproductive SCNT illegal.

[b] *Nonreproductive SCNT Not a Slippery Slope to Reproductive Cloning*

That argument begins with the prediction that use of nonreproductive SCNT in research and therapy will add to scientific knowledge about reproductive cloning, and that this will hasten the day when reproductive cloning becomes so reliable as to tempt us. Thereupon, it is suggested. we might repeal any statute forbidding it and bring upon ourselves its detrimental effects. Hence we are urged to forbid nonreproductive SCNT now.

The slippery slope is an overworked metaphor. Not every decisionmaking surface is slippery. As the philosopher Richard M. Hare once observed, we decided to allow right turns from red traffic lights, and have not seen significantly more traffic accidents of right-turning vehicles. Now we discuss whether to allow reproductive cloning. For purposes of this discussion, we routinely abstract from the problem of defective clones, for we know that such a technical problem is solvable in principle. Even so, the public, so we are reliably informed, easily summons the collective will to prohibit cloning. That tells us that strong objections lie against even a perfectly reliable cloning procedure. Indeed it is argued that cloning may in various ways diminish respect for human life. Other objections to cloning gain expression in H. R. 1644, § 2, findings [3]-[5]. If the day arrives when cloning's already anticipated reliability becomes actual, those objections will survive with undiminished force. It is not a foregone conclusion that if cloning becomes reliable, we shall approve it.

On the other hand, we must be realistic in anticipating that even if reproductive cloning is declared illegal within various jurisdictions, someone may someday clone humans so as to gain, in the eyes of others, some advantage. In that event, competitors may follow suit. (This scenario has been broached concerning germ line genetic intervention in general. See my "Norms for Patents Concerning Human and Other Life Forms," *Theoretical Medicine* 17: 279-314 [1996].) Competitors might migrate to jurisdictions where cloning is legal. Sovereign countries might themselves behave in the same way, rushing to follow the first rival who legalizes cloning, this for fear of being dominated by genetic superiors. The salient defect in the slippery slope argument against nonreproductive SCNT does not lie in the prediction that mercurial mankind will find reliable cloning irresistible, for that outcome is possible.

Rather the slippery slope argument falls by virtue of its mistaken assumption that we can somehow attenuate or delay reproductive cloning if we preclude nonreproductive SCNT in the U. S. To state the obvious, what must happen to make reproductive cloning alluring is the successful performance of reproductive cloning. For such success, there must occur experiments and cloning attempts. This is a tough row to hoe, since it doubtless begins with a spate of deformed offspring. To produce healthy clones will require surmounting many challenges, among them the shorter interval before gene activation in humans than in sheep, the effects of aging and mutation on donated somatic cells, and cloning's failure to produce normal genetic imprinting. If progress against birth defects or later health problems of clones requires studies of development *in utero*, or even of development *ex utero* beyond fourteen days, the work of scientists using nonreproductive SCNT will not provide the solution. Scientists working on embryonic stem cells and cellular reprogramming culture embryos for only a matter of days. (In fact when an embryo reaches about

day 10, if it does not implant in a uterus, it will so badly deform that it can no longer properly be called an embryo.) Suppose nonetheless that as mainstream scientists come to understand and publish accounts of how cellular reprogramming works, they inevitably issue knowledge dividends that can be cashed by those trying to perfect cloning. We are powerless to prevent such dividends. For instance, under authority of recent approval by Parliament, outstanding scientists in Oxford, Cambridge, and other British universities and research institutions will be using SCNT in research generally and in the study of cellular reprogramming in particular. So too will scientists elsewhere in the world. Their results will be reported in leading journals. New scientific knowledge disseminates rapidly. We cannot forestall improvements in cloning by any ban on SCNT in the U. S. A ban on nonreproductive SCNT can only strike a blow against those who suffer. Viewed from the perspective of years hence, the measure of damage wrought by a ban on use of SCNT in research would be the amount of suffering that could have been relieved if our extensive research enterprise had joined the worldwide effort to benefit from embryonic stem cells and cellular reprogramming.

8. TIGHTENING A BAN ON REPRODUCTIVE CLONING WITHOUT OVERBREADTH

The prohibition of proposed 18 U.S.C. § 302(a) set forth in H. R. 1644 extends to SCNT that produces an embryo "at any stage of development." This would bar all presently envisioned research use of SCNT, which produces and grows embryos to the blastocyst stage (day 5 of development). The prohibition would bar SCNT even for therapy. Thus if scientists learn how to use eggs to accomplish autologous transplants, the clinical implementation of this boon for sick patients would be a crime. No comfort can be taken from mention in H. R. 1644 (in § 2, clause [9] and proposed 18 U.S.C. § 302[d]) of research that the bill would not prohibit. We are told that the prohibition does not extend to "nuclear transfer or other cloning techniques" to produce, *inter alia*, "cells other than human embryos." But the sundry methods other than SCNT for producing copies of various life forms—methods that vary by life form even though some commentators (and the bill) lump them all under the name "cloning"—are not within the scope of the prohibition in the first place.

For the moral reasons that I have now recounted, if Congress were to thwart nonreproductive SCNT, that move would disserve morality. It would thwart our ability to fulfill our duty to aid those in need. If Congress chooses to legislate against reproductive cloning, I recommend the following four statutory features to preserve the availability of nonreproductive SCNT while tightening the proscription of reproductive cloning.

(1) The offense may be defined as

> "intentional transfer to a uterus of an embryo created by somatic cell nuclear transfer."

This would paint without using too broad a brush. "Intentional" assures that, as is appropriate in defining a crime, accidental conduct is not punished. Congress could consider making reckless transfer a lesser offense.

(2) It may also be provided that

> "A physician shall not effect intrauterine transfer of an embryo unless the embryo was (i) created in a laboratory under the physician's control or (ii) received from a licensed physician accompanied by a certificate that the embryo was created, without use of SCNT, in a laboratory under the latter physician's control."

This provision assures that fertility clinicians will know the means by which any embryos that they transfer to a uterus were created. It blocks the possibility of a woman inveigling an unwitting fertility clinician into a transfer into her of an SCNT-created embryo carried into the clinic by her. The transferability provision of (ii) allows a scenario such as the following. A woman engages an IVF procedure in Connecticut, then later moves to Oregon. By virtue of (ii), her frozen embryos may be sent to an Oregon fertility clinician for intrauterine transfer. She will not have to return to Connecticut for that procedure.

(3) In the preamble of H. R. 1644 appears language about what "many" think concerning morality. There exist many who believe many things. Rather than legislate morality, Congress could declare that it is prohibiting a procedure that would effectively constitute a clinical experiment with a probable success rate that is unacceptably low. This is consistent with H. R. 2172 in that the enactment becomes part of the federal scheme of regulation of drugs and medical devices.

(4) Within the several states have already been enacted a potpourri of interdictions pertinent to this technological genre. We can expect more such statutes. Only preemptive federal legislation can assure a uniform norm, at least within the U. S. It behooves us, for the sake of the public health, to foster a reliable basis of expectations for those making decisions about where to direct research efforts. This espe-

cially applies to young scientists who wisely shun fields of work whose regulatory environment is unstable. (Here it may be added that we should be grateful for the commendable caution of senior scientists who, upon discovering the techniques of nonreproductive embryo creation, have evoked an open moral discussion. This follows a pattern in the recent history of science, of which the introduction of recombinant DNA technology is another example, in which the bright light of public exposure shines early on morally sensitive innovations by virtue of their discoverers' candor and alertness to moral questions.) For preemptive legislation, precedent obtains. We look to the Food and Drug Administration, not to the several states, for a national system of regulating drugs and medical devices.

9. CONCLUSION

The burden of my testimony today is that it would disserve the cause of morality, disserve fulfillment of our duty to come to the aid of those who suffer, if any government action, whether a proscription of conduct or a constraint on the public purse, were to thwart nonreproductive SCNT. When I speak of morality, I refer to the intersection of the leading moral views of our time—including especially those sometimes imagined to hold otherwise—whose common kernel holds it virtuous to relieve suffering in actual lives when we can do so at no cost in potential lives.

Mr. BILIRAKIS. Thank you very much, sir. And I apologize for cutting you off, but, you know, we have got to try to stay on point here.

Dr. Newman?

STATEMENT OF STUART A. NEWMAN

Mr. NEWMAN. I thank the chairman for giving me the opportunity to testify today on this historical issue. My name is Stuart Newman. I have been a Professor of Cell Biology and Anatomy at New York Medical College since 1979 where I teach medical and graduate students, and direct a laboratory in developmental biology.

This is a scientific field that studies embryo development, cloning, regeneration, and stem cells. My work on the development of the skeletal system in animals embryos has been supported over the past 25 years by grants from the National Science Foundation and the National Institutes of Health. I am currently the recipient of two Federal grants in this area.

Since my student days, I have also been concerned with the uses to which scientific research is put. Having become convinced that scientists, who are beneficiaries of public resources, have a deep responsibility to anticipate what lies down the road in their own fields, and to themselves act as a resource for the public on the complex issues around applications of scientific research, I joined with other scientists, social-scientists, feminists, and progressive community advocates to found the Council for Responsible Genetics in the late 1970's.

The Council is now the Nation's oldest organization scrutinizing and interpreting the new genetic technologies, and has worked for protecting genetic privacy, ending genetic discrimination, exercising caution in the development and dissemination of genetically engineered crops, banning biological weapons, and banning the introduction of inheritable genetic modifications into humans.

This last issue relates to my own field of expertise. Over the past quarter century, I have seen laboratory findings, such as virus-based gene therapies and implantation of fetal tissues employed prematurely or inappropriately in humans through a process that,

while often having noble motivations, has also been mixed with appreciable amounts of wishful thinking, hype, and greed.

Last year, the Council issued the Genetic Bill of Rights, which is appended to my written testimony, which touches on all the above issues.

The last of the 10 listed Rights states, "All people have the right to have been conceived, gestated, and born without genetic manipulation."

This position arose, in part, from scientific consideration of the inherent uncertainties in performing such manipulations, which include cloning. Reviewing the animal studies in this area led Professor Rudolf Jaenisch, of the Massachusetts Institute of Technology, to state, "I believe there probably isn't a normal clone around."

Our position also emanated from the fact that any person engineered in this fashion will be an experiment subject to the kinds of disappointments associated with experiments failing to meet expectations.

A grim aspect of this experimental approach to producing people would be the devaluation of unfavorable outcomes if, as in cloning, the same procedure could be performed repeatedly until a desired outcome was reached.

In addition, while the Council for Responsible Genetics is unequivocally committed to a woman's right not to proceed with a pregnancy, if that is her choice, we, along with many feminists and others who affirm this right, are concerned that reproductive choice is increasingly being taken to include the right to genetically improve the next generation.

If this is allowed, it may soon lead to baby design and reproductive boutiques. Eugenics, defining humans as genetically superior or inferior, and implementing those definitions, has a horrific history that we dare not repeat.

In line with the Genetic Bills of Rights, and in light of new experimental results and proposals to generate and modify human embryos, the Council for Responsible Genetics issued a policy statement on human embryo research earlier this month.

The statement is appended, and I will summarize it here. The Council for Responsible Genetics opposes the utilization of human eggs and embryos for experimental manipulations and as items of commerce.

We, therefore, call for a ban on the buying or selling of human eggs or embryos, and the manipulation of any and all human eggs or embryos by transfer of cells, nuclei, cytoplasm, mitochondria, chromosomes, or isolated DNA or RNA molecules of human or nonhuman origin.

These bans are to apply whether or not the embryos are to be implanted and gestated. No human embryo is to be produced solely for purposes of research. These bans are to apply, irrespective of the sources of funding, whether public or private.

It is essential that the United States join the many other nations that have banned reproductive cloning. But note that we call for a ban not just on reproductive cloning, but on so-call therapeutic cloning as well.

That is, even if a cloned embryo is not intended for gestation, we are opposed to its manufacture. We have become convinced that if a construction of modified or cloned human embryos is permitted, there will be little standing in the way of using them for reproductive purposes.

At that point, gestation of cloned embryos would easily become defined as a matter of individual choice.

The bans that we call for would not—would, in no way, curtail the option to employ in vitro fertilization for reproductive purposes. Moreover, while we do not explicitly reject the production of embryo stem cells from excess embryos produced by in vitro fertilization, my own view is that other scientific avenues, specifically adult stem cell research, have greater promise.

A group of my colleagues at New York Medical College recently published on the repair of damaged mouse hears with adult mouse stem cells. I know of no comparable successes with embryo stem cells in the mouse, even though such cells have been available and researched for more than a decade.

Any objective view of the relevant animal research would conclude that adult stem cells are the better bet.

As recently as a year or 2 ago, advocates of human cloning were careful to state that an embryo produced by cloning had no less dignity as a potential human than an embryo produced by fertilization.

Now that some technical advance is seen in making donor-matched stem cells from cloned embryos, distinctions are being made by interested parties between producing embryos for research by fertilization still not acceptable, and doing so by cloning, now acceptable.

If we let purely technical and utilitarian considerations determine what is acceptable in human reproduction and production, in a few brief years, human error will assuredly lead to production of humans with avoidable errors.

As a scientist, I am personally concerned that the products of our research not be used for dangerous and divisive purposes, which would bring disrepute to science and undermine our ability to do beneficial work.

As these new technologies proliferate, the question continually arises as to where to draw the line. I am convinced that the biotechnology industry does not want any line to be drawn that would curtail any of their activities.

The Greenwood bill, with its limited moratorium on reproductive cloning, will just be an opportunity to soften up public opinion, even on this issue. I say——

Mr. BILIRAKIS. Please summarize, Doctor. I would appreciate it.

Mr. NEWMAN. I say this with regret, as a life-long progressive and a democratic voter. Because embryo cloning will, with virtual certainty, lead to the production of experimental human beings, both as a scientist and a citizen, I urge you to draw the line here.

[The prepared statement of Stuart A. Newman follows:]

PREPARED STATEMENT OF STUART A. NEWMAN, PROFESSOR OF CELL BIOLOGY AND ANATOMY, NEW YORK MEDICAL COLLEGE

My name is Stuart Newman. I have been a professor of Cell Biology and Anatomy at New York Medical College since 1979, where I teach medical and graduate stu-

dents and direct a laboratory in developmental biology. This is the scientific field that studies embryo development, cloning, regeneration, and stem cells. My work on the development of the skeletal system in animal embryos has been supported over the past 25 years by grants from the National Science Foundation and the National Institutes of Health. I am currently the recipient of two Federal grants.

Since my student days I have also been concerned with the uses to which scientific research is put. My doctoral research in chemistry at the University of Chicago was conducted at the James Franck Institute. Professor James Franck was a Nobel prize winning atomic physicist who was the principal author of the May 1945 Franck Report. This document anticipated the horrors of nuclear weapons and was the first call by scientists for international controls over these weapons. The Franck report was a landmark in scientific responsibility and its message ultimately prevailed.

Having become convinced that scientists, who are beneficiaries of public resources, have a deep responsibility to anticipate what lies down the road in their own fields and to themselves act as a resource for the public on the complex issues around applications of scientific research, I joined with other scientists, social scientists, feminists and community advocates to found the Council for Responsible Genetics in the late 1970s. The Council is now the Nation's oldest organization scrutinizing and interpreting the new genetic technologies, and has worked for protecting genetic privacy, ending genetic discrimination, exercising caution on the development and dissemination of genetically engineered crops, banning biological weapons, and banning the introduction of inheritable genetic modifications into humans. This last issue relates to my own field of expertise. Over the past quarter century I have seen laboratory findings such as virus-based gene therapies and implantation of fetal tissues employed prematurely or inappropriately in humans through a process that while often having noble motivations has also been mixed with appreciable amounts of wishful thinking, hype and greed.

Last year the Council issued the Genetic Bill of Rights (appended) which touches on all the above issues. The last of the ten listed Rights states:

All people have the right to have been conceived, gestated, and born without genetic manipulation.

This position arose, in part, from scientific consideration of the inherent uncertainties in performing such manipulations, which include cloning. Reviewing the animal studies in this area led Professor Rudolf Jaenisch of the Massachusetts Institute of Technology to state "I believe there probably isn't a normal clone around." Our postion also emanated from the fact that any person engineered in this fashion will be an experiment, subject to the kinds of disappointments associated with experiments failing to meet expectations. A grim aspect of this experimental approach to producing people would the devaluation of "unfavorable" outcomes if, as in cloning, the same procedure could be performed repeatedly until a desired outcome was reached. In addition, while the Council for Responsible Genetics is unequivocally committed to women's right not to proceed with a pregnancy if that is her choice, we, along with many feminists and others who affirm this right, are concerned that "reproductive choice" is increasingly taken to include the right to genetically improve the next generation. If this is allowed it may soon lead to baby design and reproductive boutiques. Eugenics, defining humans as genetically superior or inferior and implementing those definitions, has a horrific history that we dare not repeat.

In line with the Genetic Bill of Rights, and in light of new experimental results and proposals to generate and modify human embryos, the Council for Responsible Genetics issued a policy statement on human embryo research earlier this month. The statement is appended and I will summarize it here:

- The Council for Responsible Genetics opposes the utilization of human eggs and embryos for experimental manipulations and as items of commerce.
- We therefore call for a ban on the buying or selling of human eggs or embryos, and the manipulation of any and all human eggs or embryos by transfer of cells, nuclei, cytoplasm, mitochondria, chromosomes, or isolated DNA or RNA molecules of human or non-human origin.
- These bans are to apply whether or not the embryos are to be implanted and gestated.
- No human embryo is to be produced solely for purposes of research.
- These bans are to apply irrespective of the sources of funding, whether public or private.

It is essential that the United States join the many other nations that have banned reproductive cloning. But note that we call for a ban not just on reproductive cloning but on so-called "therapeutic cloning" as well. That is, even if a cloned embryo is not intended for gestation we are opposed to its manufacture. We have

become convinced that if the construction of modified or cloned embryos is permitted there will be little standing in the way of using them for reproductive purposes. At that point gestation of cloned embryos would easily become defined as a matter of individual choice.

The bans that we call for would in no way curtail the option to employ in vitro fertilization for reproductive purposes. Moreover, while we do not explicitly reject the production of embryo stem cells from excess embryos produced by in vitro fertilization, my own view is that other scientific avenues, specifically adult stem cell research, have greater promise. A group of my colleagues at New York Medical College recently published on the repair of damaged mouse hearts with adult mouse stem cells. I know of no comparable successes with embryo stems cells in the mouse, even though such cells have been available and researched for more than a decade. Any objective view of the relevant animal research would conclude that adult stem cells are the better bet.

As recently as a year or two ago advocates of human cloning were careful to state that an embryo produced by cloning had no less dignity as a potential human than an embryo produced by fertilization. Now that some technical advantage is seen in making donor-matched stem cells from cloned embryos, distinctions are being made by interested parties between producing embryos for research by fertilization (still not acceptable) and doing so by cloning (now acceptable). If we let purely technical and utilitarian considerations determine what is acceptable in human reproduction and production, in a few brief years human error will assuredly lead to the production of humans with avoidable errors.

As a scientist, I am personally concerned that the products of our research not be used for dangerous and divisive purposes, which would bring disrepute to science and undermine our ability to do beneficial work. As these new technologies proliferate the question continually arises as to "where to draw the line." Because embryo cloning will, with virtual certainty, lead to the production of "experimental" human beings, both as a scientist and a citizen I urge you to draw the line here.

APPENDIX I

COUNCIL FOR RESPONSIBLE GENETICS STATEMENT ON EMBRYO RESEARCH

June 2001

The Council for Responsible Genetics unequivocally supports a woman's right to make her own reproductive decisions. However, we oppose the utilization of human eggs and embryos for experimental manipulations and as items of commerce because of the potential for eugenic applications and health risks to women and their offspring.

The Council for Responsible Genetics therefore calls for a ban on the buying or selling of human eggs or embryos, and the manipulation of any and all human eggs or embryos by transfer of cells, nuclei, cytoplasm, mitochondria, chromosomes, or isolated DNA or RNA molecules of human or non-human origin.

This ban would apply whether or not the embryos are to be implanted and gestated and irrespective of the sources of funding, whether public or private.

No human embryo is to be produced solely for purposes of research.

APPENDIX II

THE GENETIC BILL OF RIGHTS

PREAMBLE

Our life and health depend on an intricate web of relationships within the biological and social worlds. Protection of these relationships must inform all public policy.

Commercial, governmental, scientific and medical institutions promote manipulation of genes despite profound ignorance of how such changes may affect the web of life. Once they enter the environment, organisms with modified genes cannot be recalled and pose novel risks to humanity and the entire biosphere.

Manipulation of human genes creates new threats to the health of individuals and their offspring, and endangers human rights, privacy and dignity.

Genes, other constituents of life, and genetically modified organisms themselves are rapidly being patented and turned into objects of commerce. This commercialization of life is veiled behind promises to cure disease and feed the hungry.

People everywhere have the right to participate in evaluating the social and biological implications of the genetic revolution and in democratically guiding its applications.

To protect our human rights and integrity and the biological integrity of the earth, we, therefore, propose this Genetic Bill of Rights.

THE GENETIC BILL OF RIGHTS

1. All people have the right to preservation of the earth's biological and genetic diversity.
2. All people have the right to a world in which living organisms cannot be patented, including human beings, animals, plants, microorganisms and all their parts.
3. All people have the right to a food supply that has not been genetically engineered.
4. All indigenous peoples have the right to manage their own biological resources, to preserve their traditional knowledge, and to protect these from expropriation and biopiracy by scientific, corporate or government interests.
5. All people have the right to protection from toxins, other contaminants, or actions that can harm their genetic makeup and that of their offspring.
6. All people have the right to protection against eugenic measures such as forced sterilization or mandatory screening aimed at aborting or manipulating selected embryos or fetuses.
7. All people have the right to genetic privacy including the right to prevent the taking or storing of bodily samples for genetic information without their voluntary informed consent.
8. All people have the right to be free from genetic discrimination.
9. All people have the right to DNA tests to defend themselves in criminal proceedings.
10. All people have the right to have been conceived, gestated, and born without genetic manipulation.

Mr. BILIRAKIS. Thank you very much, Doctor.

Mr. Perry?

STATEMENT OF DANIEL PERRY

Mr. PERRY. Chairman Bilirakis and members of the committee, I very much appreciate the opportunity to come before this committee today to address the promise and the peril surrounding cloning technologies.

My name is Daniel Perry, and I am the Executive Director of the Alliance for Aging Research. And as the head of a not-for-profit group eager to find cures, preventions and overall better health and vitality for the elderly, my views on research reflect the medical needs of the growing population of older Americans.

The Alliance for Aging Research works to stimulate academic, governmental, and private sector research into the chronic diseases of human aging.

Our organization also takes up the cause of the vast majority of Americans who fervently wish to benefit from scientific discoveries that improve the human experience with aging.

Our survey research tells us that most Americans believe the Federal Government has a critical role to play to prepare the way for new medical breakthroughs and to hurry applications of science in health care in order to relieve human suffering and improve the quality of life for their family members and for themselves.

On behalf of a growing American constituency for healthy aging, powered by the aging of the Baby Boom generation, I am here to express a concern to this committee.

The Alliance for Aging Research believes that broadly drafted legislation intended to prevent the cloning of a human being could have the effect of derailing promising lines of health research,

which could ultimately benefit older Americans, their families, and the Nation as a whole.

Every day in America, another 6,000 people celebrate their 65th birthday. And just behind them, the Baby Boomers are cruising into their 50's in even greater numbers.

In just 10 years, the post-World War babies will begin swelling the Medicare rolls. In less than 30 years, the whole of our largest generation will be old enough to receive health care paid by Medicare.

If, during these years just ahead, we fail to reduce the threat of age-related diseases, the U.S. will encounter staggeringly high economic costs, as well as we will face a toll on human lives due to mounting debts and disabilities from cancer, stroke, macular degeneration, joint and bone diseases, Alzheimers and Parkinson's disease.

If we stifle future medical breakthroughs and must end up managing the aging of 75 million Baby Boomers with today's halfway technologies, we risk economic and social catastrophe within a generation.

Fortunately, we can choose a wiser, more humane, and ultimately less costly alternative. That alternative is to encourage rapid advances and applications from medical and behavioral research to prevent much of the declining health status we now associate with old age.

There is good reason to hope that scientific understanding of the mechanisms of aging within the—within our own cells, genes, and proteins may ultimately permit a significant delay in disabilities caused by diseases of aging.

Regenerative medicine is the concept of harnessing powers of growth and healing within our own bodies at a fundamental level of human biology.

We can look forward to future health technologies that use stem cells, engineered tissues, grown factors, and other tools of regenerative medicine. It is a growing possibility that physicians 1 day will be able to replace damaged tissues using a person's own cells to treat blindness, spinal cord injury, coronary artery disease, diabetes, and other diseases that result from injured, malfunctioning, or aged cells.

Scientists involved in this research say that human somatic cell nuclear transfer is an enabling technology that can be used to generate healthy cells and tissues for repair or replacement in a vast variety—in a vast array of medical applications.

To deny our aging population the opportunity to benefit from this research would be a tragic reversal of our recent biomedical progress toward permanent cure of diseases that compromise quality of life, and which account for so much of our Nation's health care expenditures.

A prominent member of the Alliance's Science Advisory Board is Dr. George M. Martin of the University of Washington in Seattle. Dr. Martin writes, "Those of us in the Alzheimers Disease Research Center are using cell cultures in attempts to discover the fundamental molecular mechanisms that lead to differing rates of neuronal damage in dementias of the Alzheimers type. For obvious

reasons, we cannot work with samples of brain tissues from living subjects."

"We are forced to utilize surrogate cells, typically fibroblasts that can be grown from tiny skin biopsies. The ability to reprogram such cells so that they can exhibit the properties of the donor's neural cells would represent an enormous advance."

I want to make it abundantly clear that the Alliance for Aging Research is strongly opposed to cloning of a human being. To my knowledge, that position is supported by virtually every responsible scientific and health advocacy organization in the United States.

The Alliance does support responsible and sound biomedical research, including emerging cellular therapies which could lead to the development of treatments for cures for scores of age-related diseases.

We urge this committee to lead the way by drawing a clear distinction between cloning for human reproductive purposes, which we oppose, and cloning cells for human therapeutic purposes.

Millions of patients and families, organizations, and advocates for health and scientific research across the land would applaud that kind of leadership.

Some measures before this committee propose to avoid the cloning of a human being by bringing into the laboratory the full police powers of the Federal Government.

These intended anti-cloning proposals would criminalize laboratory techniques that otherwise might help us find cures for diseases such as cancer and Alzheimers. To threaten university scientists with massive fines and prison sentences would constitute a massive and unprecedented assault on research.

Mr. BILIRAKIS. Please summarize, Mr. Perry.

Mr. PERRY. I will, Mr. Chairman. I would cast a pall over the conduct of academic science, and it would diminish and contradict the accomplishments of a U.S. Congress that, even now, is working nobly to double research funding to through the National Institutes of Health.

Mr. Chairman, it is likely that we will continue to be confronted with scientific advances that pose difficult social and ethical questions. Congress is at its best when its actions are informed and enriched by slow and careful debate, by advice from expert sources, and when taken in respect for minority opinion.

On behalf of the Alliance for Aging Research, I think the committee again for its deliberation and the opportunity to speak to this issue.

[The prepared statement of Daniel Perry follows:]

PREPARED STATEMENT OF DANIEL PERRY, EXECUTIVE DIRECTOR, ALLIANCE FOR AGING RESEARCH

Chairman Bilirakis, and Members of the Committee: Thank you for the opportunity to come before this committee today to address the promise and perils surrounding cloning technologies.

As the head of a not-for-profit group eager to find cures, preventions and overall better health and vitality for the elderly, my views on research reflect the medical needs of the growing population of older Americans.

The Alliance for Aging Research works to stimulate academic, governmental and private sector research into the chronic diseases of human aging. Our organization takes up the cause of the vast majority of Americans who fervently wish to benefit from scientific discoveries that improve the human experience with aging. Our sur-

vey research tells us that most Americans believe the federal government has a critical role to play to prepare the way for new medical breakthroughs and to hurry applications of science in health care in order to relieve human suffering and improve the quality of life for their family members and for themselves.

On behalf of a growing American constituency for healthy aging—powered by the aging of the Baby Boom generation—I am here to express a concern to the committee. The Alliance for Aging Research believes that broadly drafted legislation, intended to prevent the cloning of a human being, could have the effect of derailing promising lines of health research which could ultimately benefit older Americans, their families and the nation as a whole.

Every day in America another 6,000 people celebrate a 65th birthday. Just behind them, the Baby Boomers are cruising into their 50s in even greater numbers. In just 10 years the post World War babies will begin swelling the Medicare roles.

In less than 30 years, the whole of our largest generation will be old enough to receive health care paid by Medicare. If, during these years just ahead, we fail to reduce the threat of age-related diseases, the U.S. will encounter staggeringly high economic costs, as well as we will face a toll on human lives due to mounting deaths and disabilities from cancer, stroke, macular degeneration, joint and bone diseases, Alzheimer's and Parkinson's diseases.

If we stifle future medical breakthroughs, and must manage the aging of 75 million Baby Boomers with today's halfway health technologies, we risk economic and social catastrophe within a generation.

Fortunately, we can choose a wiser, more humane, and ultimately less costly alternative. That alternative is to encourage rapid advances and applications from medical and behavioral research to prevent much of the declining health status we now associate with old age.

There is good reason to hope that scientific understanding of the mechanisms of aging within our own cells, genes and proteins may ultimately permit a significant delay in disabilities caused by diseases of aging.

Regenerative medicine is the concept of harnessing powers of growth and healing within our own bodies at a fundamental level of human biology. We can look forward to future health technologies that use stem cells, engineered tissues, growth factors and other tools of regenerative medicine. It's a growing possibility that physicians one day will be able to replace damaged tissues, using a person's own cells to treat blindness, spinal cord injury, coronary artery damage, diabetes and other diseases that result from injured, malfunctioning or aged cells.

Scientists involved in this research say that human somatic cell nuclear transfer is an enabling technology that can be used to generate healthy cells and tissues for repair or replacement in a vast array of medical applications. To deny our aging population the opportunity to benefit from this research would be a tragic reversal of recent biomedical progress toward permanent cure of diseases that compromise quality of life, and which account for so much of our nation's health care expenditures.

A prominent member of the Alliance's Science Advisory Board is Dr. George M. Martin of the University of Washington in Seattle. Dr. Martin has written: "those of us in the Alzheimer's Disease Research Center are using cell cultures in attempts to discover the fundamental molecular mechanisms that lead to differing rates of neuronal damage in dementias of the Alzheimer type and related disorders. For obvious reasons, we cannot work with samples of brain tissue from living subjects. We are forced to utilize surrogate cells, typically fibroblasts that can be grown from tiny skin biopsies. The ability to reprogram such cells so that they can exhibit the properties of the donor's neural cells would represent an enormous advance."

I want to make it abundantly clear that the Alliance for Aging Research is strongly opposed to the cloning of a human being. To my knowledge that position is supported by virtually every responsible scientific and health advocacy organization in the U.S. The Alliance does support responsible and sound biomedical research, including emerging cellular therapies, which could lead to the development of treatments or cures for scores of age-related diseases and disabilities.

We urge this committee to lead the way by drawing a clear distinction between cloning for human reproductive purposes—which we oppose—and cloning cells for human therapeutic purposes. Millions of patients and families, organizations and advocates for health and scientific research across the land would applaud that kind of leadership.

Some measures before this committee propose to avoid the cloning of a human being by bringing into the laboratory the full police powers of the federal government. These intended anti-cloning proposals would criminalize laboratory techniques that otherwise might help us find cures for diseases such as cancer and Alzheimer's.

To threaten university scientists with massive fines and prison sentences would constitute a massive and unprecedented assault on research. It would cast a pall over the conduct of academic science. And it would diminish and contradict the accomplishments of a U.S. Congress that even now is working nobly to double research funding through the National Institutes of Health.

At this very moment, tens of millions of older Americans are suffering from Alzheimer's, Parkinson's, cancer, diabetes and chronic health problems of aging. Not only are they suffering, but their families and caregivers are suffering too, and they are hoping that scientists will find cures for these devastating diseases and conditions while there is still time. They are in a hurry for answers, and they look to leaders like you to be their advocates and protectors.

Mr. Chairman, it is likely that we will continue to be confronted with scientific advances that pose difficult social and ethical questions. The present momentum in the life sciences, and the profound implications of what we are learning, will inevitably raise public concerns.

There is ample time for policymakers, ethicists, scientists, and patient groups to discuss options that would prevent human cloning, but which would preserve promising health research. Congress is at its best when its actions are informed and enriched by slow and careful debate, by advice from expert sources, and when taken in respect for minority opinion.

In the case of proposals to limit any of the tools for scientific and medical research, the need for prudence is especially important, due to the technical complexity of the issues and the consequences for public health and well being.

On behalf of the Alliance for Aging Research, I thank the committee again for its deliberations and for the opportunity to speak to this issue.

Mr. BILIRAKIS. Thank you so much, Mr. Perry.

Ms. Norsigian?

STATEMENT OF JUDY NORSIGIAN

Ms. NORSIGIAN. Thank you, Chairman Bilirakis and members of the committee for the opportunity to speak. My name is Judy Norsigian. I am Executive Director of the Boston Women's Health Book Collective, which is best known for the landmark women's health and sexuality book entitled, "Our Bodies, Ourselves," published first in 1970.

There are now 4.5 million copies in print in 20 languages around the world, with 10 on the way. The most recent edition is entitled, "Our Bodies, Ourselves for the New Century." And there is a new Spanish language cultural adaptation that appeared last year.

Our organization has a long track record in the area of women's health and reproductive rights. And I personally serve on the Board of Directors of a public interest organization devoted to medical research issues.

And I also have served in the capacity of advisor and on some planning committees for the Office of Research on Women's Health at the National Institutes of Health.

I am deeply interested in many avenues of research. I would like to endorse the comments by Drs. Kass and Newman, so I will try not to repeat them again.

Our organization joins many other national and international organizations in calling for a universal ban on human reproductive cloning. As we said, allowing for cloning would open the door to treating our children like manufactured objects. It would pave the way for an unprecedented new form of eugenics. And it really would serve no justifiable purpose.

Supporters of women's health and reproductive rights have particular reasons to oppose human cloning. Those who would encourage human cloning appear oblivious to the enormous risks to women and children's health that cloning would pose. And there is

no way that human cloning could be developed without, in effect, mass experimentation on human beings, women and children, of a sort that has been outlawed since the formulation of the Nuremburg Principles following World War II.

For these reasons, we call for a permanent ban on the creation of cloned human beings. And our opposition to human cloning in no way diminishes our support for a woman's right to safe, legal, and accessible contraception and abortion services.

Some medical researchers support the creation of clonal human embryos for experimental purposes leading to potential therapeutic applications.

While many women's health advocates may not, in principle, oppose the use of human embryos for valid medical research, including their use to generate embryonic stem cells, they do oppose the creation of clonal human embryos.

To allow this procedure would make it all but impossible to enforce the ban on the creation of fully formed human clones. I think that point has been made. There is no such thing as an enforceable ban, and I won't repeat that.

Further, it would open the door to other, more profound forms of human genetic manipulation. And for these reasons, we call for a moratorium on the creation of clonal human embryos for research purposes.

During such a period, the many non-controversial alternatives for these purposes could be explored.

I also want to point out that we, along with many others, have never taken the position that a woman or a man has a right to biological parenthood and, the corollary position that would follow, an unlimited right to pursue any type of reproductive technology that may lead to biological parenthood.

There are many reasons why such a position would be untenable from the basic view of health and safety alone. More than 30 countries worldwide already have banned the creation of human clones and/or imposed constraints on the creation of clonal embryos.

It is time for the United States to do likewise. The majority of women's health and reproductive advocates want this to happen as the future of our common humanity is at stake.

And I do want to say that my interpretation of the Weldon-Stupak bill is that it goes just the right distance. It will prevent the things we don't want to have happened from happening, and it will allow appropriate clonal techniques to proceed ahead with somatic cells.

And a good deal of the therapeutic benefits that we would like to see developed can be developed while we oppose the development of clonal human embryos. Thank you very much.

[The prepared statement of Judy Norsigian follows:]

PREPARED STATEMENT OF JUDY NORSIGIAN, EXECUTIVE DIRECTOR, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE

I am Judy Norsigian, the Executive Director of the Boston Women's Health Book Collective (BWHBC), co-authors of *Our Bodies, Ourselves,* the most widely read book about women's health and sexuality since it was first published in 1970. There are now 4½ million copies in print in 20 languages around the world, with 10 more editions on the way. The 7th and latest English language edition in the United States is entitled *Our Bodies, Ourselves for the New Century.* The Spanish language cultural adaptation—*Nuestros Cuerpos, Nuestras Vidas*—was published last year. Our

organization has also produced similar books for teenagers and for older women and sustains a variety of advocacy and activist efforts related to the health of women, families and communities. We have a long track record in the field of reproductive rights and reproductive health.

The BWHBC joins many other national and international organizations in calling for a universal ban on human reproductive cloning. To allow the creation of human clones would open the door to treating our children like manufactured objects. It would violate deeply and widely held values concerning human individuality and dignity. It would pave the way for unprecedented new forms of eugenics. And it would serve no justifiable purpose.

Supporters of women's health and reproductive rights have particular reasons to oppose human cloning. Those who encourage human cloning appear oblivious to the enormous risks to women and children's health that human cloning would pose. There is no way that human cloning could be developed without, in effect, mass experimentation on human beings—women and children—of a sort that has been outlawed since the formulation of the Nuremberg Principles following World War II.

Further, cloning advocates are seeking to appropriate the language of reproductive rights to support their case. This is a travesty. There is an immense difference between seeking to end an unwanted pregnancy and seeking to create a genetic duplicate human being. Our opposition to human cloning in no way diminishes our support for a woman's right to safe, legal, and accessible contraception and abortion services.

For these reasons, we call for a permanent ban on the creation of cloned human beings.

Some medical researchers support the creation of clonal human embryos for experimental purposes leading to potential therapeutic applications. While we do not in principle oppose the use of human embryos for valid medical research, including their use to generate embryonic stem cells, we do oppose the creation of clonal human embryos. To allow this procedure would make it all but impossible to enforce the ban on the creation of fully formed human clones. Further, it would open the door to other, more profound forms of human genetic manipulation. For these reasons, we call for at least a moratorium on the creation of clonal human embryos for research purposes. During such a period the many non-controversial alternatives to using clonal embryos for these purposes could be explored.

More than thirty countries worldwide have already banned the creation of human clones and/or imposed constraints on the creation of clonal embryos. It is time for the United States to do likewise. The vast majority of women's health and reproductive rights advocates want this to happen. The future of our common humanity is at stake.

Mr. BILIRAKIS. Thank you very much, Ms. Norsigian.

Mr. Doerflinger?

STATEMENT OF RICHARD M. DOERFLINGER

Mr. DOERFLINGER. Thank you. I will forego the opportunity to debate Dr. Guenin on what Catholicism means unless someone raises it in a question.

The only Catholic quote I will use is this statement from the Pontifical Academy of Life, which advises the Holy See, "In the cloning process, the basic relationships of the human person are perverted; filiation, consanguinity, kinship, parenthood. A woman can be the twin sister of her mother, lack a biological father, and be the daughter of her grandmother. In in vitro fertilization"—I am sorry, "In vitro fertilization has already led to the confusion of parentage, but cloning will mean the radical rupture of these bonds."

By reducing human reproduction to simple manufacture in the laboratory, cloning reduces the new human being to a product and then to a commodity, and obviously opens the door to these human beings, at any age, being treated as mere research fodder, as second-class human beings.

We all agree that in the present state of science, it would be irresponsible to try to produce a live-born child by cloning, as evi-

denced by the 95 to 99 percent death rate of cloned embryos in animal trials.

I would note, though, that if people think that the human embryo has no status, is chopped liver, then I don't know why even my pro-choice colleagues agree that that 95 to 99 percent death rate, most of which happens at the embryonic and fetal stage, is a problem.

I think the abortion issue and its politics have really confused the fact that biologically, we are speaking about a being that is a member of the family with us, and is a member of the human species.

And the fact that in our current legal situation, there are other considerations involving competing rights of a pregnant woman that have been found to override those interests, does not make the human embryo into a goldfish, as the International Chairman of the Juvenile Diabetes Foundation has been known to say.

Now, I want to go into the problem that some people want to solve the problem of 95 to 99 percent death rate by simply jacking the death rate up to 100 percent for research purposes. I don't think that is the right direction.

I think that if you are—if you are going to make new human beings in such a way that the death rate is anywhere between 95 and 100 percent, it would be a very good idea to decide not to create those human beings.

But I would like to cite particularly the Greenwood bill. I agree with Dr. Kass about what the Greenwood bill does, except I think he has been too kind. I think the Greenwood bill doesn't ban anything at all in the area of reproductive cloning.

And Dr. Kass has set forth a number of scenarios in which one person would make the embryo and another transfer it, or ship it, and so on. And those are all true.

But let us take the very simplest, most straightforward case of outright reproductive cloning with one researcher. Now, that researcher is authorized by this bill, and gets a registered laboratory, to do research in cloning, presumably including research to see how efficient the cloning process can be made in the laboratory to prepare for the day, 10 years hence, when all bans drop away, and the safety record is sufficient to argue that we should do reproductive cloning.

Now, on that basis alone, I would call this bill the Railian agenda with a speed bump. But let us see what happens in the meantime.

He makes these embryos in the laboratory to test the efficiency of the process. This time, the embryos look really good; they look a lot more viable than in the past. So, he now intends to initiate a pregnancy with them. That is the way this would happen.

You would never know in advance which embryos are going to be good enough to try a pregnancy with. And when he initiates that pregnancy, he is acting fully in accord with this bill.

He is not evading the law. He is obeying the law because his intent to implant happened after he made the embryos.

So, if this bill does nothing to stop reproductive cloning, what does it do? It does two things. First, it bans any State from trying to ban reproductive or research cloning by saying that the only

thing a new State law may do is exactly what this bill does, which is nothing to stop cloning.

The second thing it does is to actually inject the Federal Government in a much more active way into the licensing, the registration, of laboratories to do that process which Mr. Greenwood quoted me a moment ago, as "morally abhorrent and medically questionable," except that he was stating that as the position of the Catholic Church. And actually, I was paraphrasing President Clinton, Senator Specter, the NIH, and The Washington Post and The Chicago Sun Times.

This is not something that has been a dividing matter between pro-life and pro-choice people. Just to cite The Washington Post, "The creation of human embryos specifically for research that will destroy them is unconscionable . . . [I]t is not necessary to be against abortion rights, or to believe human life literally begins at conception, to be deeply alarmed by the notion of scientists purposely causing conceptions in a context entirely divorced from even the potential of reproduction."

Likewise, The Chicago Sun Times has editorialized that creating research embryos solely for research that will kill them is an idea that is "grotesque, at best."

This is an ethical principle that has united us in the past. The NIH guidelines forbid creation of embryos for this stem cell research.

The Specter bill forbids this. And he recently said twice on the Charlie Rose Show that he continues to hold firmly against any special creation of embryos for research purposes.

Even among those who support other forms of embryo research, this has been seen as a moral step too far to the totally utilitarian demoting of human life into a research entity.

In short, I think we can support research and support useful medical progress, but also we should be serious. Do we want to ban human cloning?

The Greenwood bill does not do it, and we believe the Weldon bill does, and does so in a way that is very carefully crafted and effective. Thank you.

[The prepared statement of Richard M. Doerflinger follows:]

PREPARED STATEMENT OF RICHARD M. DOERFLINGER ON BEHALF OF THE COMMITTEE FOR PRO-LIFE ACTIVITIES, NATIONAL CONFERENCE OF CATHOLIC BISHOPS

I am Richard M. Doerflinger, Associate Director for Policy Development at the Secretariat for Pro-Life Activities, National Conference of Catholic Bishops. I am grateful for this opportunity to testify on human cloning, and to express our Conference's support for a federal ban on the practice as proposed in Congressman Weldon's "Human Cloning Prohibition Act of 2001" (H.R. 1644).

The sanctity and dignity of human life is a cornerstone of Catholic moral and social teaching. We believe a society can be judged by the respect it shows for human life, especially in its most vulnerable stages and conditions.

At first glance, human cloning may not seem to threaten respect for life because it is presented as a means for creating life, not destroying it. Yet it shows disrespect for life in the very act of generating it. Here human life does not arise from an act of love, but is manufactured in the laboratory to preset specifications determined by the desires of others. Developing human beings are treated as objects, not as individuals with their own identity and rights. Because cloning completely divorces human reproduction from the context of a loving union between man and woman, such children have no "parents" in the usual sense. As a group of experts advising the Holy See has written:

> In the cloning process the basic relationships of the human person are perverted: filiation, consanguinity, kinship, parenthood. A woman can be the twin sister of her mother, lack a biological father and be the daughter of her grandmother. In vitro fertilization has already led to the confusion of parentage, but cloning will mean the radical rupture of these bonds.[1]

From the dehumanizing nature of this technique flow many disturbing consequences. Because human clones would be produced by a means that involves no loving relationship, no personal investment or responsibility for a new life, but only laboratory technique, they would be uniquely at risk of being treated as "second-class" human beings.

In the present state of science, attempts to produce a liveborn child by cloning would require taking a callous attitude toward human life. Animal trials show that 95 to 99% of cloned embryos die. Of those which survive, many are stillborn or die shortly after birth. The rest may face unpredictable but potentially devastating health problems. Those problems are not detectable before birth, because they do not come from genetic defects as such—they arise from the disorganized expression of genes, because cloning plays havoc with the usual process of genetic reorganization in the embryo.[2]

Scenarios often cited as *justifications* for human cloning are actually *symptoms* of the disordered view of human life that it reflects and promotes. It is said that cloning could be used to create "copies" of illustrious people, or to replace a deceased loved one, or even to provide genetically matched tissues or organs for the person whose genetic material was used for the procedure. Each such proposal is indicative of a utilitarian view of human life, in which a fellow human is treated as a means to someone else's ends—instead of as a person with his or her own inherent dignity. This same attitude lies at the root of human slavery.

Let me be perfectly clear. In objective reality a cloned human being would not be an "object" or a substandard human being. Whatever the circumstances of his or her origin, he or she would deserve to be treated as a human person with an individual identity. But the depersonalized technique of manufacture known as cloning disregards this dignity and sets the stage for further exploitation. Cloning is not wrong because cloned human beings would lack human dignity—it is wrong because they *have* human dignity, and are being brought into the world in a way that fails to respect that dignity.

Ironically, startling evidence of the dehumanizing aspects of cloning is found in some proposals ostensibly aimed at *preventing* human cloning. These initiatives would not ban human cloning at all—but would simply ban any effort to allow cloned human embryos to survive. In these proposals, researchers are allowed to use cloning for the unlimited mass production of human embryos for experimentation—and are then required by law to destroy them, instead of allowing them to implant in a woman's womb.

In other words: Faced with a 99% death rate from cloning, such proposals would "solve" the problem by ensuring that the death rate rises to 100%. No live clones, therefore no evidence that anyone performed cloning. This is reassuring for researchers and biotechnology companies who may wish the freedom to make countless identical human guinea pigs for lethal experiments. It is no great comfort to the dead human clones; nor is it a solution worthy of us as a nation.

Congressman Greenwood's "Cloning Prohibition Act of 2001" (H.R. 2172) is even worse than previous bills of this kind. It would actually have the Department of Health and Human Services authorize and *license* the practice of destructive cloning. In a new way, our government would be actively involved in human cloning—but only to ensure that no cloned embryos get out of the laboratory alive. Under the guise of a ban on cloning, the government would assist researchers in refining their procedure; then, ten years after the date of enactment, it would obligingly drop all penalties for using cloning to initiate a pregnancy, so they could use their newly honed skills to manufacture babies. This bill would even invalidate any future state law seeking to establish a genuine ban on cloning, by preempting any such law that does not take the same irresponsible approach.

Sometimes it is said that such proposals would ban "reproductive cloning" or "live birth cloning," while allowing "therapeutic cloning" or "embryo cloning." This may

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[1] Reflections from the Pontifical Academy for Life, "Human Cloning Is Immoral" (July 9, 1997), in *The Pope Speaks,* vol. 43, no. 1 (January/February 1998), p. 29. Also see: Congregation for the Doctrine of the Faith, *Donum Vitae* (Instruction on Respect for Human Life in its Origin and on the Dignity of Procreation)(March 10, 1987), I.6 and II.B.

[2] See Testimony before the House Energy and Commerce Subcommittee on Oversight and Investigations, March 28, 2001, presented by Dr. Mark E. Westhusin and Dr. Rudolf Jaenishch (http://energycommerce.house.gov/107/hearings/03282001Hearing141/hearing.htm).

sound superficially reasonable. If banning all cloning is too difficult a task, perhaps we could ban half of it—and the half that is "therapeutic" sounds like the half we'd like to keep.

But this description relies on a fundamental confusion as to what cloning is. I can sum up the real situation in a few propositions.

1. All human cloning is embryo cloning. Some accounts of cloning seem to imagine that cloning for research purposes produces an embryo, while cloning for reproductive purposes produces a baby or even a fully grown adult—like new copies of Michael Keaton or Arnold Schwarzenegger springing full-grown from a laboratory. This is, of course, nonsense. In the words of Professor Lee Silver of Princeton University, a leading advocate of human cloning: "Real biological cloning can only take place at the level of the cell."[3]

Cloning technology can also be used to produce other kinds of cells; these are not the subject of this hearing, and they are explicitly excluded from the scope of Congressman Weldon's legislation. But when somatic cell nuclear transfer is used to replace the nucleus of an egg with the nucleus of a human body cell and the resulting cell is stimulated, a human embryo results, whatever one's ultimate plans on what to do next.[4]

2. In an important sense, all human cloning is reproductive cloning. Once one creates a live human embryo by cloning, one has engaged in reproduction—albeit a very strange form of asexual reproduction. All subsequent stages of development—gestation, birth, infancy, etc.—are simply those which normally occur in the development of any human being (though reaching them may be far more precarious for the cloned human, due to the damage inflicted by the cloning procedure).

To say this is not to make a controversial moral claim about personhood or legal rights.[5] It is to state a biological fact: Once one produces an embryo by cloning, a new living being has arrived and the key event in reproduction has taken place. The complete human genome that once belonged to one member of the human species now also belongs to another. Anything that now happens to this being will be "environmental" influence upon a being already in existence—transfer to a womb and live birth, for example, are chiefly simple changes in location.

Moreover, even government study commissions favoring harmful human embryo experiments concede that with the generation of a new embryo, a new life has come into the world. They describe the early embryo as "a developing form of human life" which "warrants serious moral consideration."[6]

Thus generating this new human life in the laboratory confronts us with new moral questions: Not "Should we clone?" but "What do we do with this living human we have produced by cloning?" If all the available answers are lethal to the cloned human 95% to 100% of the time, we should not allow cloning.

3. All human cloning, at present, is experimental cloning. The line between "reproductive" and "experimental" cloning is especially porous at present, because any attempt to move toward bringing a cloned child to live birth would first require many thousands of trials using embryos *not* intended for live birth. Years of destructive research of this kind may be necessary before anyone could bring a cloned human through the entire gestational process with any reasonable expectation of a healthy child. Therefore legislation which seeks to bar creation of a cloned embryo for purposes of live birth, while allowing unlimited experimental cloning, would actually facilitate efforts to refine the cloning procedure and prepare for the production of liveborn children. This would be irresponsible in light of the compelling principled objections to producing liveborn humans by cloning.

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[3] Lee M. Silver, *Remaking Eden: How Genetic Engineering and Cloning Will Transform the American Family* (Avon Books 1998) at 124.

[4] See the Fact Sheet, "Does Human Cloning Produce an Embryo?", Secretariat for Pro-Life Activities, National Conference of Catholic Bishops, March 31, 1998 (www.nccbuscc.org/prolife/issues/bioethic/fact398.htm).

[5] Professor Silver, for example, agrees that cloning is accomplished at the embryonic level, while also claiming that the cloned embryo (and all other embryos) lack full moral significance until later in development. To his Princeton colleague Peter Singer and some other bioethicists, humans do not acquire the rights of persons until some time after birth. See P. Singer, "Justifying Infanticide," in *Writings on an Ethical Life* (HarperCollins 2000), 186-193.

[6] *Final Report of the Human Embryo Research Panel* (National Institutes of Health: September 27, 1994) at 2. The National Bioethics Advisory Commission, which defined the embryo as "the beginning of any organism in the early stages of development," likewise said that "the embryo merits respect as a form of human life" (though not, the Commission thought, the level of respect owed to persons). See *Ethical Issues in Human Stem Cell Research* (National Bioethics Advisory Commission: September 1999) at 85, 50. Also see the sources cited in the Fact Sheet, "What is an Embryo?", Secretariat for Pro-Life Activities, National Conference of Catholic Bishops, Feb. 26, 1998 (www.nccbuscc.org/prolife/issues/bioethic/fact298.htm).

4. No human cloning is "therapeutic" cloning. The attempt to label cloning for purposes of destructive experiments as "therapeutic cloning" is a stroke of marketing genius by supporters of human embryo research. But it does serious damage to the English language and common sense, for two reasons.

First, the experiments contemplated here are universally called "nontherapeutic experimentation" in law and medical ethics—that is, the experiments harm or kill the research subject (in this case the cloned human embryo) without any prospect of benefitting that subject. This standard meaning of "nontherapeutic" research is found, for example, in various state laws forbidding such research on human embryos as a crime.[7] Experiments performed on one subject solely for possible benefit *to others* are never called "therapeutic research" in any other context, and there is no reason to change that in this context.

Second, the "therapeutic" need for human cloning has always been highly speculative; it now seems more doubtful than ever in light of recent advances in adult stem cell research and other noncontroversial alternatives. In the stem cell research debate, as one recent news report observes, "There is one thing everyone agrees on: Adult stem cells are proving to be far more versatile than originally thought."[8] Adult stem cells have shown they can be "pluripotent"—producing a wide array of different cells and tissues.[9] They can also be multiplied in culture to produce an ample supply of tissue for transplantation.[10] Best of all, using a patient's own cells solves all problems of tissue rejection, the chief advantage cited until now for use of cloning.[11]

In 1997 the National Bioethics Advisory Commission reviewed the idea of cloning human embryos to create "customized stem cell lines" but described this as "a rather expensive and far-fetched scenario"—and added that a moral assessment is necessary as well:

> Because of ethical and moral concerns raised by the use of embryos for research purposes it would be far more desirable to explore the direct use of human cells of adult origin to produce specialized cells or tissues for transplantation into patients.[12]

Now PPL Therapeutics, the Scottish firm involved in creating "Dolly" the sheep, says it has indeed found a way to reprogram ordinary adult cells to become stem cells capable of being directed to form almost any kind of cell or tissue—without creating or destroying any embryos.[13]

Even in the field of embryonic stem cell research, new developments have called into question the need for cloning. The problem of tissue rejection may not be as serious as once thought when cells from early human development are used, and

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[7] For example, see La. Rev. Stat. tit. 14 § 87.2 (a crime to conduct any experiment or study on a human embryo except to preserve the health of that embryo) and tit. 40 § 1299.35.13 (prohibiting experimentation on an unborn child unless it is therapeutic to that child); Mich. Comp. Laws § 333.2685 (prohibiting use of a live human embryo for nontherapeutic research that will harm the embryo); Pa. Cons. Stat. tit. 18 § 3216(a) (nontherapeutic experimentation on an unborn child at any stage is a felony; defining "nontherapeutic"); S.D. Codified Laws §§ 34-14-16 through 34-14-20 (prohibiting nontherapeutic research that harms or destroys a human embryo; defining "nontherapeutic research").

[8] A. Zitner, "Diabetes Study Fuels Stem Cell Funding War," *Los Angeles Times,* April 27, 2001 (www.latimes.com/news/nation/updates2/lat—stemwar010427.htm).

[9] Citing eleven other studies, a study funded by the National Institutes of Health (NIH) and the Christopher Reeve Paralysis Foundation states: "Pluripotent stem cells have been detected in multiple tissues in the adult, participating in normal replacement and repair, while undergoing self-renewal." D. Woodbury et al., "Adult Rat and Human Bone Marrow Stromal Cells Differentiate Into Neurons," 61 *Journal of Neuroscience Research* 364-370 (August 15, 2000) at 364.

[10] See: D. Colter et al., "Rapid expansion of recycling stem cells in cultures of plastic-adherent cells from human bone marrow," 97 *Proc. Natl. Acad. Sci.* USA 3213-8 (March 28, 2000)(adult stem cells amplified a billion-fold in six weeks, retaining their multipotentiality for differentiation); E. Rosler et al., "Cocultivation of umbilical cord blood cells with endothelial cells leads to extensive amplification of competent CD34+CD38-cells," 28 *Exp. Hematol.* 841-52 (July 2000).

[11] A recent report on use of adult stem cells to form new muscles, nerves, liver cells and blood vessels observes: "None of these approaches use embryonic stem cells, which some oppose on ethical grounds. Another advantage is that they use tissue taken from the patient's own body, so there is no risk of rejection or need for drugs to suppress immune system defenses." See "Approach may renew worn hearts," Associated Press, November 12, 2000.

[12] *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* (Rockville, MD: June 1997) at 30-31. The Commission outlined three alternative avenues of stem cell research, two of which seemed not to involve creating human embryos at all.

[13] "PPL follows Dolly with cell breakthrough," *Financial Times,* February 23, 2001.

there are other ways of solving the problem—for example, by genetically modifying cells to become a closer match to a patient.[14]

For all these reasons, a recent overview of the field concludes that human "therapeutic cloning" is "falling from favour," that "many experts do not now expect therapeutic cloning to have a large clinical impact." Even James Thomson of the University of Wisconsin, a leading practitioner and advocate of embryonic stem cell research generally, calls this approach "astronomically expensive"; in light of the enormous wastefulness of the cloning process and the damage it does to gene expression, "many researchers have come to doubt whether therapeutic cloning will ever be efficient enough to be commercially viable" even if one could set aside the grave moral issues involved.[15]

We should clearly understand what would be entailed by any effort to implement a "therapeutic cloning" regimen for stem cell transplants. This would not be a case in which human embryos are destroyed once to form a permanent cell line for future use. For *each individual patient,* countless human embryos—the patient's genetic twin brothers or sisters—would have to be created in the laboratory and then destroyed for their stem cells, in the hope of producing genetically matched tissue for transplantation. Thus the creation and destruction of human life in the laboratory would become an ongoing aspect not only of medical research but of everyday medical practice. And what would become of those who have profound moral objections to cloning, and to having new lives created and destroyed for our benefit? Would we be told that we must choose between our life and our conscience?

In short, the "therapeutic" case for cloning is as morally abhorrent as it is medically questionable. Which brings me to a final proposition on how to assess proposals for preventing human cloning.

5. Because cloned humans are humans, any proposal to prevent human cloning must not do to cloned humans anything that would be universally condemned if done to other humans at the same stage of development.

This proposition can be universally endorsed by people on both sides of the cloning issue, and on both sides of the abortion issue. To quote Lee Silver once more: "Cloned children will be full-fledged human beings, indistinguishable in biological terms from all other members of the human species."[16] Thus, for example, cloned embryos deserve as much respect as other human embryos of the same stage—whatever that level of respect may be.

Silver's point about cloned humans being "indistinguishable" from others raises a major practical problem for efforts to allow creation of cloned embryos while forbidding their transfer to a womb. Once the embryo is created in a fertility clinic's research lab (as such a law would permit) and is available for transfer, *how could the government tell* that this embryo was or was not created by cloning? And if it cannot do so, how can it enforce a prohibition on transferring cloned embryos (but not IVF embryos) to a woman's womb?

However, an even more serious moral and legal issue arises at this point. If the government allows use of cloning to produce human embryos for research but prohibits initiating a pregnancy, what will it be *requiring* people to do? If pregnancy has already begun, the only remedy would seem to be government-mandated abortion—or at least, jailing or otherwise punishing women for remaining pregnant and giving birth. We need not dwell on the abhorrence such a solution would rightly provoke among people on all sides of the abortion issue. It would be as "anti-choice" as it is "anti-life."

However, even if the law could act before transfer actually occurs, the problem is equally intractable. For the law would have to *require* that these embryos be killed—defining for the first time in U.S. history a class of human embryos that it is a crime *not* to destroy. It is impossible to reconcile such a law with the profound "respect" and "serious moral consideration" that even supporters of human embryo research say should be accorded to all human embryos.

If the law *permitted* (or, even worse, *licensed*) creation of cloned embryos for research, while prohibiting their creation for any other purpose (or prohibiting any other use of them once created), the government would be approving the one practice in human embryo research that is widely condemned even by supporters of abortion rights: specially creating human embryos solely for the purpose of research that will kill them.

In 1994 the National Institutes of Health did propose funding such abuses, as part of a larger proposal for funding human embryo research generally. The moral outcry against this aspect of the proposal, however, was almost universal. Opinion

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[14] P. Aldhous, "Can they rebuild us?", 410 *Nature* 622-5 (5 April 2001) at 623.
[15] Id. at 622.
[16] Silver at 125.

polls showed massive opposition, and the NIH panel making the recommendation was inundated with over 50,000 letters of protest. The *Washington Post,* while reaffirming its support for legalized abortion, attacked the Panel's recommendation:

> The creation of human embryos specifically for research that will destroy them is unconscionable . . . [I]t is not necessary to be against abortion rights, or to believe human life literally begins at conception, to be deeply alarmed by the notion of scientists' purposely causing conceptions in a context entirely divorced from even the potential of reproduction.[17]

The *Chicago Sun-Times* likewise editorialized:

> We can debate all day whether an embryo is or isn't a person. But it is unquestionably human life, complete with its own unique set of human genes that inform and drive its own development. The idea of the manufacture of such a magnificent thing as a human life purely for the purpose of conducting research is grotesque, at best. Whether or not it is federally funded.[18]

In the end, President Clinton set aside the recommendation for creation of "research embryos."

Every year since then, Congress has prohibited funding for all harmful embryo research at the National Institutes of Health, through the Dickey amendment to the annual Labor/HHS appropriations bills.[19] However, *even members of Congress who have led the opposition to the Dickey amendment agree with its rejection of special creation of human embryos for research.* On the only occasion when an amendment was offered on the House floor to weaken the Dickey amendment, the sponsors emphasized that it would leave intact the clause rejecting the creation of embryos for research.[20] Similarly, the recent NIH guidelines for embryonic stem cell research, as well as Senator Specter's "Stem Cell Research Act of 2001," explicitly reject the idea of using embryos specially created for research purposes.[21]

As mentioned above, at least nine states generally prohibit harmful experiments on human embryos living outside a woman's body. A federal law that facilitates such experimentation, by approving it as the only *accepted* use for human embryo cloning, would mark a radical departure from state precedents on respect for nascent human life.[22] In short, human embryos produced by cloning would be created specifically, and solely, for destructive embryo experiments that are a crime in some states.

Ironically, it seems the cloning procedure is so demeaning and dehumanizing that people somehow assume that a brief life as an object of research, followed by destruction, is "good enough" for any human produced by this technique. The fact that the procedure invites such morally irresponsible policies is another reason to ban it. For if an embryo produced by cloning cannot even garner the respect that we

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[17] Editorial, "Embryos: Drawing the Line," *The Washington Post,* October 2, 1994 at C6.

[18] Editorial, "Embryo Research Is Inhuman," *Chicago Sun-Times,* October 10, 1994 at 25.

[19] The current version is Section 510 of the Labor/HHS appropriations bill for Fiscal Year 2001, H.R. 5656 (enacted through Section 1(a)(1) of H.R. 4577, the FY '01 Consolidated Appropriations Act, Public Law 106-554). It bans funding any creation of human embryos (by cloning or other means) for research purposes, and any research in which human embryos are harmed or destroyed.

[20] "Let me say that I agree with our colleagues who say that we should not be involved in the creation of embryos for research. I completely agree with my colleagues on that score," said Rep. Nancy Pelosi, arguing in favor of research on "spare" embryos originally created for fertility treatment. The sponsor of the weakening amendment, Rep. Nita Lowey, said: "I want to make it very clear: We are not talking about creating embryos . . . President Clinton again has made it very clear that early-stage embryo research may be permitted but that the use of Federal funds to create embryos solely for research purposes would be prohibited. *We can all be assured that the research at the National Institutes of Health will be conducted with the highest level of integrity. No embryos will be created for research purposes . . .*" 142 Cong. Record at H7343 (July 11, 1996)(emphasis added). The weakening amendment failed nonetheless, 167 to 256. Id. at H7364. While this debate concerned federal funding, supporters of the Lowey amendment said it was "very hard to understand" why standards for ethical research should be different for publicly funded and privately funded research. See remarks of Rep. Fazio at H7341-2.

[21] The NIH guidelines deny funding for "research utilizing pluripotent stem cells that were derived from human embryos created for research purposes," and "research in which human pluripotent stem cells are derived using somatic cell nuclear transfer, *i.e.,* the transfer of a human somatic cell nucleus into a human or animal egg." *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells,* 65 *Fed. Reg.* 51976-81 (August 25, 2000) at 51981. Senator Specter's bill supports embryonic stem cell research but insists that "the research involved shall not result in the creation of human embryos." 107th Congress, S. 723, Sec. 2.

[22] In Louisiana, for example, a human embryo fertilized in the laboratory may generally be used *only* for efforts at a live birth, not for research. La. Rev. Stat. tit. 9 § 122. What would happen if a new federal law turned this on its head, and banned creating embryos for live birth while allowing their creation for destructive research—keeping in mind that cloned embryos may be biologically indistinguishable from IVF embryos once created?

all agree should be accorded to all other human embryos, but is treated as a dangerous entity that must not be allowed to survive, how will we view any human clone who *is* ultimately born alive? As a mere "organ farm" for others? Or could we compartmentalize our thinking, so that an embryo created solely for destructive research will be greeted as a new individual with full human rights if someone *does* bring him or her to full term? In light of some uses proposed even now for born human clones, it would be foolish to assume that our society will shift gears so easily.

We must remember that it is morally wrong and irresponsible to *make* human clones, not to *be* a human clone. The innocent victim of cloning should not receive a government-sanctioned death penalty simply for the crime of existing. Therefore the approach taken by the Weldon bill, prohibiting the use of cloning to *initiate* the development of a new human organism, is the only morally responsible approach as well as the clearest and most effective one in practical terms.

The Weldon bill even incorporates key distinctions and recommendations made by the Biotechnology Industry Organization (BIO) and its leading spokesperson on cloning. It bans the specific act of using cloning to make a new human organism, but does not ban "therapeutic cloning" as defined in Dr. Okarma's recent House testimony on behalf of BIO: "cloning specific human cells, genes and other tissues that do not and cannot lead to a cloned human being."[23] This bill clearly exempts from its scope the use of cloning to make any cells other than human embryos. And the Weldon bill's distinction between human embryos, which are complete human organisms, and other cells such as pluripotent stem cells, which are not, was strongly affirmed by BIO's chief spokesperson on cloning in December 1998 as a basis for federal policy on embryo research.[24]

By contrast, the Greenwood bill is not only morally unacceptable because of the encouragement it gives to experimental human cloning—it also contains features which BIO has said are unacceptable in any cloning ban. For example, instead of prohibiting the specific act of cloning a human being, it relies heavily on the "intent" of researchers in an attempt to define good and bad uses for human cloning. BIO has declared that such a subjective standard "could grant undue discretion to enforcers, create uncertainty for researchers, and consequently have a broad chilling effect among researchers."[25] Moreover, unlike the Weldon bill, the Greenwood proposal has a forfeiture clause calling for the confiscation of all a violator's assets, which BIO has said will have "a definite chilling effect of investor interest in funding research."[26]

Contrary to what the biotechnology industry may now claim in a clumsy attempt to block any real ban on cloning, then, BIO's own standards suggest that the Greenwood bill is a far greater threat to legitimate medical research than the Weldon bill could be. In addition, the Greenwood bill is singularly ineffectual at doing what it was supposedly designed to do—that is, preventing the live birth of human clones. While it seeks to ban the creation of cloned embryos with the "intent" to initiate a pregnancy, it freely allows the unlimited creation of these embryos in the laboratory—and then freely allows anyone (except the person who first created them) to use them to initiate a pregnancy, since the act of doing so is not itself prohibited. The only way to prevent the live birth of cloned humans once this is allowed to

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[23] Testimony of Dr. Thomas Okarma on behalf of the Biotechnology Industry Organization (BIO) before the House Energy and Commerce Subcommittee on Oversight and Investigations, March 28, 2001.

[24] In his December 2, 1998 testimony before the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education, Dr. Okarma joined other scientists and ethicists in agreeing that a stem cell is not a human "organism" as a human embryo is, and therefore is not covered by the statutory ban on federal funding for human embryo research. HHS General Counsel Harriet Rabb also relied heavily on this distinction (and this testimony) in finding that the federal government may fund embryonic stem cell research. If this distinction between human embryos and all other cells were problematic, unclear or unenforceable, the current NIH guidelines for stem cell research would clearly be illegal. (As I pointed out to the same Senate subcommittee in my January 26, 1999 testimony, the NIH guidelines are in fact illegal but on other grounds. See www.nccbuscc.org/prolife/issues/bioethic/test99.htm.)

[25] Actually the bill's "intent" standard makes its enforceability doubtful. A researcher's "intent" for future use of a cloned embryo is inherently changeable and unknowable, so it will be extremely difficult to prove until he or she *acts* on that intent by using the embryo to initiate a pregnancy—at which point it is too late for any morally defensible or constitutionally sound way to prevent the birth of cloned humans. If BIO's charges about a chilling effect on legitimate research are also correct, the Greenwood bill will be an unusual achievement—a bill that would never lead to a conviction against its supposed targets, but in the meantime would harass and frighten those who conduct research the bill ostensibly seeks to protect.

[26] See BIO's criteria for cloning legislation, posted on the organization's Web site at www.bio.org/laws/cloning__paper2.html.

occur, of course, would be the odious and unacceptable solution of coercing an abortion.

In any event, the Greenwood bill's "rule of construction" vitiates any ban in two ways. First, it exempts from the ban any use of cloning to create "cells" regardless of one's further intent on how to use them—and a new human embryo is, of course, a cell of a very special type. Second, it exempts "[t]he use of in vitro fertilization, the administration of fertility-enhancing drugs, *or the use of other medical procedures to assist a woman in becoming or remaining pregnant*"—and of course, the transfer of an embryo (whether produced by cloning or not) to a woman's womb is a medical procedure which could assist her in becoming pregnant.

This is a cloning ban that only a supporter of cloning could love.[27] It combines the moral defect of establishing a regimen for the government-mandated destruction of human lives, and the practical defect of massive loopholes that will ensure the arrival of live-birth cloning as well.

In short: **Some would reject the most straightforward and effective legislation against human cloning, solely to protect the use of cloning for a practice (creating human embryos solely for research) which is of highly questionable use and has been rejected by policy makers on both sides of the abortion and stem cell debates. Such advocacy should not prevent Congress from taking the right course on this issue.**

Research in the cloning of animals, plants, and even human genes, tissues and cells (other than embryos) can be beneficial and presents no intrinsic moral problem. However, when research turns its attention to human subjects, we must be sure not to undermine human dignity in the pursuit of human progress. Human experimentation divorced from moral considerations might progress more quickly on a technical level—but at the loss of our humanity.

A ban on human cloning will help direct the scientific enterprise toward research that benefits human beings without producing, exploiting and destroying fellow human beings to gain those benefits. Creating human life solely to cannibalize and destroy it is the most unconscionable use of human cloning—not its highest justification.

Mr. BILIRAKIS. Thank you very much, Mr. Doerflinger.

Mr. Fukuyama?

STATEMENT OF FRANCIS FUKUYAMA

Mr. FUKUYAMA. Thank you, Mr. Chairman, for the opportunity to testify before this subcommittee on the subject of human cloning. I am Dr. Francis Fukuyama. For another 10 days, I will be a professor at George Mason University, at which point I become Bernard Schwartz Professor of International Political Economy at the Paul H. Nitze School of Advanced International Studies, John Hopkins University.

And I have been working very intensively over the past few years on the implications of modern biology for politics, and particularly for issues—on issues of international governance related to biotechnology.

Now, one advantage of being the last speaker is that I have found that most of my points have already been made by other panelists, so I skip over a number of sections.

I am opposed to cloning for the reasons I think that have been, particularly by Dr. Kass, articulated, by other speakers as well articulated, very well. And I think that it is extremely important, in

[27] Indeed BIO, which now supports the Greenwood bill, previously announced on several occasions that it favors *no* new legislation against human cloning. BIO recommended to the National Bioethics Advisory Commission that a "voluntary moratorium" on cloning (which is to say, no moratorium at all) be continued "in lieu of any new federal law or regulation regarding the cloning of an entire human being." See www.bio.org/bioethics/nbac.html. In its recent March 28 testimony BIO reaffirmed its opposition to any new federal ban on human cloning. The Greenwood bill is exempt from this policy because it is no ban at all. It would even preempt and thus invalidate any effective future ban a state may enact, creating a situation better for the most irresponsible researchers (and far

light of the consensus on reproductive cloning that is evident in this room, that the Congress act quickly on this to establish the principle that it is not scientists who are sovereign, but the political community, the Democratic political community as such, that is sovereign and has the power to control the pace and scope of such technological developments.

There is another reason I think for Congress to act quickly, which is related to our American political system. In the past, it has been the case that the Courts have stepped into controversial areas of social policy when the Legislature has failed to negotiate acceptable political rules. This was the case in abortion and bussing, among other things.

In the absence of Congressional action on cloning, it is conceivable that the Courts, at some later point, may be tempted or compelled to step into the breach and discover, for example, that human cloning, or research on cloning, is a Constitutionally protected right.

I think this would be an absurd outcome. It would certainly be a very poor approach to the formulation of law and public policy.

So, the American people, therefore, need to express their will on human cloning at the first opportunity through their democratically elected representatives.

Of the two bills, H.R. 1644 and H.R. 2172, I support the former, the Weldon bill again, primarily because of the non—what I regard as the non-enforceability of the ban on reproductive cloning, which has, again, been articulated by earlier speakers.

I would make one further point. I believe that creation of embryos for research purposes, in itself, is morally questionable. I am fairly agnostic on the question of abortion. But it does seem to me that there is an intermediate position.

You do not have to believe that a one-cell embryo is a human being, a full human being, to believe also that it is not just another cell, because it has the potential to develop into a full human being.

One of the earlier speakers said that Kant would have said, well, the rule about treating people as ends, not as means applies only to rational human beings. If that were the case, you could experiment on infants because I have never met an infant that was particularly rational in my conversation with them.

The issue I would like to raise before this committee concerns the international dimensions of any effort to regulate a medical technology like human cloning. Opponents of a legislative ban frequently argue that such a ban would be rendered ineffective by the fact that we live in a globalized world, and any attempt to regulate a medical technology by sovereign nation states can easily be sidestepped by moving the research to another jurisdiction.

There are other advanced countries in Europe and Asia that are eager to move ahead in biotechnology, it is said, and the U.S. will risk falling behind technologically if we hobble ourselves by restricting either research into or the actual practice of cloning.

In the absence of comprehensive international regulation, no national regulation will work. This is part of a widespread, larger belief that technological advance should not and cannot be stopped.

I believe that this line of reasoning is fundamentally flawed. In the first place, it is simply not the case that the pace and scope of technological advance cannot be controlled politically.

There are many dangerous and controversial technologies, including nuclear weapons and nuclear power, ballistic missiles, biological and chemical warfare agents, replacement of human body parts, neuropharmacological drugs, and, indeed, genetically engineered crops and the like, which cannot be freely developed or traded internationally.

We have successfully regulated experimentation in human subjects internationally for many decades. And the fact that none of these regulator regimes has ever been leak-proof or the regulations fully implemented is not an excuse for not trying to put them in place in the first instance.

And second, I think that to argue that any national ban or regulation cannot precede an international agreement on the subject is to put the cart before the horse. Regulation never starts at an international level.

Nation states have to set up enforceable rules for their own societies before they can even think about international ones.

The United States is economically, politically, and culturally a dominant force in the world and will have an enormous impact on other societies.

Council on Europe has already passed a ban on cloning. To date, 24 countries have enacted national bans on cloning. And in regard to the difference between the two bills, I should point out although it is mentioned that England has passed a very permissive legislation on research cloning, that France, Germany, Austria, Switzerland, Norway, Brazil and Peru have already passed explicit legislation prohibiting it.

And laws in Ireland, Hungary, Poland, Costa Rica and Ecuador implicitly ban this procedure. So, there is an open question whether England will be an outlier in this regard, or whether it is the tip of an iceberg. It is hard to predict that in advance, but we can't know that unless we try to do the legislation.

I finally believe that international competition in biomedical research is an important problem. But we cannot answer it by simply agreeing to join in a technological arms race.

My final point is that human cloning is the first of many political decisions and battles that will occur over biotechnology. I think in the future total bans on research and technology development of the sort envisioned by H.R. 1644 will not be the right model.

We will soon need a regulatory structure that will permit us, on a routine basis, to make decisions that distinguish between technologies that we regard as positive, and helpful advances for human wellbeing, and those that raise troubling moral and political questions.

However, that is not the case with the issue of human cloning where there is a large consensus that it is not acceptable and very few interests in its favor. Thank you very much for your attention.

[The prepared statement of Francis Fukuyama follows:]

PREPARED STATEMENT OF FRANCIS FUKUYAMA, OMER L. AND NANCY HIRST PROFESSOR OF PUBLIC POLICY, GEORGE MASON UNIVERSITY

Thank you, Mr. Chairman, for the opportunity to testify before this subcommittee on the subject of human cloning. I am Dr. Francis Fukuyama, and as of July 1 of this year I will be Bernard Schwartz Professor of International Political Economy at the Paul H. Nitze School of Advanced International Studies, Johns Hopkins University. I have been working intensively for the past several years on the implications of modern biology for politics, and particularly on issues of international governance related to biotechnology.

I am opposed to human cloning for two reasons. The first is that human reproductive cloning, if and when it becomes possible, will constitute a highly unnatural form of reproduction, one that interferes with the normal process of conception and establishes a very abnormal relationship between parent and child. I believe that human nature is a valid standard for establishing human rights, and that technological procedures that interfere egregiously with normal human functioning should be viewed very skeptically in the absence of very powerful reasons to do so. I do not have time today to defend this position at greater length, but would be happy to provide the subcommittee with further materials at a later time.

The second reason that I am opposed to human cloning, and in support of legislation to curtail it, is that cloning represents the opening wedge for a series of future technologies that will permit us to alter the human germline and ultimately to design people genetically. I believe that we must proceed extremely cautiously in this direction because such a capability of altering human nature has extremely grave political, social, and moral implications. It is therefore extremely important that Congress act legislatively at this point to establish the principle that our democratic political community is sovereign and has the power to control the pace and scope of such technological developments.

There is another reason for Congress to act quickly, one that is related to our American political system. In the past, it has been the case that the courts have stepped into controversial areas of social policy when the legislature failed to act to negotiate acceptable political rules. This was the case, for example, with both abortion and busing. In the absence of Congressional action on cloning, it is conceivable that the courts at some later point may be tempted or compelled to step into the breech and discover, for example, that human cloning or research on cloning is a constitutionally protected right. This has been and will be a very poor approach to the formulation of law and public policy. The American people must therefore express their will on human cloning at the first opportunity through their democratically elected representatives, a will that I believe the courts will be predisposed to respect.

Of the two bills before this committee, H.R. 1644, "The Human Cloning Prohibition Act of 2001," and H.R. 2172, "The Cloning Prohibition Act of 2001," I would strongly urge Congress to pass the former. The reason for this is that while both bills ban reproductive cloning, the latter in effect legalizes non-reproductive cloning and the deliberate creation of embryos for research purposes. I believe that this would legitimate the first step toward the manufacture of human beings, and I do not believe that it will be possible to enforce a ban on reproductive cloning once embryos can be easily produced for research purposes.

The issue that I would like to raise before this committee concerns the international dimensions of any effort to regulate a medical technology like human cloning. Opponents of a legislative ban frequently argue that such a ban would be rendered ineffective by the fact that we live in a globalized world in which any attempt to regulate technology by sovereign nation-states can easily be sidestepped by moving to another jurisdiction. There are other advanced countries in Europe and Asia eager to move ahead in biotechnology, it is said, and the United States will risk falling behind technologically if we hobble ourselves by restricting either research into or the actual procedure of cloning. In the absence of comprehensive international regulation, no national regulation will work. This is part of a larger widespread belief that technological advance should not and cannot be stopped.

I believe that this is a fundamentally flawed argument. In the first place, it is simply not the case that the pace and scope of technological advance cannot be controlled politically. There are many dangerous or controversial technologies, including nuclear weapons and nuclear power, ballistic missiles, biological and chemical warfare agents, replacement human body parts, neuropharmacological drugs, and the like which cannot be freely developed or traded internationally. We have successfully regulated experimentation in human subjects internationally for many decades. The fact that none of the regulatory regimes controlling these technologies has

ever been leakproof or regulations fully implemented has never been a valid reason not to try to put them in place in the first instance.

Second, to argue that no national ban or regulation can precede an international agreement on the subject is to put the cart before the horse. Regulation never starts at an international level: nation-states have to set up enforceable rules for their own societies before they can even begin to think about international rules. The United States, as an economically, politically, and culturally dominant force in the world will have an enormous impact on other societies. The Council on Europe has already passed a ban on cloning; to date, twenty-four countries (including Germany, France, Italy, and Japan) have already enacted national bans on cloning, while sixteen have banned creation of embryos for research purposes. The United States can do a great deal to either reinforce (or else undermine) an emerging international consensus that human cloning is an unacceptable use of medical technology.

I do believe that international competition in biomedical research creates problems for any nation that wants to limit or control new technology. There are a number of countries that will try to exploit a human cloning ban or any other constraints the United States places on the development of future biotechnologies. We should not be prematurely defeatist, however, in thinking that we have no choice but to join in this technological arms race. If we can establish a general consensus among civilized nations that human cloning is unacceptable, we will then have a range of traditional diplomatic and economic instruments at our disposal to persuade or pressure countries outside that consensus to join. If human cloning ends up being a procedure that can be performed, but only in states regarded as renegade or pariahs, then so much the better. But none of this will be possible unless we first begin by establishing laws on this subject for the United States.

Let me close by saying that human cloning is the first of many political decisions and battles that will occur over biotechnology. In the future, total bans on research and technology development of the sort envisioned by H. R. 1644 will not be the right model. What we will soon need is a broader regulatory structure that will permit us, on a routine basis, to make decisions that distinguish between those technologies that represent positive and helpful advances for human well-being, and those that raise troubling moral and political questions. Ultimately, this regulation will have to become international in scope if it is to be more effective. We will need to think carefully about the institutional form that such a regulatory structure must take. A blanket ban on human cloning is appropriate at this time, however, because it is necessary at an early point to establish the principle that the political community has the legitimacy, authority, and power to control the direction of future biomedical research, on an issue where it is difficult to come up with compelling arguments about why there is a legitimate need for human cloning.

Thank you very much for your attention.

Mr. BILIRAKIS. Thank you, Mr. Fukuyama.

Well, are we all agreed that the Weldon bill, the former of the two bills as it has been referred to here, does not ban or preclude the cloning of human tissue that does not give rise to an embryo? We are all agreed there, Mr. Okarma? We are agreed? Because you made comments about the Weldon bill would——

Mr. OKARMA. (No audible response, nodded.)

Mr. BILIRAKIS. Okay. Dr. Newman, can we take stem cells from our own bodies to be used for an affliction in another part of our body, bone marrow I suppose?

Mr. NEWMAN. Well, these are called adult stem cells.

Mr. BILIRAKIS. Yeah.

Mr. NEWMAN. And adult stem cells can be taken from the bone marrow, from fat, from muscle, from the brains of recently deceased people. And——

Mr. BILIRAKIS. Can take it from my body, for instance, for—to help an affliction that I have?

Mr. NEWMAN. Yes, you could take your own bone marrow——

Mr. BILIRAKIS. Right.

Mr. NEWMAN. [continuing] and stem cells can be isolated from your own bone marrow, from your own fat tissue, yes.

Mr. BILIRAKIS. Thank you, sir. You referred to the ultimate adult stem cell, which appears to have been discovered in the bone marrow that can transform itself into almost any organ in the body. And this is according to the study published in the May 4 issue of New York University School of Medicine. You mention Yale University School of Medicine——

Mr. NEWMAN. The publication of Cell.

Mr. BILIRAKIS. Issue of Cell by New York, published in an issue of Cell by NYU School of Medicine, Yale University School of Medicine, and Johns Hopkins School of Medicine and Researchers.

There is a comment made by Dr. Tice, "There is a cell in the bone marrow that can serve as the stem cell for most, if not all, of the organs in the body." And then, "This is an exciting study," etcetera, etcetera. I know at the University of Florida, one of my alma maters, they have announced that they have reversed diabetes in mice using adult stem cells.

I might add that to—for the benefit of Ms. DeGette, that JDF was invited to come here to testify, and they for some reason or other——

Ms. DEGETTE. If the gentleman would——

Mr. BILIRAKIS. [continuing] were not able to do so——

Ms. DEGETTE. [continuing] yield.

Mr. BILIRAKIS. [continuing] which is unfortunate.

Ms. DEGETTE. Mr. Chairman, if the gentleman would yield one moment? The Juvenile Diabetes Foundation would have liked to have testified. This weekend is their big Children's Congress.

Mr. BILIRAKIS. I see.

Ms. DEGETTE. They are bringing children from all around the country to lobby Congress on Type-1 diabetes. So, I am sorry they couldn't come.

Mr. BILIRAKIS. Okay. No, and I appreciate that explanation because they are really one of my favorite groups. I feel very strongly about them, and I am glad to hear that explanation.

In any case, there has been some research done in that regard. And we also know that Americans presently destroy some 4 million placentas and umbilical cords every year, which could be an abundant supply of stem cells.

I guess I raise the question, there is this controversial issue of the use of the embryo. If we can help the people who need help—and we have all had members of families—I lost my youngest brother to Parkinson's.

If we can help the people that need to be helped through the adult stem cells which appear to have been discovered through the use of placentas and umbilical cords, which are just thrown away, why is it that we have got to insist on this—this controversial, very controversial, area of using an embryo, cloning an embryo, and using that?

Does that make too sense, Mr. Doerflinger?

Mr. DOERFLINGER. Well, obviously, Mr. Chairman, I would ask that question too. I wanted to respond to what Ms. DeGette said about—about diabetes research. I think the Canadian trial——

Mr. BILIRAKIS. Do it real quickly, but I would like to have a response——

Mr. DOERFLINGER. Yes.

Mr. BILIRAKIS. [continuing] a few responses to my question.

Mr. DOERFLINGER. Yes, I think—absolutely. President Clinton's National BioEthics Advisory Commission said that it would be ethically unjustified even to use spare embryos from IVF clinics if there are less morally controversial alternatives available. And I think it has been proved again, and again, and again those alternatives are there.

The Canadian study, I think we are talking about the University of Ottawa trials? Yes. Those were adult islet cell transplants. Those had nothing to do with embryonic stem cells. They were taken from cadavers.

And the reason why these trials worked and had several patients walking around without any further need for insulin injections were two advances in the transplant technique.

One was that they used two cadavers for each transplant instead of one to get a bigger volume of the islet cells, and the other was a new immuno-suppressive drug that greatly reduced the tissue rejection problem, the very problem that we are now being told human cloning is essential for. And that is just not true.

Mr. BILIRAKIS. Any other comments? Dr. Newman? —— 1 Mr. NEWMAN. These problems of tissue repair, the repair of the heart wall after a mild cardio infarction, the repair of damaged skin and so—— all of these can be addressed by cells that have the potential to repair those tissues.

A study that I briefly alluded to, but it was published recently in Nature by some colleagues of mine at New York Medical College and at the NIH, took bone marrow cells from the mouse and isolated adult stem cells from those bone marrows, and implanted them into the heart walls of mice whose hearts had been damaged by a heart attack, an induced heart attack.

And those bone marrow stem cells were able to repair the damage in the wall of those damaged hearts. So, it seems to me that there is a tremendous amount of promise in therapeutics using adult stem cells.

I don't—I mean, as I said, the Council for Responsible Genetics isn't, in principle, against using embryo stem cells from non-cloned embryos. But I see much more promise in the adult stem cells, actually.

Mr. BILIRAKIS. How close are we to their being available in a way that we would be confident that they would be helpful?

Mr. NEWMAN. Well, adult stem cells are already available. I guess approval needs to be done based on good animal experiments, which are coming out now. But I think it is just a regulatory issue now because I think that there are adult stem cells that have shown promise. Human adult stem cells have shown promise in culture, in vitro, and animal adult stem cells have shown promise in vivo.

So, I think that it is just a few steps now to get the adult human stem cells to be used in humans.

Mr. BILIRAKIS. I would like to hear from all of you, but my time has expired. And I just want to be fair to the rest of the members of the committee. Mr. Brown?

Mr. BROWN. Thank you, Mr. Chairman, and you always are. Thank you. This morning—and this is a question for the scientists

on the panel, and then I would like an answer as scientific as possible. This morning's edition of The Hill, Dr. Doris Platika of Curesis, Inc., a firm that works in adult stem cells, is quoted as arguing, "that embryonic stem cells work as a prerequisite for research in adult stem cells."

Dr. Michael Bishop, a Nobel laureate, who is now at the University of California's Biomedical Complex, a chancellor there in San Francisco, said also, "What scientists need to learn is how to direct the cells to develop in one direction or another. Once you have that, you have the makings of tissue replacement."

Would the scientists on the panel comment on the validity of these two statements, which seem to suggest that without research involving human embryos, the promising treatments for diabetes, or spinal injury, or a whole host of medical problems might never come to fruition?

Mr. NEWMAN. Well, without seeing the context, I can just say that from what you have said, I have to disagree with those statements. The problem of getting an embryo cell or an embryo stem cell to become directed toward a differentiated cell type is an interesting scientific problem.

But it is a different problem from getting an adult stem cell to be directed toward a particular differentiated cell type. And there is no way that studying the embryo stem cells is a prerequisite for studying that process in the adult stem cells. They are two, distinct scientific issues.

Mr. BROWN. Others? Mr. Okarma, or whoever else wants to answer? Mr. Okarma, if you——

Mr. OKARMA. Thank you. Well, first of all, it is true that there is recent and exciting, with major medical potential, work coming out of the adult stem cell field, a field in which I had personally worked for about 12 years in my first company.

And in no way are any of my comments to be construed as being arguing against continuing to work on adult stem cells. There are, however, some major issues which provide immense advantages for the embryonic stem cell technology, first and foremost which is the scalability of the production of replacement cells from embryonic stem cells.

These cells are immortal. We have had them growing in culture continuously for over 2 years. They have undergone 450 population doublings without any change in their ability to be turned into functioning neurons, functioning liver cells, functioning cardiomyocytes.

And that transformation process can be scaled so that the cells we make can be characterized and experimented upon with the same rigor as a drug or a biological. The issue is scalability. And inherent in that is the cost of goods.

The cost of extracting a rare adult stem cell, which grows slowly and must be manipulated to grow into a different cell from—than what it is programmed to do, will be prohibitive and will make the cost of goods of the therapy so high as to prevent its commercialization.

Those are the advantages of the embryonic stem cell, which are scalability, rapid growth, and the ability to grow into literally all cells of the human body.

Mr. BROWN. Other—yes, Ms.——

Ms. NORSIGIAN. I just want to say that I believe that some reproductive rights advocates would agree that embryonic stem cell research should continue. Others would disagree. And the issue of scalability and mass production, I think comes into play when you think about the development of clonal embryos.

And although you might argue that we will not know what we could have developed or learned by not going down the path of allowing clonal embryos, you can also argue that the risks that we would take are just simply not worth it.

I think that is where the vast majority of reproductive health advocates I have spoken with are at right now. And even though we disagree about the subject of embryo—of embryonic stem cell research, the Weldon bill doesn't really address that. It only addresses clonal embryos, so that you get away from that disagreement.

You will, in fact, impede mass production in some ways. I think that is a given. But I think, given what is at stake, we have to say we are going to say no to that, and acknowledge that there are some things that we have to bypass.

Mr. BROWN. Dr. Kass?

Mr. KASS. Yes, your question to Dr. Okarma was answered and, I think, made a case for the great benefits of using embryonic stem cells as a scale—a scalable source. But he didn't yet speak to why they have to be from embryonic clones.

And if I read his testimony right, I think he argues that this would be a great benefit for eventual adult stem cell research because you would learn how to reprogram the adult nucleus to get adult stem cells in quantity.

But that technique, as I understand it, has not yet been worked out in animals, this kind of reprogramming process. That could be done in animal research.

And if it should turn out 5 years from now that the adult stem cells and the non-cloned embryonic stem cells don't produce the kind of therapeutic benefits we want, under the Weldon bill, there is an opportunity to come back and say, "Look, we absolutely—we absolutely have to have cloned embryos in order to do this therapeutic work."

I think the burden of proof has to be placed there, given the great risks that we have all argued for before. And so——

Mr. OKARMA. May I just respond to that specifically?

Mr. BROWN. Sure.

Mr. OKARMA. The burden of proof we accept fully and, in fact, has been satisfied. A group in Australia has used nuclear transfer in mice to produce blastocysts from which mouse embryonic stem cells have been successfully derived, and those nuclear transfer derived stem cells have exactly the same properties of immortality and pluri-potentiality as embryonic stem cells derived from embryos produced sexually in mice.

So, the data are here, presented and published in peer review literature, that the cells produced in that way are, in fact, fully functional.

Mr. BILIRAKIS. I thank the gentleman. Mr. Greenwood?

Mr. GREENWOOD. Thank you, Mr. Chairman. I think we are at a very critical point here. Everyone agrees, no reproductive cloning.

Everyone agrees we want to take advantage of the amazing potentiality for curing things that harm, and hurt, and kill children and adults in terms of these terrible diseases and injuries that inflict us.

I think—I don't know if maybe—you are shaking your head; maybe you don't agree we want to—we want——

Ms. NORSIGIAN. Not all of the potentiality——

Mr. GREENWOOD. Okay, but the point that I am making is it seems that there is widespread agreement that if we could find ways to cure spinal injury, and Parkinson's, and so on, that we would do it.

What seems to separate us is a question of whether you need clonal embryonic research in order to get there. And we have heard questions about can't we use placentas? Can't we use umbilical cords? Can't we use cadavers? Can't we use adult stem cells from bone marrow?

And that is the critical question? We either get to this great potentiality to relieve human suffering in all of those other ways, in which case we don't need clonal embryonic research, or we can't.

And I think that is the critical question. And I would like Dr. Okarma—I know that you addressed this, to some degree, in response to Mr. Brown's question. But this question of scalability seems to be critical. It seems to me that if you are going to help thousands or hundreds of thousands or millions of people, you need to have this issue of scalability dealt with. And I wonder if you would address that?

Mr. OKARMA. Well, that is true actually in two contexts. The first, as you correctly say, it is relevant for the embryonic stem cell technology, itself. It is equally important, however, on the point that we are debating here today, the use of cloning techniques to arrive at a scalable way to produce hysto-compatible cells.

But let me emphasize once again, the objective of the work is not to produce a process that would consume human oocytes or which would generate embryos on a case-by-case basis. That could never be commercialized for practical——

Mr. GREENWOOD. Let me just interrupt you. I always do this when you say "oocytes" because I am not——

Mr. OKARMA. Egg cells.

Mr. GREENWOOD. Egg cells, okay. So, this is not a question—it is not the question that in order to meet this potential, we need to continually harvest human eggs. This is a—this is a bridge technology or bridge research. Is that correct?

Mr. OKARMA. Precisely. The objective of the exercise is to identify the factors in the eggs that achieve reprogramming so that we could use those factors outside of any egg to directly transform a skin cell into a heart cell, or a skin cell into a brain cell, precisely the challenge Mr. Stupak enunciated in his opening statements.

That is where this work is going. We could never, ethically or practically, scale nuclear transfer the way it is currently performed, for human therapy.

The objective of the research is to understand the biology, the magic behind the oocyte's ability to take a differentiated cell all the way back to development, and allow the gene expression pattern to be changed, which is precisely what we are trying to learn how to

do in order to scalably produce the process, allow it to happen, reproducably, in a regulated way, and with sufficiently low cost of goods that it can, in fact, be widely commercialized.

Mr. GREENWOOD. My concern is, I am afraid that people on this subcommittee, people on the committee, people in the Congress, this administration, are going to take the position that although they do want all of these people to be relieved of their suffering through these wonderful therapeutic opportunities coming up, but they can vote for a Weldon-style bill to ban clonal embryonic somatic cell research and feel that they haven't—that those two are not in conflict.

And is it possible that—for members of this committee to feel that they can vote for a Weldon research—a Weldon bill and still hold out the promise that, in our lifetimes, we are going to see the kind of results that you have envisioned?

Mr. OKARMA. In my view, no. No other cell, other than an egg cell, has ever been demonstrated to possess the reprogramming biology that we are seeking through the research.

Mr. GREENWOOD. Mr. Newman, you are——

Mr. NEWMAN. Yeah, I have something to say about this. People may not recognize that embryo stem cells and cloning have been available in frogs—well, cloning in frogs for 25 or 30 years, and embryo stem cells in mice for more than 10 years.

And this research about what it takes for an egg to reprogram a nucleus, well, it is progressing. It is progressing slowly. And there is absolutely no reason to do this research in humans. It is——

Mr. GREENWOOD. Well, Mr. Okarma, is that—do you have a difference of opinion? Can we do these with other species, mammals and other species, and learn just as much?

Mr. OKARMA. Well, we are certainly doing that, as we speak. We are working very diligently in sheep, and in mice, and in cow models of nuclear transfer to understand—get hints at the animal way that that process is performed.

But these are only models. And in point of fact, the early embryology, as I am sure Dr. Newman will agree, of these species versus humans are enormously different. We now have the human genome project, right? So, we know what these genes could be if we would simply identify the factors in the egg that perform this biology.

We don't have that data base from these animals. The animals are only a distant approximation to the condition in humans.

Mr. GREENWOOD. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Deutsch?

Mr. DEUTSCH. Thank you, Mr. Chairman. Dr. Kass, you testified that once human embryos are produced and available in laboratories, it will be virtually impossible to control what is done to them. How will the ban you support, the Weldon-Stupak ban, prevent the actual creation of these cloned embryos?

Mr. KASS. How will it prevent it?

Mr. DEUTSCH. Correct.

Mr. KASS. If you are saying it will not prevent some rascal who wants to disobey the law from doing it, I would have to say that it won't prevent that, just as the law against incest doesn't prevent cases of incest from cropping up.

But it will deter—it will deter all reputable scientists from going down this road. It will give them the opportunity 5 years down the road to have a report that makes the case that we now actually have to have this kind of therapeutic cloning.

Mr. DEUTSCH. Let me just follow up.

Mr. KASS. Please.

Mr. DEUTSCH. Why would you believe that the criminal and civil penalties contained in the Greenwood-Deutsch bill, which are virtually identical to the Weldon-Stupak bill, also do not act as effective deterrents to the prohibited acts?

Mr. KASS. As I say in my testimony, with all due respect, the Greenwood-Deutsch bill does not ban the implantation of a cloned embryo to initiate a pregnancy. It simply prohibits the creation of that embryo with the intent to do so.

But once the embryo is there, there is no governing language on what shall subsequently be done with it.

Mr. DEUTSCH. All right, well——

Mr. KASS. That is partly why——

Mr. DEUTSCH. [continuing] let me just follow up. If you were to make the changes that you note, specifically prohibiting the act of transferring the embryo to a uterus and making it a crime to also receive cloned embryo products with the intent to initiate a pregnancy, would you then say that the Greenwood-Deutsch bill would, in fact, do what you want?

Mr. KASS. It would be better. It would be better, but it wouldn't be good enough. And that is partly because we now know that there is a market for reproductive cloning. And I don't think, at that particular stage, we are going to have the requisite enforceability.

I would much rather—and if people who—well, I would much rather say, given the grave seriousness, not just of curing disease, but of going down this road to the brave, new world in the posthuman future, given the grave seriousness of that, that we make every effort to find morally, unproblematic means of finding these therapies that we need——

Mr. DEUTSCH. But——

Mr. KASS. [continuing] and not producing this kind of clear and present danger at this time.

Mr. DEUTSCH. Let me follow up directly to that point because in your comments, and actually in Mr. Stupak's legislation specifically—and you have said this actually several times in your testimony and in answers to questions, that if alternatives to therapeutic cloning fail, and animal studies demonstrate that embryonic cloning has therapeutic potential, and I am going to quote, "Congress could later revisit this issue and consider lifting the ban on cloning of embryos."

All right, is your position then that the morality of cloning embryos is a relative, not absolute, concept?

Mr. KASS. It is a complicated question for me, and I do not have a right-to-life position on this matter. But I think that whatever you think about the moral status of the embryo—and Professor Fukuyama, I think spoke very movingly about this.

The human embryo is at least potentially one of us. It is not nothing, and it is different from other cells. The attempt to call it

cell cloning or blastocyst cloning, whatever we do, we should call things by their right name. This is nascent human life. And it seems to me you create that and treat it as mere cellular tissue to be experimented with at our peril.

One of the things—one of the dehumanizing effects in this area already seen is that people can stand and talk about creating new human life that is potentially you or potentially me—I am not saying it is already a person. I am not saying it has rights.

But it has some kind of standing. And to create that——

Mr. DEUTSCH. Well, let me——

Mr. KASS. [continuing] sort of indifference, it seems to me, is already worrisome.

Mr. DEUTSCH. Dr. Kass, thank you. Let me—you know, for Mr. Okarma, you are in the field doing this research. And I think, in some ways, the strongest argument that you have made is your actual experiential research, saying that all of the alternatives are already secondary alternatives, that what—Dr. Kass' comments have already been made in the real world; that everything else is not as good; that it is less likely to bring successful research outcomes.

And to me, you know, that—you know, for literally the hundreds of thousands, if not millions, of Americans who potentially can benefit from this research—I mean, to hear that issue I think is the real issue. So, if you can, you know, comment to that?

Mr. OKARMA. Well, you are correct in that in our professional judgment, the application of nuclear transfer research to get to the process we have spoken about, not the nuclear transfer process itself, but the use of that biology, is the perfect solution to enable regenerative medicine.

And all others fail in a variety of technical respects. We are pursuing other ways to achieve this. So, for example, would it be possible to genetically engineer the embryonic stem cell to render it immunologically null? It would not, for example, potentially evoke an immune response.

That is theoretically possible. We are working on that. But we are asking genetic engineering to do a lot to enable that engineered trait to be passed through the manufacturing process, all the way down to the differentiated cell that would, in fact, be the product.

And we worry about the durability of that nullness. So if, for example, we use that process to repair your heart or mine, it is very possible that a year or 2 after the implantation of the cell, that nullness is lost, and you suddenly reject that tissue, and you are back to where we started from.

So, the point is well-taken, Mr. Deutsch, that the use of nuclear transfer research could lead to a perfect and permanent solution to that set of problems.

Mr. BILIRAKIS. Dr. Ganske to inquire?

Mr. GANSKE. Mr. Chairman, I am just going to ask one question, but I will ask all members of the panel to answer it. I apologize because I have had to be gone for part of this. And so, you may have spoken to this. I thought the administration was quite clear with its statement today that, "As we interpret the bill, it prohibits not only the use of human somatic cell nuclear transfer to initiate a pregnancy, but also all other applications of somatic cell nuclear transfer with human somatic cells, such as cloning to produce cell

or tissue-based therapies. That is consistent with Secretary Thompson's and the President's views."

I also asked the question, is it the administration's position that it should be illegal for anyone to do somatic cell nuclear transfer? And the answer was yes. So, I guess my question to all of you is, what is your response to that, if we could start on my left?

Mr. OKARMA. Well, I——

Mr. GANSKE. And if you could keep your—since there is—what do we have—eight respondents, maybe to 30 seconds?

Mr. OKARMA. Two points; first, I think it will—it is a giant step toward rendering the American biomedical research community a second-rate resource. And second, it will clearly encourage the exportation of this research to countries that are bit more enlightened.

Mr. KASS. I don't agree. I think the international community, for the most part, supports this position. I think we could take the lead to achieve—since what I am mostly interested in is preventing human cloning and the road that it leads to, we need to take a lead in the international community, and I think we can do so.

And if I might just say one word on a question you asked the Deputy Secretary before about the importing business and stuff that goes elsewhere, as I read the Weldon bill, that product of somatic cell nuclear transplantation, the trafficking in which is prohibited, are not the drugs that might come somewhere else, but simply on the cloned embryonic product.

I think if you look at that language, it is quite clear on that.

Mr. GANSKE. But you are—you say you don't agree with their position; is that right?

Mr. KASS. Well, I thought the question was what the language—the language of the bill about importing the products. I am sorry, I do not agree with Dr.—with Dr. Okarma.

Mr. GANSKE. Okay, next?

Mr. KASS. Thank you.

Mr. GUENIN. I can imagine only one rationale for the administration's position this morning, and that is that the administration believes that it is immoral to use an embryo as means. And if—there was otherwise no rationale stated. If that is the case, then we can surmise that the President will announce its opposition to embryonic stem cell research.

In such a case, I think we will have stymied the most promising frontier of biomedical research that has faced us in our lifetime for the relief of suffering.

I think, therefore, it falls to the Congress to consider those two issues together, because they are the same problem. May an embryo be used as means?

I would point out that under the so-called rider to the NIH appropriations bill that has been discussed with respect to embryonic stem cell research, the creation of an embryo for research purposes is already prohibited. But here we are today still discussing whether it should be.

So, it seems to me, in all committees of the Congress, those two issues will be discussed in the future. And I hope the resolution will be an explicit authorization of this line of research, rather than placing us in the circumstance of statutory gymnastics.

Mr. GANSKE. Mr. Newman?

Mr. NEWMAN. Insofar as the administration has come out against embryo cloning, I would agree with that. On the issue of stem cell research using embryos that haven't been produced experimentally, I would disagree with the administration's position on that.

I have questions about it, but I wouldn't call for a legislative ban on it.

Mr. PERRY. The vast community of patient support groups and research advocacy organizations have been waiting on tenter-hooks for months to hear the administration's position on the use of embryonic stem cells for research.

Today's announcement, I think, presages a negative response on that, and it presupposes that we now know enough as political leaders to decide which areas of research are going to produce the breakthroughs that we all want so much.

The reality is that in the scientific community, there is considerable uncertainty as to the viability long-term of stem cells from adult sources.

There seems to be a lot more power in embryonic stem cells, and the cloning technologies, or the cell replication technologies, open up yet another avenue that has great promise.

And the decision from the Bush Administration seems to be closing one door after another, leaving us with fewer options, even as we face an explosion of chronic diseases related to the aging of the population.

Ms. NORSIGIAN. I don't agree with the administration's position, but I think there was some confusion this morning as I read Claude Allen's statement, which interpreted the Weldon bill as prohibiting all applications of somatic cell nuclear transfer with human somatic cells.

He didn't—this didn't say "human egg cells." And then under questioning from you, Representative DeGette, I heard something different. So, I think there is a little confusion about what the administration really is saying right now.

But I agree with the statements that were made earlier by Dr. Kass and Dr. Newman. And I don't read the bill, the Weldon-Stupak bill, as others have read it, as being much more restrictive than it is.

Mr. DOERFLINGER. Congressman Ganske, I don't know whether you were here for the colloquy between Congressman Stupak and Deputy Secretary Allen because he clarified that awkward phrase in the testimony and said what the administration is against is any use of this technology to make human embryos for cell and tissue-based therapy. And we certainly agree with that stance.

I am rather surprised at the scientific witnesses who are now moving over into the debate on the NIH stem cell guidelines for embryonic stem cell research because given their new testimony, the President would have to be a fool to endorse the NIH stem cell guidelines. They have just announced they are useless.

Those guidelines forbid the special creation of embryos for research. Dr. Okarma testified that use—that moving on to cloning is essential to making these therapies work.

Apparently, the stem cell guidelines were a bait-and-switch. As soon as you got to human use, they were going to tell us, we forgot

to tell you; you had to go to this further step that everybody, including the supporters of stem cell research, had said was ethically off the table.

They have now raised the stakes, but they have called into serious question their earlier claims about the usefulness of these spare embryos.

Mr. FUKUYAMA. Well, this whole discussion, I think, has conflated embryonic—this embryonic stem cell research with the issue before us, which is cloning for research purposes. And I think you can support the former and oppose the latter perfectly consistently.

Again, just to repeat myself on the international thing, if this research, as the result of the Weldon bill, moves to less enlightened countries overseas, so be it. It may be that this is the kind of research that will only be done in places like China, you know, or Singapore. But I think that is something we can live with.

Mr. BILIRAKIS. Thank you. The gentleman's time is expired. Mr. Stupak?

Mr. STUPAK. Thank you. Dr. Okarma, in your testimony, you cite there are two cloning—cloning specific human eggs or, excuse me, cloning specific cells, genes, and other tissues that do not and cannot lead to a cloned human being.

Since a live human embryo, by its nature, can lead to a cloned human being, you seem to be drawing a line or a distinction between therapeutic cloning and human embryo cloning. Is that correct?

Mr. OKARMA. Thank you for the opportunity to clarify. It is really crucial to understand that what we are supporting is research in somatic cell nuclear transfer for the sole purpose of understanding its mechanism so that those factors that perform—that achieve——

Mr. STUPAK. But——

Mr. OKARMA. [continuing] reprogramming can be isolated and used in a scalable way.

Mr. STUPAK. But you were really—no, yes or no, are you drawing a distinction then between therapeutic cloning and human embryo cloning?

Mr. OKARMA. No.

Mr. STUPAK. Are you saying we need human embryo cloning in order to further our therapeutic?

Mr. OKARMA. Yes, I am.

Mr. STUPAK. Okay. Then, our bill bans only the use of cloning to create new human embryos. How can you say that we would be banning therapeutic cloning?

Mr. OKARMA. I am sorry, I don't understand it.

Mr. STUPAK. All right. So, if our bill bans human embryo—and you really need human embryo to do your research, right?

Mr. OKARMA. Yes.

Mr. STUPAK. Okay, then let me take this step. Then, how do you—as Dr. Kass and others have indicated, where do you draw the line then between manipulating that research for hair color, for eye color, for intelligence? Once you create that human embryo, where do you draw the line?

How do you do it with either our bill or—well, our bill, you just don't do it—or the other bill, the Greenwood bill?

Mr. OKARMA. By intent and by restrictions on the purposes to which such a cloned embryo could be placed.

Mr. STUPAK. But see, by "intent"—then I am really confused because on your web-page, the BIO web-page, you say, "Some bills do not prohibit the act of cloning a human being and focus on the intent or purpose of the researchers. The terms intent and purpose used in some bills are criminal law concepts which could grant undue discretions to enforcers, create uncertainty for researchers, and consequently have a broad-chilling effect among researchers."

"Using a specific act as the trigger for violation makes it clear that, to all scientists and enforcers, what activities are not acceptable."

Mr. OKARMA. On my web-page?

Mr. STUPAK. On your web-page.

Mr. OKARMA. I am sorry, sir, that is——

Mr. STUPAK. I just pulled it down.

Mr. OKARMA. [continuing] that is not correct.

Mr. STUPAK. On your BIO——

Mr. BILIRAKIS. The BIO web-page.

Mr. STUPAK. The web-page from BIO.

Mr. OKARMA. Oh, that is not my——

Mr. STUPAK. I am sorry, but that is the organization you represent, isn't it?

Mr. OKARMA. I am representing—I am testifying on behalf of BIO. I represent my own company, sir.

Mr. STUPAK. Okay. Well, I am sorry to have the misnomer. I thought your—BIO was your company. All right, so I guess that would be sort of in conflict to what you are testifying? The BIO web-page would be in conflict, then, as to the intent?

Mr. OKARMA. I would have to read it and study it, sir, to give you an honest answer.

Mr. STUPAK. All right. The blastocysts that you speak of on page 4 of your testimony, isn't that really another term for an early, living human embryo?

Mr. OKARMA. Yes, sir, it is, absolutely. And do we not mean to obviscate the intent or the actuality of what we are talking about here. And we do, as our Ethics Advisory Board constantly reminds us, recognize that these early embryos do, in fact, have moral status, and they are special cells, which is why we are so adamant about their utility for very special circumstances, treating these diseases which we view have no other alternative.

Mr. STUPAK. Well, would——

Mr. OKARMA. We would also draw the line between the degree of moral status that these undifferentiated, unindividuated, and unenabled embryos have compared to embryos later in gestation.

Mr. STUPAK. But how do you really draw the line? If blastocysts are early human embryo, then what—aren't you really saying is that reproductive cloning and research cloning proceed exactly through the same initial stages, and they really aren't separated?

Mr. OKARMA. No, the reason we draw the distinction, the——

Mr. STUPAK. Where and when do you draw the distinction?

Mr. OKARMA. It has to do with the biology. The stage of these blastocysts that we use to derive our ES cells, or that we would use in the cloning debate we are engaged in——

Mr. STUPAK. Which are the same as living human embryos?
Mr. OKARMA. They are living, human embryos.
Mr. STUPAK. Okay.
Mr. OKARMA. But they are completely unindividuated, which means that they have the capability after we would use them to divide into two human beings.
Mr. STUPAK. But——
Mr. OKARMA. So, they are not individuated.
Mr. STUPAK. [continuing] how can they——
Mr. OKARMA. They are not——
Mr. STUPAK. [continuing] not be individuated——
Mr. OKARMA. Let me finish, sir.
Mr. STUPAK. Go ahead.
Mr. OKARMA. They are completely undifferentiated in that every single cell in that early embryo is exactly like every other one. And we know that from doing genetic work on in vitro fertilized embryos.
Those cells can be removed, identified as being—as containing or not containing that genetic defect, and those which do not, are implanted successfully.
Mr. STUPAK. But we also know, and maybe it is more from our side of the aisle here, that frozen embryos in the lab have parental rights associated with them. So, how are they, then, unidentifiable? And aren't you really creating the issue of peril rights and conflicts with privacy rights?
Mr. OKARMA. Well, sir, that is a legal question that I am really not competent to answer.
Mr. STUPAK. But you said they were unidentifiable. If we already attach, as a country, legal rights to these embryos in these stages, which are the same, you said, at the early stages, and there are parental rights, then how are they unidentifiable?
Mr. OKARMA. Well, I——
Mr. STUPAK. It is no different than the example of Dr. Guenin there when he talked about Mary giving her cells to research or whatever. What if Mary changes her mind? Does she then have parental rights that can be enforced in the courts? What if she changed her mind?
Mr. GUENIN. Let me distinguish here. There isn't any problem about keeping track of which parents own these. What we are discussing is individuation, which is the question of moral importance, as to whether we have one embryo, or whether we have 2, or 3, or 4.
Mr. STUPAK. Did you say "more" or "moral"?
Mr. GUENIN. Moral.
Mr. STUPAK. Oh, moral.
Mr. GUENIN. So, the individuation idea reflects on the possibility of twinning. But so far as tracking who they belong to, that is not a problem.
Mr. STUPAK. Dr. Kass?
Mr. KASS. Just one small point on this argument of non-individuation; yes, the embryo, as a blastocyst, is not yet differentiated. But each one of those blastocysts is different from every other one. That is the whole purpose of making the argument that you need the identical clone.

Mr. STUPAK. Right.

Mr. KASS. They are genetically different from one another, even if they can subsequently split.

Mr. STUPAK. Even in the early stages?

Mr. KASS. And they came from specific sources, so they have that kind of individual origin.

Mr. STUPAK. Mr. Chairman, are we doing a second round later?

Mr. BILIRAKIS. I am not disposed on doing that. I suppose we could. I don't know that we should go another 5 minutes.

Mr. STUPAK. So, we could follow-up then, at least with written questions?

Mr. BILIRAKIS. I would say so. You raised the question of the support by the bio-tech industry of the Greenwood bill, which seems to be in conflict——

Mr. STUPAK. Right.

Mr. BILIRAKIS. [continuing] with their web-page.

Mr. STUPAK. Right.

Mr. BILIRAKIS. You never did really—did you get an answer for that?

Mr. STUPAK. Yeah, I did. It was—I don't think it is fair to Dr. Okarma. It is not his—it is his organization, but it is not his company, and I asked "company". And——

Mr. BILIRAKIS. But he——

Mr. STUPAK. [continuing] he is not—you are not here to speak on behalf——

Mr. BILIRAKIS. But you are representing the biotech industry here today?

Mr. OKARMA. Sir, I am not in a position to respond.

Mr. BILIRAKIS. You don't know.

Mr. STUPAK. I would just ask the unanimous consent to put the biotech webpage——

Mr. BILIRAKIS. Without objection, that is the case. I want to note that Ms. Erica Yamat, and I may have mispronounced that, with Health and Human Services, is here. She has sat here the entire hearing.

I think that is of note because a lot of times, we have administration witnesses who will testify and then leave. They don't get the benefit of the testimony from sometimes the more important witnesses like yourselves. But she is here, and we appreciate that.

The Chair now will yield to Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman. Mr. Okarma, if someone were to take a cloned embryo out of your laboratory and implant it into a woman's womb, under the Greenwood bill, you or your company would not be liable, would you? The Greenwood bill, I think, requires that for a violation to have occurred, the person who created the cloned embryo had to have done so with the intent to implant.

Mr. OKARMA. I believe that is correct, and your point, I think, underscores the fact that the Greenwood bill could be tightened. Its intent we understand. If there are, in fact, legal loopholes and difficulties in enforcement, I believe the Greenwood and Deutsch group are very willing to improve the language to achieve that end.

Mr. PITTS. Okay.

Mr. GREENWOOD. If the gentleman will yield for 3 seconds. I would concur with that. We do intend to tighten that up.

Mr. PITTS. Your testimony hints that you are already doing somatic cell nuclear transfer in humans. Have you already attempted human somatic cell nuclear transfer using human somatic cell nuclei or human egg cells?

Mr. OKARMA. That was not my testimony. In fact, the work that we are doing in the U.K. is all in animals. We do have plans to perform nuclear transfer with human material. We have not yet begun that.

Mr. PITTS. Okay. Now, as recently as March 28, before the Oversight and Investigations Subcommittee, this BIO Group you are representing testified that the FDA already has jurisdiction to regulate cloning, and so no new legislation is needed or appropriate.

Do you know why this—is this a change of position? Have you concluded that the FDA does not currently have authority over human cloning?

Mr. OKARMA. I can't answer that. I just don't know the legal foundation of that.

Mr. PITTS. One other question: What if it could be shown that the only effective way to prevent reproductive cloning was to stop the process at the first step, that all other measures were almost certain to fail to do the job? Would you favor that?

You said in your testimony that the Greenwood bill bans reproductive cloning. Actually, it is a 10-year moratorium, right?

Mr. OKARMA. Certainly, sir, I am in favor of appropriate legislation to prevent human reproductive cloning. The hypothetical situation that you ask in your—in your question, I don't think is valid. I think there are ways to do that, short of prohibiting the research.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Strickland?

Mr. STRICKLAND. Thank you, Mr. Chairman. I will not take my full time because I would like to yield to my friend, Mr. Stupak in case he has need for additional questions. But I would just like to make some observations.

Much of what we talked about today has involved, I think, moral considerations. And I would like to ask each of the panel members, if they are willing to do so, to share with us whether or not they consider themselves and the position they take a moral position?

Mr. OKARMA. Thank you. I certainly view my position, and that of our company, and the Ethics Advisory Board, who continues to advise us in these matters, as being wholly ethical and moral.

Mr. STRICKLAND. Thank you.

Mr. KASS. The same.

Mr. GUENIN. The view that I described was an attempt to find that, indeed, there is a moral consensus. And so, I contribute that, and that is my personal opinion, but as a scholarly observation. And I think that that could puncture the difficulty here, that there is an unrecognized common understanding if we look to the deepest commitments of moral views.

And that is why I mentioned Catholicism because it is the most prominent articulation of a religious opposition, that there isn't any ground for restraining ourselves when, at no cost to a potential life,

we can do good. If we forego this research, not one more baby will be born.

Mr. NEWMAN. Well, I think morality is about drawing lines, and I think that drawing the line between cloning humans and not cloning humans is a relevant and important moral line to draw. So, yes, I think that the position that I have presented to you is a moral position.

Mr. STRICKLAND. May I interrupt? My understanding is that every one of you here has taken the position that you oppose the cloning of human beings, though. Is that not right?

Mr. NEWMAN. I think that is the case for all the speakers on this panel. But I think that the point has been made, and I agree with it, that manipulating human embryos by cloning, or by genetic engineering, is just an invitation to get used to the idea, and eventually have people say well, it is out there; it is a product; why can't I use it for my own purposes?

Mr. STRICKLAND. Okay.

Mr. GUENIN. To be completely forthcoming in answering your question, I have to say that I am not prepared to defend reproductive cloning because it is presently manifestly unsafe. But if it were safe, then I think we—and we probably will in some future time have a discussion again.

I am not prepared to say it would be wrong in all instances, but it needs discussion.

Mr. PERRY. I believe it is one of the highest moral obligations to relieve human suffering, to extend the benefits of health to as many of our fellows as possible, and to use our brains and our free institutions to drive toward that goal.

Ms. NORSIGIAN. I do think it is a moral position, and I agree with what Dr. Newman just said. But I also think that it is absolutely clear to any of us who have looked at our past track record in related fields that there is no way to prevent human reproductive cloning if we allow the development of clonal embryos.

And so, if we feel very strongly about that moral line, and that we really do not want to see human clones produced, we do have to say no to human—to reproductive—excuse me, to embryo clones being produced.

That may mean that some—although I think, at this point, we don't have evidence. It is a very broad array of options. Some options might not be pursued that would benefit humankind. I will admit that.

But I think that it is a position, a moral position, to say that we should not allow for that.

Mr. DOERFLINGER. Well, the Catholic Bishops Conference certainly thinks that our position is the morally right one. But it is not a position based solely on morality. We think that on legal, practical, political, and even Constitutional grounds, the Weldon bill is an effective and well-written ban on cloning, and the Greenwood bill is not.

Mr. FUKUYAMA. Well, I have never encountered a speaker that identified themselves as taking an immoral position, so I guess my position is based on morality.

But I do think that morality cannot be reduced to utility, and the relief of suffering is an important, you know, human goal. But it

is not the—it is not the only way to define how you approach moral issues.

Mr. STRICKLAND. The reason I asked the question I think is very important because someone's morality may be someone else's immorality. And I think—I think it is important for us to understand that. We set priorities. Is the relief of human suffering the highest good?

I guess what I am describing here is a kind of situational ethic. And I am sorry, Mr. Stupak, I have taken all the time, but I would just like to end with this comment.

I don't know which of these bills I am ultimately going to support or endorse. But I think this issue is so complicated and so important that I question whether or not many of us in this Congress are informed well enough to proceed with making a decision at this point in time.

I certainly feel that I am not. I respect each of you and your points of view. But there is—there are variations here. This is an important issue, and I hope we do not go down a path which we will, at some point in the future, regret. And I yield back the time I don't have, Mr. Chairman.

Mr. BILIRAKIS. Yield back the time you don't have, yeah. We have three votes on the floor, so we are going to have to finish up. Ms. DeGette?

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Again, we extend courtesy to you.

Ms. DEGETTE. I appreciate it. And I would like to speak on behalf of all of the members of this panel for calling these—both of these excellent panels.

I was just sitting here thinking I have books by many of these panelists on my bookshelves. And I think it is a wonderful panel.

Having said that, I just have a couple questions. First of all, Mr. Doerflinger was correct about the Ottawa study. That was done—that was a study done with pancreatic eyelet cells from human cadavers.

The study I was talking about in my question earlier was an NIH study using mouse embryonic stem cells. It was a different study, and it was using mouse cells. So, just to clear the record up on that; no need for an answer, sir, because I have a lot of questions.

And one question I have for Mr. Okarma, do you know of any research laboratories, biomedical research laboratories such as yours, who do also in vitro fertilization techniques on individuals?

Mr. OKARMA. No, I do not.

Ms. DEGETTE. And I guess I—Ms., how do you pronounce your name?

Ms. NORSIGIAN. Norsigian.

Ms. DEGETTE. I should know since your book is one of my great personal references—references. Do you know, in your experience, of any in vitro fertilization clinics that also do biomedical research?

Ms. NORSIGIAN. There are some that are involved, but I cannot name them right now. I could get it for you.

Ms. DEGETTE. So, they are actually performing——

Ms. NORSIGIAN. The relate——

Ms. DEGETTE. [continuing] research?

Ms. NORSIGIAN. There is a relationship in terms of collaboration, but I am not sure about the——

Ms. DEGETTE. Are they actually performing research at the—at the clinics, do you know?

Ms. NORSIGIAN. Well, I hope not; not the kind you are suggesting.

Ms. DEGETTE. Right, okay. The reason I ask that question is because we were talking earlier about—about the issue that you can't really differentiate between these cells.

And I believe the administration witness said well, for in vitro fertilization, you will be able to tell because that is a reproductive clinic where they are transplanting the embryos in the uterus. But this kind of research is done in different kinds of clinics.

And I think that—that you have to have that view consistently throughout. A lot of folks are saying, "Well, if you allow the somatic cell research, then it will be—then it will be too difficult to prevent actual humans from being cloned."

But I think you could set up that firewall because I think those research and the reproductive clinics are two, totally different things. And the evidence would bear that out.

I have a question, a couple questions, for Dr. Kass. I read your recent New Republic article with great interest, and I really agree with something you say in there, which is that we have this problem with cultural pluralism and easygoing relativism. So, we can't really tell what we support or not.

Most of the witnesses here seem to support in vitro fertilization, but yet they don't support cloning even for research purposes.

And then, you go on to say, actually earlier in your article, that "Some transforming powers are already here: the Pill, in-vitro fertilization, bottled embryos, surrogate wombs, cloning, genetic screening, genetic manipulation, organ harvesting, mechanical spare parts, brain implants, Ritalin for the young, Viagra for the old, Prozac for everyone."

So, is what we should do, do you think, on a moral basis, is just ban all of this, since all of this is, at essence, messing with human biology?

Mr. KASS. No.

Ms. DEGETTE. And where—how do we figure out where that line should be, Dr. Kass?

Mr. KASS. Of course not, no. Thank you very much for the question.

Ms. DEGETTE. You are welcome.

Mr. KASS. It is very important, I think, that we not see this isolated—this issue before us out of the larger context. We are in the midst of acquiring wonderful powers for the treatment of disease and the relief of suffering.

Some of those techniques have other uses that go beyond therapy——

Ms. DEGETTE. Right.

Mr. KASS. [continuing] and we should wake up to that fact.

Ms. DEGETTE. Right.

Mr. KASS. Professor Fukuyama said that in most of the areas that we will have to make decisions, legislative ban is a blunt and inappropriate instrument.

Ms. DEGETTE. Right.

Mr. KASS. It is the wrong way to do most things because the good—the benefits and the harms are very closely linked, and one needs more sophisticated means of doing the regulation.

However, here you have an issue where, in fact, for all our moral pluralism, the poles continue—and I am not—I don't take my moral compass from the Pope, but the American——

Ms. DEGETTE. And thank God for that.

Mr. KASS. Well, the American people want to see reproductive cloning stopped. And if we don't act—and this—Congressman Strickland, if I might, Congress' silence this time will be acquiescence if somebody does it while we are silent.

Ms. DEGETTE. Well, Doctor, everybody here would agree, reproductive cloning should——

Mr. KASS. Fine.

Ms. DEGETTE. [continuing] be banned.

Mr. KASS. Okay.

Ms. DEGETTE. But let us say we could——

Mr. BILIRAKIS. Well——

Ms. DEGETTE. [continuing] we could somehow stop research—or reproductive cloning without stopping the research——

Mr. BILIRAKIS. I apologize——

Ms. DEGETTE. [continuing] cloning. Would that be——

Mr. BILIRAKIS. [continuing] to the gentlelady——

Ms. DEGETTE. [continuing] acceptable?

Mr. BILIRAKIS. [continuing] but we have about 5 minutes left for a vote. We are going to have to get going there. Can you take 30 seconds to respond?

Ms. DEGETTE. Thank you.

Mr. KASS. I am very long-winded. No, I think—this is so serious that I think we should not—we should lock the barn door before the embryo clones get out into reproductive places.

Ms. DEGETTE. Thank you.

Mr. BILIRAKIS. Honestly, I agree with Ms. DeGette. This was a terrific panel. We hold these hearings hopefully without pre-deciding, hopefully to learn. If anyone sitting in on these hearings has not learned an awful lot about this subject, I think they have had their ears bottled up.

We appreciate you being here very, very much. We will have questions in writing to you. We would hope that you would be willing to respond to those in a timely fashion.

And second of all, any other ideas that you all have that might be helpful in terms of helping us make our decisions on this very complex and significant subject, we would welcome them with open arms. And again, our gratitude. Thank you. This hearing is now adjourned.

[Whereupon, at 2:22 p.m, the subcommittee was adjourned.]