

ISSUES RAISED BY HUMAN CLONING RESEARCH

HEARING
BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
OF THE
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COMMERCE
HOUSE OF REPRESENTATIVES
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ISSUES RAISED BY HUMAN CLONING RESEARCH

WEDNESDAY, MARCH 28, 2001

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

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Stearns, Largent, Burr, Whitfield, Bass, Tauzin (ex officio), Deutsch, Strickland, DeGette, John, and Rush.

Staff present: Alan Slobodin, majority counsel; Julie Corcoran, majority counsel; Ray Shepherd, majority counsel; Robert Simison, professional staff member; Chris Knaur, minority investigator; and John Ford, minority counsel.

Mr. GREENWOOD. All right, the hearing before the Oversight and Investigations Subcommittee will now come to order. We thank the witnesses for their indulgence and the Chair recognizes himself for 5 minutes for the purposes of an opening statement.

Nearly 80 years ago, Aldous Huxley wrote his literary masterpiece *Brave New World*. In that book he posited a future where genetic engineering is commonplace and human beings, aided by cloning, are mass produced. Controllers and predestinators replaced mothers and fathers. The words themselves considered smut.

As the new authors of human life in an uncompromising search for human happiness and stability, the possibility of human individuality had been entirely jettisoned. For most of its 80 years, *Brave New World* could be seen as a disturbing work of science fiction. That is no longer the case. The possible cloning of human beings is now relegated to the world—not relegated to the world of fiction. The question we must now ask is this: what should we do with this science? That is what brings us here today.

Several scientists claim that they are poised to take the fateful next step and actually produce a human clone. We in this subcommittee will focus not only on the scientific, but on the moral and ethical questions raised by the astonishing possibility that an exact copy of a human being might be cloned in the near future.

What then is cloning? The *World Book Encyclopedia* describes cloning as a process that involves “destroying the nucleus of an egg cell of the species to be cloned. The nucleus is then removed from a body cell of an animal of the same species. This donor nucleus

is injected into the egg cell. The egg, with its new nucleus, develops into an animal that has the same genetic makeup as the donor.”

Just 4 years ago, the Scottish researcher Ian Wilmut and his colleagues, announced that they had successfully cloned a lamb they called Dolly from a single cell of an adult sheep. Since then various other mammals have been cloned. Recently, however, two groups of scientists have announced their intention to manufacture the first human clone. One group, the Raelians, a Canadian-based religious cult, announced late last year that it had found an American couple willing to pay \$500,000 to clone their deceased child. The Raelians claim to be conducting experiments in a laboratory in the United States. Several publications including Wired Magazine and the New York Times, have published in-depth stories which take the Raelians announcement quite seriously.

The other group, an international consortium of scientists led by Dr. Panos Zavos, a reproduction researcher, and his partner, Severino Antinori, an Italian fertility doctor, have stated their intent to develop clones for infertile couples. In January of this year, Dr. Zavos' group announced that within 2 years it intends to clone the first human being at a site outside the United States.

Capitalizing on the fascination with human cloning, other groups have established websites offering cloning services. We have a demonstration of that.

Although federally funded human cloning research is prohibited, such privately funded research is not. In fact, no definitive Federal statute governs privately funded human cloning experiments. Experimentation in science has outpaced the law on the underlying issues raised by human cloning.

As one of our witnesses, Dr. Arthur Caplan recently put it, “the science horse ran out of the barn, jumped over the fence and has gone down the highway and the law is still hanging around the barn.”

The FDA has asserted that it has jurisdiction over human cloning, based on the Public Health Service Act and the Food, Drug and Cosmetic Act. Is this a sufficient safeguard?

Although there is no Federal ban on human cloning, a number of states, 26 other countries and the United Nations have seen the need to enact some form of ban on human cloning. But to craft a meaningful and reasonable statute that is both sound in its science and consistent with human dignity, the Congress needs to ask the hard questions posed by human cloning research.

The technique to clone other mammals has proved difficult and dangerous. Before scientists successfully produced Dolly, there were 276 failures. Last week, my staff and I met with Dr. Simon Best, a member of the Dolly research team. Extrapolating from its results, he told us the data suggests that it might take a thousand surrogate mothers to successfully clone a human being at the cost of 990 miscarriages, still births and infants born with serious and unpredictable birth defects.

The rate of failure in animal cloning should serve as a fire bell in the night. Behind the headlines of apparent success in animal cloning lies a failure rate as high as 95 to 97 percent.

Would human cloning lessen the worth of individuals and diminish respect for human life by turning procreation into a manufacturing process?

Is there a bright line between the joining of a man and a woman's reproductive cells and the replication of just one person's genetic material?

Is the one creation and the other mere construction?

The Christian philosopher G.K. Chesterton wrote, "The whole difference between construction and creation is exactly this, that a thing constructed can only be loved after it is constructed, but a thing created is loved before it exists."

We also, in fairness, need to listen to the arguments in favor of human cloning. There are those who argue that reproductive freedom includes human cloning, perhaps as a means to address the problem of male infertility. Others advocate cloning as a means to replicate a deceased loved one. For yet others, human cloning is justified because it may provide important advances in scientific knowledge.

In examining these arguments, I believe we must exercise a substantial degree of healthy skepticism and we would do well, I think, to keep in mind the powerful message contained in the simple saying that hung in Albert Einstein's office at Princeton, "Not everything that counts can be counted and not everything that can be counted counts."

This committee has a responsibility to ask these difficult questions because we are dealing with the most profound of human responsibilities, the future of our species.

The witnesses we have assembled represent a broad cross section of opinions and expertise on these complex issues. We will hear from experts in animal cloning research and bioethics, the FDA and the National Bioethics Advisory Commission, among others. The NIH, National Institutes of Health was invited to participate in this hearing, but deferred, owing to a lack of expertise in this area.

We will also hear from controversial witnesses. We hope to learn from their testimony whether the projects they envision are credible scientifically.

Other esteemed bodies can hold meetings and write reports and issue voluntary guidelines, but only the Congress can write the laws for our nation. It is said that Huxley borrowed the title for his book from these lines found in Act V of Shakespeare's play *The Tempest*: "Oh brave new world that has such people in it." And he compounded the irony by envisioning a world in which Shakespeare himself was outlawed. In fact, when one of the characters asks, "But why is it prohibited?" he is told "because it is old. That's the chief reason. We haven't any use for old things here." "Even when they are beautiful?" he then asks. "Particularly when they are beautiful" comes the reply.

But if we are wise, before we open the floodgates to a new kind of human being, we might recall the lines in *The Tempest* that preceded the ones Huxley used in his title. "How many goodly creatures are there here? How beauteous is mankind." I want to express my appreciation to the subcommittee ranking minority Congressman Peter Deutsch for working with me on this hearing. I'm

also grateful to the full committee Chairman Billy Tauzin for his support of this hearing. I thank all of the witnesses for participating in this hearing and I look forward to their testimony.

I recognize the ranking member, Mr Deutsch for 5 minutes for an opening statement.

Mr. DEUTSCH. Thank you, Mr. Chairman. I have a statement that I'd like to submit for the record. I'm anxious to hear the witnesses' testimony.

Mr. GREENWOOD. Without objection.

Mr. DEUTSCH. And I'll just maybe summarize a couple of points. One is I think it's important that we're having this hearing, obviously. I appreciate the chairman's work in setting this up and his staff work as well.

I would make one comment that as you are well aware, no one from NIH is here today and I find that lacking in the sense that the Nation's premiere health organization is not here, but hopefully if we follow up in additional hearings that's something that we can basically rectify.

I also believe that it's imperative that we go about our work in this important matter in a manner that does not curtail or chill research in other fields and I know that the biotechnology industry is concerned about this and I'm glad that they're here today.

As you know, there are some tremendously important fields that are not human cloning. These fields are recombinant technology that hold out the hope for prevention, treatment and cure for a host of diseases and conditions. These include Parkinson's, diabetes, Alzheimer's, leukemia and other cancers, heart disease, liver failure and many others. Anything that we do in the name of prohibiting the cloning of humans should not delay or deny the important work that is being done with stem cells and related fields of science.

Finally, I would also mention that if we are talking about the FDA itself being the agency that theoretically would be enforcing the ban that arguably exists, there's a question about not providing additional resources to the FDA we're talking about providing additional responsibilities and in terms of the President's budget, there's no acknowledgement of this additional research or this additional enforcement by the FDA. And I think that's a real concern I have.

But finally, and really in a sense, I have spent time reading through testimony, reading through projects and I would say to you and I think it's important to say even at the start of this hearing that I agree with you completely, that it is our job to legislate and we are the only entity able to legislate and I think it is imperative, in fact, that we make clear that human cloning is not legally acceptable in the United States of America. And I look forward to working with you to create legislation that would, in fact, do that, balancing the concerns that I think both of us share not to interfere with some of the incredibly significant research that can be done regarding other issues here. And I believe that we will be able to craft legislation to that effect and I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the chairman of the full committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman, let me first congratulate and salute you, Mr. Chairman, Congressman James Greenwood for holding this hearing and for shining the light on this issue of great public concern, that of human cloning.

This hearing is a great example of how Congress, especially the House of Representatives, serves as both a voice and a fact finder for the American people.

As you saw in the film, a religious sect called the Raelian Movement and an international group of scientists have recently announced their intent to conduct experiments on human beings to create a cloned baby. As far as we can tell, one of these experiments has already started and both are being conducted outside the scrutiny of government regulatory bodies and institutional review boards.

The issue of human cloning and these announced experiments raise scientific, medical, ethical, moral and ultimately policy questions that we as a country must confront. Cloning may literally threaten the character of our human nature. We are all imperfect beings as we often find out. All of us. And that requires us to learn and develop certain traits such as forgiveness and understanding and love and character. How is all that threatened when we produce perfect human beings through this cloning technology?

Other institutions can issue reports and hold hearings and announce voluntary policy, but only the Congress, particularly through this committee can write the laws that could regulate or even ban the cloning of human beings. This oversight hearing can be the start for an honest appraisal of the science behind human cloning, a fair inquiry to hear from the parties themselves on how they plan to conduct their human cloning experiments and a thoughtful discussion of the issues.

While we all should withhold judgment on whatever legislation may come forward, I personally feel there are problems with human cloning from a safety, legal, and ethical standpoint. I believe the burden is going to be on the proponents of human cloning to make the moral and scientific case for these experiments. The question is why do we need human cloning?

This hearing must also address whether current Federal law and regulation is adequate for monitoring human cloning experiments. The Food and Drug Administration has asserted its authority over human cloning intended to create a human being and we support the FDA and want to assist them in the considerable skills they have in overseeing the matter. However, the jurisdictional claim of the FDA may suffer from being a square peg in a round hole.

FDA says it can regulate human cloning because the agency has interpreted old Federal laws to cover new cloning activities. The FDA argues that old Federal laws regulating new drugs cover a human cell or human fetus. I frankly do not find it obvious that a human fetus is a drug. And while a court may find this argument facially plausible, I would not want to rely upon the single reed of Federal regulation to address experiments intended to create a baby from cloning technology.

In addition, FDA's authority is based only on safety concerns, not on ethical or moral concerns. This leaves open the question of whether FDA would permit the cloning of human beings, if it be-

came satisfied that it was safe. And since FDA generally does not have the authority to ban cloning on moral and ethical grounds, we should all be concerned that 1 day the FDA may simply approve the process on a safety basis.

Congress may need to pass legislation to ban human cloning or take other actions to firm up FDA's policies or grant enforcement authority to another agency. We will deliberate carefully and thoughtfully. We'll hear some very distinguished scientists and ethicists today. We'll also have controversial witnesses, including those from the Raelian Movement. The media, including Time Magazine and the TV show 60 Minutes, as you saw, covered the Raelians' announced efforts to clone a human being. If the Raelians are to be believed, they are only weeks away from implanting a human embryo into a surrogate mother. Through this hearing, the public will hopefully learn whether the Raelian experiment is a hoax or whether as Time Magazine reported, "this group may even be further along in human cloning than the competition."

If the facts and the consensus emerge to support legislation to ban the cloning experiments intended to make babies, we are going to have to be prepared to act. I will work with Chairman Greenwood and every member of the committee, Democrats and Republicans to legislate on a good bill. I welcome the witnesses and look forward to their testimony and I thank again the chairman for this very important hearing.

Mr. GREENWOOD. The Chair thanks the chairman of the full committee and yields 3 minutes to the gentle lady, Ms. DeGette, for her opening statement.

Ms. DEGETTE. Thank you, Mr. Chairman. The questions posed by human cloning span the range of legal, ethical and medical frontiers. Who is responsible for a wrongful birth or an abnormal human being born as the result of the cloning procedure, the parent, the cloners or the physician who supervises the pregnancy? Can a dead person be cloned without giving pre-death consent? Can a loved one clone a relative in a coma without consent, and if so, who is responsible for the complications that may arise out of the procedure?

As the science and medical communities continue to make incredible strides in the areas of genetic discovery as recently occurred with the mapping of the human genome, it's of paramount importance that we carefully examine the issues surrounding human reproductive cloning.

As we've heard, human cloning will receive a lukewarm at best reception today in this committee. However, the complexity of the issues, moral, scientific and ethical argues for a thoughtful and complete discussion of the issue before we pass legislation.

This analysis must examine the impact any new legislation would have on work currently underway by scientists across the globe whose goal is to further medical therapies to eradicate disease. To be clear, these two types of research are very different.

As co-chair of the Congressional Diabetes Caucus, I'm a strong advocate of medical research as the prevention and treatment of many diseases have been achieved through university, private sector and government-funded research. In particular, I'm interested in the advancement of research in the areas of stem cell therapy

and cell therapy and beta cell development as one means of further reducing or eliminating dependence on insulin for Type 1 diabetes. This research not only has implications for diabetes, but may provide profound breakthroughs for the millions of people affected by genetic diseases such as sickle cell anemia, Parkinson's, Cystic Fibrosis and Alzheimer's Disease.

A concern for people involved in medical research has also led me to introduce the Human Subject Protections Act which would, of course, apply to anyone involved in private research on human cloning and I intend to reintroduce this bill soon in the 107th. I hope I can count on co-sponsorship from the chairman and many members of this committee.

Over the years, clinical research has become increasingly complex. Human cloning adds to the complexity. Before any humans are cloned in the United States, I know we all want to ensure the ramifications of this project are fully known and that all medical and research guidelines and safeguards have been carefully followed.

Most scientists, however, tell us that today neither animal nor human reproductive cloning can be done safely, efficaciously, reliably or frankly, morally. We cannot and should not proceed without those safeguards.

Mr. Chairman, I look forward to hearing from the witnesses today and learning more about human cloning, including whether really cloning is on the horizon or if it's just a lot of talk.

I'd like to hear the process and the legal and regulatory issues surrounding it and with that, I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the lady for her statement and recognizes the vice chairman of the subcommittee, the gentleman from Kentucky, Mr. Whitfield for 3 minutes for his opening remarks.

Mr. WHITFIELD. Thank you very much, Mr. Chairman. In preparation for this hearing I went back to 1998 and read the transcript of the hearing we held at that time on this very subject matter, even though it was not the Oversight Committee and in reading that material I came across a statement from Cardinal William Keeler, Archbishop of Baltimore, and I might add that I'm certainly not a member of the Catholic faith, but I thought he touched on some very important issues that we need to think about as we proceed in the discussion of this important issue.

He stated that "cloning is presented as a means for creating life, not destroying life. Yet it shows disrespect toward human life and the very act of generating it. Cloning completely divorces human reproduction from the context of a loving union between man and woman, producing children with no parents in the ordinary sense. Here, human life does not arise from an act of love, but is manufactured to predetermined specifications. A developing human being is treated as an object, not as an individual with his or her own identity and rights."

I don't think there is any subject that this Congress can be taking up that is more important than this issue and the many complex aspects to it.

I know we have a distinguished panel of witnesses today, three panels, and while I find myself agreeing with the Cardinal's testi-

mony in 1998, I am still approaching this with an open mind and do look forward to the testimony here today. I yield back the balance of my time.

Mr. GREENWOOD. The chairman thanks the gentleman for his opening remarks and recognizes the gentleman from Illinois, Mr. Rush for 3 minutes for his opening remarks.

Mr. RUSH. Thank you, Mr. Chairman. Mr. Chairman, I want to commend you and thank you for holding this hearing on this very, very important and critical issue. I do have some statements that I will enter into the record at a later date and I'll attempt to summarize my position right now.

With the Scottish scientist Ian Wilmut's cloning of an adult sheep, Dolly, in February 1997, we all knew that it only was a matter of time before attempts would be made to clone a human. I am indeed an ordained Baptist minister and based on my calling, my personal, moral and religious views, I know that human cloning raises serious ethical, religious and moral concerns. However, as the co-chair of the House Biotech Caucus, I'm well aware of the amazing advances science and technology have made in both the medical and agricultural fields to prolong and improve the quality of human life.

As an African-American, I'm keenly aware of racist prejudices and biases. The expansion of science can never be an end unto itself. The expansion of science must be viewed in the light of the agenda of those who espouse it and the impact it has on our public, on our way of life and on our God.

Efficacy is also a major concern. Even if we simply view cloning from a purely scientific perspective, devoid of moral considerations, there are major problems. Many prominent scientists have reported that cloning has resulted in development delays, heart defects, lung problems and malfunctioning immune systems in mammals. Also, the errors created by a cloning are random and may not surface, indeed, until the cloned individual is much older, later in the cloned individual's life.

Thus, until long term research is done on cloning, we will not know the impact of cloning as cloned species age. The FDA would not release a drug for human consumption which causes major birth defects in lab animals and could therefore harm humans. Based on this same logic, cloning should not be considered for humans, not now, and never in the future. The danger of cloning as a public health concern reaches beyond the cloned infant. The physical and genetic abnormalities of a cloned infant poses serious threats to all concerned, particularly a surrogate mother.

While it is clear that there are serious problems with human cloning due to moral and public health concerns, I don't think that prudence is warranted. As noted, science and the biotech field has brought us great successes. We must not take action which will impede the legitimate and safe use of biotechnology. Many argue that Congress is slow to act or react to changes in science and technology. However, I would argue that we must act with caution to ensure that future scientific successes which will make this world healthier and more productive while tightly regulating and indeed banning those practices which pose a clear threat to the health, the

safety and the moral condition of our citizens. Human cloning must be banned now and forever.

Thank you and I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman for his statement and recognizes for 3 minutes the gentleman from Florida, Mr. Stearns for his opening statement.

Mr. STEARNS. Thank you, Mr. Chairman. No mother, no father, no parents, no family. That's what will happen if we allow human cloning. Human cloning is a form of playing God, since it intervenes with the natural order of creation. We have reached that point in our human history where human cloning is an unethical use of technology. Ever since the world was made aware of Dolly, and the infamous Dr. Seed and the possibility of cloning human beings, significant actions have been taken to outlaw this practice.

Mr. Chairman, in the 105th and 106th Congresses, I introduced legislation to prohibit the expenditure of Federal funds to conduct or support research on the cloning of humans and to express the sense of Congress that other countries should establish substantially equivalent restrictions.

Even though the President called for a ban on the use of Federal funds for research on cloning of human beings, I believe legislation to ban Federal funding of research on human cloning is still necessary. Let me explain why.

Currently, in the United States, four states prohibit cloning and eight more States have legislation pending to ban human cloning. But let's take a look at the California law for a moment. 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 "entire human" being used frequently in debates about cloning. That is just one of many problems associated with technology that may be used to clone humans.

I would like to share with my colleagues what Lori B. Andrews who teaches the legal aspects of genetics at Chicago Kent College has to say about the bans on human cloning. She has analyzed the bans under consideration in 20 states. Here's what she has to say. "Once again, technology may be running circles around the law. At least seven States ban and 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 non-human egg."

There are many issues raised by the possibility of cloning humans. There are lots of risk as my colleagues have talked about. Of the 273 tries to develop Dolly, 272 were failed, either aborted, destroyed or maimed. Obviously, we cannot go down that line.

There are also compelling and serious ethical and moral implications involved with cloning of humans. Theologians 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.

So Mr. Chairman, I look forward to this hearing. We have a lot to learn and also the Food and Drug Administration's role is something we should explore. Also, Mr. Chairman, by unanimous consent, I'd like to place the testimony of Attorney Clark D. Forsythe who is President of Americans United for Life in the record. Mr. Forsythe's testimony discusses the constitutional issues related to cloning of human beings which is an important part of the debate surrounding this complex subject.

Mr. GREENWOOD. Without objection, the testimony so referenced will be included in the record.

[The prepared statement of Clarke D. Forsythe follows:]

PREPARED STATEMENT OF CLARKE D. FORSYTHE¹

EXECUTIVE SUMMARY

Substantive due process does not restrict governmental prohibitions on human cloning. There is no constitutionally-protected right to non-coital, asexual reproduction. This is due to (1) the demonstrated authority of the state and federal governments to protect human life at every stage of development, (2) the limits of substantive due process, and (3) the compelling interests in prohibiting human cloning, which are addressed in order below.

The history of legal protection of developing human life is important because it shapes substantive due process, informs the limits of *Roe v. Wade*, 410 U.S. 113 (1973), and undergirds protection for the developing human being in non-abortion circumstances today. Governmental authority to protect human life at every stage of development is deeply rooted in English and American history, and—at least outside the context of abortion—is broadly and increasingly exercised today. Throughout American history, legal protection of human life has grown as medical knowledge has grown. State protection of human life at every stage of development has grown in criminal law and civil (tort) law throughout the 20th century. In particular, at least 38 states have affirmed, as a matter of public policy, that human life begins at fertilization (conception). There are only two exceptions to this general trend: abortion jurisprudence and state judicial decisions relating to custody decisions involving cryopreserved human embryos.

Throughout the development of Anglo-American law protecting developing human life, legal protection required medical knowledge of the existence of a human life. The common law relied on two types of medical evidence: quickening—the first sign of fetal movement—and the location of the developing child inside or outside the womb (birth). Human cloning—a byproduct of in vitro fertilization (IVF)—is conducted extracorporeally, outside the human body, *in vitro*. As with IVF, only after the cloned human embryo is allowed to divide would the embryo be implanted in a woman's uterus. There is no "pregnancy" to be terminated, and no right to "terminate pregnancy" is affected by state protection of the extracorporeal human zygote or human embryo. Since extracorporeal human embryos are outside the womb they are, for all intents and purposes, born, and as developing human beings, are entitled to the full protection of the law.

The constitutional right of privacy—or substantive due process more specifically—does not prevent legal prohibitions or regulations on human cloning. There is no fundamental right to human cloning. Supreme Court privacy cases preceding *Roe v. Wade* protect family interests related to coital reproduction. In 1973, in *Roe v. Wade*, the Supreme Court created a right to "terminate pregnancy." In the discrete area of abortion, the Supreme Court has broadly prohibited governmental regulation, as exemplified by *Planned Parenthood v. Casey*, 505 U.S. 873 (1992), and *Stenberg v. Carhart*, 120 S.Ct. 2597 (2000). But this has never been expanded beyond abortion into a broad right of "procreative liberty." Nothing in Supreme Court case law establishes non-coital reproduction, much less asexual reproduction, as a

¹B.A. Allegheny College (1980); J.D., Valparaiso University (1983); President, Americans United for Life (AUL). Copies of two of my professional articles have been submitted to the Subcommittee: Clarke D. Forsythe, Human Cloning and the Constitution, 32 Val. U.L. Rev. 469 (1998); Clarke D. Forsythe, Homicide of the Unborn Child: The Born Alive Rule and Other Legal Anachronisms, 21 Val. U.L. Rev. 563 (1987).

constitutionally protected right. None of the values deeply rooted in the nation's history and tradition or implicit in the concept of ordered liberty—such as marital intimacy, marital sexual relations, bodily integrity—are implicated by non-coital, asexual reproduction like cloning.

Finally, there are compelling reasons to prohibit human cloning. In addition to the pervasive destruction of human life inevitably caused by cloning research, cloning: (1) creates confusion of identity and individuality, (2) represents a giant step toward “transforming procreation into manufacture,” (3) represents a form of despotism of the cloners over the cloned and thus is a blatant violation of the inner meaning of parent-child relations, and (4) would constitute an unethical experiment upon the resulting child.

I. LEGAL PROTECTION OF HUMAN LIFE

The legal issues surrounding human cloning research in the United States are the grandchild of the Supreme Court's 1973 decision in *Roe v. Wade*, which legalized abortion for any reason, at any time of pregnancy, in every state. Legalized abortion fostered in vitro fertilization (IVF) and embryo experimentation, which now have led to (reported) attempts at human cloning. IVF technology was first widely publicized in 1978 with the birth of Louise Brown, the first “test tube baby,” in Britain.² IVF typically involves the fertilization of a number of eggs resulting in several human embryos in hopes of successfully implanting at least one in a woman's uterus, and IVF researchers conduct embryo experimentation in order to increase the success rates of IVF. Human cloning, in a sense, is a type of IVF and will inevitably involve embryo experimentation. Hence, the legal status of the human embryo is directly relevant to constitutional issues affecting human cloning.³

For much of the public and for many scholars, the legal and moral status of the developing human being begins and ends with *Roe v. Wade*, 410 U.S. 113 (1973), the Supreme Court's decision which legalized abortion nationwide for any reason, at every stage of gestation, a quarter of a century ago. Much public discussion today about the unborn revolves around the issue of abortion. Legal commentators who write on the legal status of the embryo commonly demonstrate only the most superficial understanding of the history of legal protection of the developing human being.⁴ For example, in justifying human cloning and “the manipulation and destruction of embryos that cloning research, if not the procedure itself, will inevitably cause,” Professor John A. Robertson, a leading advocate of reproductive technologies including cloning, contends that there is a “prevailing moral and legal consensus that views early embryos as too rudimentary in neurological development to have interests or rights.”⁵ Whether such a consensus exists in fact and history requires a detailed review of American legal history and contemporary legislation and caselaw. Hence, the history of the legal protection of developing human life is important because it shapes substantive due process, informs the limits of *Roe v. Wade*, and undergirds protection for the developing human being in non-abortion circumstances today.

A. Common Law Protection of Human Life

Anglo-American law has always considered human beings and the human species special. There has always been an important distinction in American law between the human species and all other species. The basic law protecting the inviolability of human life—the law of homicide—is reserved for human beings. The principle of the natural rights of human beings, the equal creation of human beings, and the inalienability of the right to life is deeply imbedded in the American political and

²Gina Kolata, *Clone: The Road to Dolly and the Path Ahead* 180 (1998).

³For purposes of this testimony, I adopt Congress' definition of “human embryo” in Pub. L. No. 106-554, sec. 510(b) (“any organism—that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells”).

⁴See e.g., John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. Cal. L. Rev. 942, 973 (1986) (“With the exception of former laws that prohibited abortion, the law has never regarded fetuses as rights-bearing entities”); John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 Va. L. Rev. 437, 450 n.38 (1990) (citing four articles for legal background, all of which contain only a sketchy, incomplete, and superficial review of the history of the legal protection for the unborn: Lori B. Andrews, *The Legal Status of the Embryo*, 32 Loyola L. Rev. 357, 361 (1986) (citing *Roe v. Wade* for the legal status of the human embryo in history); Patricia A. King, *The Juridical Status of the Fetus: A Proposal for Legal Protection of the Unborn*, 77 Mich. L. Rev. 1647 (1979); Robertson, *Embryos*, 59 S. Cal.; Marcia Joy Wurmbbrand, Note, *Frozen Embryos: Moral, Social, and Legal Implications*, 59 S. Cal. L. Rev. 1079 (1986) (citing Robertson, *Embryos*, supra, and John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 Va. L. Rev. 405 (1983)).

⁵Robertson, *The Question of Human Cloning*, Hastings Ctr. Rep. Mar.-Apr. 1994, at 6.

legal tradition. The founding political document of the United States, the Declaration of Independence, proclaims that all are created equal, endowed by their Creator with certain inalienable rights, including a right to life, and that government is instituted to secure (not create) that right. These were considered—by Jefferson, Madison, Adams, Franklin and the entire founding generation—to be “self-evident” truths.

At common law, the basic law protecting human life was the law of homicide. The protection of the law of homicide was very broad—extending its protection to “the killing of any human creature,” according to Blackstone, the leading authority on the common law.⁶ Contemporary debate over the moral status of the human embryo, however, forgets that the homicide law, by definition, protects human beings, not persons. This confuses the 14th Amendment (and the Court’s discussion of “person” in *Roe v. Wade*) with the criminal code.⁷ Even if a human being is not considered by the courts to be a person under the 14th Amendment, that human being still may be protected under state homicide law. Homicide law does not protect only mature or developed persons, but all human beings as human beings—all offspring of human parents. It is species-directed. *Roe v. Wade* merely created a constitutional exception to the general rule when it stipulated that that protection may not interfere with a woman’s right to “terminate pregnancy.”

The common law protected unborn human life to the greatest extent possible given contemporary medical knowledge. The law was informed by medicine, and legal protection was extended as medical knowledge progressed. The right to life was “a right inherent by nature in every individual; and it begins in contemplation of law as soon as an infant is able to stir in the mother’s womb.”⁸ But what was most important was not “personhood” but its status as a “human creature.” In the face of the limitations of primitive medical knowledge, every consideration was given to protect the life and rights of the unborn child. Thus, as Blackstone wrote, “An infant in ventre sa mere, or in the mother’s womb, is supposed in law to be born for many purposes.”⁹ The common law protection of the unborn child had direct antecedents in the Roman civil law’s protection of the unborn child from the time the mother was known to conceive.¹⁰

That English medical-legal authorities considered abortion at any stage of gestation to be the taking of human life, and thus a crime, influenced the development of English legislation.¹¹ As Glanville Williams observed, with Lord Ellenborough’s Act of 1803, Parliament “made not merely a legal pronouncement but an ethical and metaphysical one, namely that human life has a value from the moment of impregnation.”¹² Why these laws arose in the nineteenth century and not before is clear: Parliament only then learned of the medical evidence concerning human development.¹³

Anglo-American society’s consideration of the unborn human being is also seen in legal reference to the unborn human being as a “child” or “unborn child” stretching back over centuries. At common law, the unborn human being was commonly called a “child.”¹⁴ The term has been used by legal commentaries for centuries, by Fleta, Staunford, Lambarde, Dalton, Coke, Blackstone, Hawkins, and Hale.¹⁵ This is also

⁶ 4 William Blackstone, *Commentaries on the Laws of England* 177 (U. Chicago Reprint 1979) (hereafter Blackstone). See also 4 Blackstone 188 (“Felonious homicide” defined as “the killing of a human creature”); 6 *The New Encyclopaedia Britannica* 26 (15th ed. 1995) (“homicide, the killing of one human being by another”).

⁷ See e.g., Robertson, 76 VA L. Rev. at 444 n.24 (“The abortion debate has often been confused by loose use of terms such as person, human life, human being, etc. Clearly the fertilized egg, embryo, and fetus are human and are living. The question is whether they merit the moral protection accorded to clearly defined persons.”).

⁸ 1 Blackstone 125.

⁹ 1 Blackstone 126. See also *Stemmer v. Kline*, 19 N.J.Misc. 15, 17 A.2d 58, 59 (1940) (“At common law, a child en ventre sa mere was separate entity entitled to recognition and protection by courts and recognized as a ‘person.’”).

¹⁰ See e.g., Dennis J. Horan, Clarke D. Forsythe & Edward R. Grant, *Two Ships Passing in the Night: An Interpretivist Review of the White-Stevens Colloquy on Roe v. Wade*, 6 St. Louis U. Pub. L. Rev. 229, 276 & n.276 (1987) (citing writings of Paulus and Marcianus in *Corpus Juris Civilis*).

¹¹ John Keown, *Abortion, Doctors and the Law* 26-48 (1988).

¹² Glanville Williams, *The Sanctity of Life and the Criminal Law* 227 (1957); Keown, *supra* note 10, at 20.

¹³ Keown, *supra* note 10, at 26-48.

¹⁴ 1 Blackstone 450 (“his child, either born or unborn”)

¹⁵ Horan, Forsythe & Grant, 6 St. Louis at 289-90 & nn.359-378.

seen in the common phrase, being “with child.”¹⁶ Early texts on midwifery, medicine, and jurisprudence used the term “child” at any time of pregnancy.¹⁷

Though limited by contemporary medicine, American law incorporated a general rule of protection. Thus, the Massachusetts Supreme Judicial Court stated, “[t]o many purposes, in reference to civil rights, an infant *in ventre sa mere* is regarded as a person in being.”¹⁸ Or, as the New Jersey Supreme Court stated as long ago as 1849 in *State v. Cooper*, “[i]t is true, for certain civil purposes, the law regards an infant as *in being* from the time of conception . . .”¹⁹

The centuries during which legal protection was burdened by the limitations of medical knowledge dwarf the relatively few, recent years during which heightened medical knowledge has allowed treatment and surgery *in utero*. The novelty of medical technology that allows treatment and visualization of the unborn human being was highlighted by the famous Swedish photographer, Lennart Nilsson. “New technology has made it possible to see the actual events surrounding fertilization and to visualize the growing fetus more clearly. At the same time, new medical knowledge has reduced the risks of pregnancy . . .”²⁰

B. Quickening As An Evidentiary Line

Quickening was established centuries ago as the most reliable medical line showing evidence of life. From the fourteenth through the nineteenth centuries, quickening was the only reliable evidence that a woman was pregnant or that the unborn human being was alive. As late as 1800, a standard text on midwifery (the forerunner to obstetrics) concluded that “there appears to be no unequivocal sign, whereby that state [pregnancy] can with certainty be determined, till between the fourth and fifth months, when the child quickens, that is, when its motions are distinctly felt.”²¹ Texts of midwifery typically contained chapters on the “signs of pregnancy,” in which quickening was emphasized.²² Thomas Denman, a widely cited authority on the subject, expressed the developing understanding of quickening in his 1829 text:

The changes which follow quickening have been attributed to various causes. By some it has been conjectured, that the child then acquired a new mode of existence; or that it was arrived to such a size as to be able to dispense with the menstuous blood, before retained in the constitution of the parent, which it disturbed by its quantity or malignity. But it is not now suspected, that there is any difference between the aboriginal life of the child, and that which it possesses at any period of pregnancy, though there may be an alteration in the proofs of its existence, by the enlargement of its size, and the acquisition of greater strength.²³

Beck, in his *Elements of Medical Jurisprudence*—one of the primary authorities in the 19th century—emphasized the same understanding:

It is important to understand the sense attached to this word [quickening] formerly, and at the present day. The ancient opinion, on which indeed the laws of some countries have been founded, was, that the foetus became animated at this period—that it acquired a new mode of existence. This is altogether abandoned. The foetus is certainly, if we speak physiologically, as much a living being immediately after conception, as at any other time before delivery; and its future progress is but the development and increase of those constituent principles which it then received.²⁴

Wharton and Stille emphasized the same point:

This symptom [quickening] was formerly given much weight, because at that time the child was supposed to receive its spiritual nature—to become animate. Such ideas have now become entirely obsolete in the scientific world. The time perfecting the child is at its conception. After then, in all ways, it is merely a question of growth and development.²⁵

¹⁶ 1 Blackstone 446 (“declares herself with child”).

¹⁷ Horan, Forsythe & Grant, 6 St. Louis at 290 n.369; 1st Cite Forsythe, 21 Val. U.L. Rev. at 563.

¹⁸ Parker, 50 Mass. at 266 (citing 1 Blackstone 129).

¹⁹ 22 N.J. 52, 56-57 (1849). The court finished this statement by saying that “yet it seems no where to regard it as *in life*, or to have respect to its preservation as a living being.” Id. The answer here is the difference between different burdens of proof in civil and criminal law, as well as the evidentiary issues involved.

²⁰ Lennart Nilsson, *A Child Is Born* 15 (1990).

²¹ Valentine Seaman, *The Midwives Monitor and the Mothers Mirror* 70-72 (1800).

²² See Forsythe, 21 Val. U.L. Rev. at 571 n.42, 572-73.

²³ Thomas Denman, *An Introduction to the Practice of Midwifery* 287 (3d ed. 1829).

²⁴ 1 John Beck, *Elements of Medical Jurisprudence* 276 (11th ed. 1860).

²⁵ 3 Wharton and Stille, *Medical Jurisprudence* 7 (5th ed. 1905).

Based on the primitive medical knowledge of the day, the common law adopted the presumption that the fetus first became alive at quickening.²⁶

At the earliest time of the common law, in the thirteenth century, Bracton and Fleta held that the killing of a “quickened child” in the womb was homicide without any explicit requirement of live birth.²⁷ However, there is substantial common law authority that abortion was a crime at common law without regard to quickening and without regard to the time of gestation. As the highest court in Maryland stated in 1887, “[A]s the life of an infant was not supposed to begin until it stirred in the mother’s womb [quickening], it was not regarded as a criminal offense to commit an abortion in the early stages of pregnancy. A considerable change in the law has taken place in many jurisdictions by the silent and steady progress of judicial opinion; and it has been frequently held by Courts of high character that abortion is a crime at common law without regard to the stage of gestation.”²⁸

Prior to this Maryland decision, two of the most prestigious criminal law scholars of the 19th century, Bishop and Wharton, also criticized the quickening rule, concluding that abortion was a crime at common law regardless of the stage of gestation.²⁹ Wharton’s discussion revealed the dynamic between medical evidence and increasing protection for unborn human life:

There is no doubt that at common law the destruction of an infant unborn is a high misdemeanor, and at an early period it seems to have been deemed murder. If the child dies subsequently to birth from wounds received in the womb, it is clearly homicide, even though the child is still attached to the mother by the umbilical cord. It has been said that it is not an indictable offense to administer a drug to a woman, and thereby to procure an abortion, unless the mother is quick with child, though such a distinction, it is submitted, is neither in accordance with the result of medical experience, nor with the principles of the common law. The civil rights of an infant in ventre sa mere are equally respected at every stage of gestation; and it is clear that no matter at how early a stage he may be appointed executor, is capable of taking as a legatee, or under a marriage settlement, may take specifically under a general devise, as a “child”; and may obtain an injunction to stay waste . . . It appears, then, that quickening is a mere circumstance in the physiological history of the foetus, which indicates neither the commencement of a new stage of existence, nor an advance from one stage to another—that it is uncertain in its periods, sometimes coming at three months, sometimes at five, sometimes not at all—and that it is dependent so entirely upon foreign influences as to make it a very incorrect index, and one on which no practitioner can depend, of the progress of pregnancy. There is as much vitality, in a physical point of view, on one side of quickening as on the other, and in a social and moral point of view, the infant is as much entitled to protection, and society is as likely to be injured by its destruction, a week before it quickens as a week afterwards.³⁰

Today, for obvious reasons, quickening “provides only corroborative evidence of pregnancy and itself is of little diagnostic value.”³¹

C. *The Evidentiary Meaning of the Born Alive Rule*

The born alive rule was a rule of medical jurisprudence.³² It was an evidentiary rule, a bright-line rule of evidence used to eliminate cases of uncertain evidence in the killing of a child.³³ As a leading 19th century legal authority described the purpose of the born alive rule:

It is well known that in the course of nature, many children come into the world dead, and that others die from various causes soon after birth. In the latter, the signs of their having lived are frequently indistinct. Hence, to provide

²⁶ 6 St. Louis at 279-280 (collecting authorities); 21 Val. U.L. Rev. at nn. 39-53 (collecting authorities).

²⁷ 6 St. Louis Pub. L. Rev. at 285 & n.338. For a description of the common law history of abortion, see Horan, Forsythe & Grant, 6 St. Louis at 278-300; Robert Bryn, *An American Tragedy: The Supreme Court on Abortion*, 41 Fordham L. Rev. 807 (1973); Robert Destro, *Abortion and the Constitution: The Need for a Life-Protective Amendment*, 63 Cal. L. Rev. 1250 (1975); Joseph Dellapenna, *The History of Abortion: Technology, Morality and Law*, 40 U. Pitt. L. Rev. 359 (1979); Shelley Gavigan, *The Criminal Sanction as it Relates to Human Reproduction: The Genesis of the Statutory Prohibition of Abortion*, 5 J. Legal Hist. 20 (1984).

²⁸ *Lamb v. State*, 10 A. 208, 208 (Md. Ct. App. 1887).

²⁹ Joel Prentiss Bishop, *Bishop on Statutory Crimes* sec. 744, at 447 (2d ed. 1883); Frances Wharton, *American Criminal Law* secs. 1220-30, at 210-218 (6th rev. ed. 1868).

³⁰ Wharton, *supra* note 28, at secs. 1220-1230 (cit. omit.).

³¹ J. Pritchard, P. MacDonald & N. Gant, *Williams Obstetrics* 218 (17th ed. 1985).

³² See generally, Forsythe, *Homicide of the Unborn Child: The Born Alive Rule and Other Legal Anachronisms*, 21 Val. U.L. Rev. 563 (1987).

³³ 21 Val. U.L. Rev. 563; 6 St. Louis Pub. L. Rev. at 285-88.

against the danger of erroneous accusations, the law humanely presumes that every newborn child has been born dead, until the contrary appears from medical or other evidence. The onus of proof is thereby thrown on the prosecution; and no evidence imputing murder can be received, unless it be made certain by medical or other facts, that the child survived its birth and was actually living when the violence was offered to it.³⁴

It was generally recognized at common law that pre-viable children could be born alive.³⁵ The medical purpose of the born alive rule 400 years ago has been completely eliminated by modern medical science and technology. It is outmoded, and its existence no longer makes sense in the law.³⁶

The Supreme Court in *Roe v. Wade* misconstrued the born alive rule and converted it from an evidentiary rule dependent on location (in or out of the womb) into a gestational rule (fullterm). This is indicated by the Court's statement that the rights of persons do not begin until term birth, after the third trimester.³⁷

The evidentiary nature of the born alive rule is also seen in the congruence between injury in the womb and death after birth outside the womb. As a renowned 19th century commentator stated the rule: "If a person intending to procure abortion does an act which causes a child to be born so much earlier than the nature time that it is born in a state much less capable of living, and afterwards dies in consequence of its exposure to the external world, the person who by her misconduct so brings the child into the world, and puts it thereby into a situation in which it cannot live, is guilty of murder."³⁸ If the born alive rule was a gestational rule and a moral rule, both the injury and death would have had to occur after birth. Russell's explication shows both the evidentiary nature of the born alive rule and the irrelevance of viability. Modern courts have increasingly recognized this congruence.³⁹ This demonstrates that the born alive rule recognized biological and existential continuity between the unborn child (at any stage of gestation) and the born child.

What the common law demonstrates is that law and medicine had a dynamic relationship with regard to the unborn child. As medical knowledge of fetal development increased, legal protection increased. The law considered the offspring of human parents to be a human being, and the law considered the unborn child to be a human being whenever it could be determined to be alive. Evidence of life—a living human being—was what was important for legal protection, not personhood. The modern debate about "personhood" began with the Supreme Court's consideration of the 14th Amendment liberty clause (protecting "persons") in *Roe v. Wade* in 1973 and subsequent philosophical discussions about *Roe*. The common law protected unborn human life to the greatest extent possible given contemporary medical knowledge.⁴⁰ The common law protection encompassed living members of the human species.

D. The Irrelevance of Viability

The common law placed significance on quickening and live birth. Viability, was not a concern of the common law.⁴¹ It played no role in the development of the common law and its protection of the unborn child.⁴² A leading 19th century legal authority confirmed this:

The English law does not act on the principle that a child, in order to become the subject of a charge of murder, should be born viable, i.e., with the capacity to live... The capacity of a child continuing to live has never been put as a medical question in a case of alleged child murder; and it is pretty certain, that if

³⁴ A. Taylor, *Medical Jurisprudence* 411 (7th ed. 1861).

³⁵ Forsythe, 21 Val. U.L. Rev. at 568 & n.28.

³⁶ See Forsythe, 21 Val. U.L. Rev. 563.

³⁷ 410 U.S. at 161-162, 163.

³⁸ 2 Walter Russell, *A Treatise on Crimes and Misdemeanors* 671-72 (Garland Pub. reprint 1979) (1865).

³⁹ *State v. Cotton*, 197 Ariz. 584, 5 P.3d 918, 922 (Ariz.App. 2000) (adopting rule that "the death of an infant who is born alive from injuries inflicted in utero constitutes homicide," citing *United v. Spencer*, 839 F.2d 1341 (9th Cir. 1988); *Ranger v. Georgia*, 249 Ga. 315, 290 S.E.2d 63 (1982); *Illinois v. Bolar*, 109 Ill.App.3d 384, 440 N.E.2d 639 (1982); *Williams v. Maryland*, 316 Md. 677, 561 A.2d 216 (1989); *New Jersey v. Anderson*, 135 N.J.Super. 423, 343 A.2d 505 (1975), reversed on other grounds, 173 N.J.Super. 75, 413 A.2d 611 (1980); *People v. Hall*, 158 A.D.2d 69, 557 N.Y.S.2d 879 (1990); *Cuellar v. State*, 957 S.W.2d 134 (Tex. Ct. App. 1997); *Wisconsin v. Cornelius*, 152 Wis.2d 272, 448 N.W.2d 434 (1989)).

⁴⁰ Mark Scott, *Quickening in the Common Law: The Legal Precedent *Roe* Attempted and Failed to Use*, 1 Mich. Law & Pol. Rev. 199, 261 (1996) (legal protection extended to "a living member of the human species"); Forsythe, 21 Val. U.L. Rev. at 265ff.

⁴¹ See Horan, Forsythe & Grant, 6 St. Louis at 281-82 n.306-311 (collecting authorities).

⁴² Forsythe, 21 Val. U.L. Rev. at 569 & n.33.

a want of capacity to live were actually proved, this would not render the party destroying it irresponsible for the offense.⁴³

In American law, viability first began as a judicially-imposed gloss on the law, with Oliver Wendell Holmes' 1884 opinion in *Dietrich v. Inhabitants of Northampton*⁴⁴ for the Massachusetts Supreme Judicial Court. *Dietrich* denied recovery for the death of a child born alive but premature from a miscarriage and created a viability requirement for civil recovery that had no basis in statute or common law.⁴⁵

As the "dean of torts," William Prosser made clear, some American courts followed *Dietrich* for about 50 years, but with developing medical knowledge in the 20th century and the 1946 decision in *Bonbrest v. Kotz*, 65 F.Supp. 138 (D.D.C. 1946), American courts increasingly rejected the viability rule until the Supreme Court's decision in 1973 in *Roe v. Wade* placed such great emphasis on viability. Relying on *Roe*, some state courts limited legal protection for the unborn to viability. More recently, other courts have recognized that *Roe*—and its emphasis on viability—does not apply outside abortion law.

F. Modern Criminal and Tort Law Developments

1. *Tort Law*—Until modern scientific advances allowed greater knowledge of human life in utero, abortion law was the primary—but not exclusive—legal field for the protection of unborn human life. Until nearly the 20th century, homicide and abortion law proceeded on two different, evidentiary tracks based on location of the child—homicide law applied to human beings *outside* the womb, abortion law applied to human beings *inside* the womb.

Dean Prosser explained both the evidentiary reasons for the born alive rule in tort law and the advancements in medical science that eliminated its rationale:

When a pregnant woman is injured, and as a result the child subsequently born suffers deformity or some other injury, nearly all of the decisions prior to 1946 denied recovery to the child. Two reasons usually were given: First, that the defendant could owe no duty of conduct to a person who was not in existence at the time of his action; and second, that the difficulty of proving any causal connection between negligence and damage was too great, and there was too much danger of fictitious claims.

So far as duty is concerned, if existence at the time is necessary, *medical authority has recognized long since that the child is in existence from the moment of conception, and for many purposes its existence is recognized by the law . . .* So far as causation is concerned, there will certainly be cases in which there are difficulties of proof, but they are no more frequent, and the difficulties are no greater, than as to many other medical problems. All writers who have discussed the problem have joined in condemning the old rule, in maintaining that the unborn child in the path of an automobile is as much a person in the street as the mother, and in urging that recovery should be allowed upon proper proof.⁴⁶

The Court in *Roe* cited Prosser to support its erroneous description that courts had granted recovery for prenatal injuries only where the fetus was viable or at least "quick."⁴⁷ But Prosser stated just the opposite, pointing out that, in fact, most states permitted recovery for prenatal injuries regardless of the stage of gestation in which the injuries are inflicted:

Most of the cases allowing recovery have involved a fetus which was then viable . . . Many of them have said, by way of dictum, that recovery must be limited to such cases, and two or three have said that the child, if not viable, must at least be "quick." But when actually faced with the issue for decision, *almost all of the jurisdictions have allowed recovery even though the injury occurred during the early weeks of pregnancy, when the child was neither viable nor quick.*⁴⁸

As Professor David Louisell summarized the law two years before *Roe*:

[T]he progress of the law in recognition of the fetus as a human person has been strong and steady and roughly proportional to the growth of knowledge of biology and embryology. For centuries the law of property has recognized the unborn as living persons and the criminal law, although unevenly, has accorded them substantial protection. The law of torts, because of biological misconcep-

⁴³ A. Taylor, *Medical Jurisprudence* 413 (7th ed. 1861).

⁴⁴ 138 Mass. 14, 16 (1884).

⁴⁵ See generally, Clarke D. Forsythe, *The Legacy of Oliver Wendell Holmes*, 69 U. Det. Mercy L. Rev. 677, 685-89 (1992).

⁴⁶ William Prosser, *Law of Torts* 335-36 (4th ed. 1971) (emphasis added); Prosser & Keeton on *Torts* 367-72 (5th ed. 1984); Prosser *Wade & Schwartz, Torts* 421-36 (9th ed. 1994).

⁴⁷ 410 U.S. at 161-162.

⁴⁸ Prosser, *Law of Torts*, at 337 (4th ed. 1971) (emphasis added).

tions among judges and practical difficulties of medical proof, was something of a laggard, but since World War II there has been an explosive recognition “that the unborn child in the path of an automobile is as much a person in the street as the mother.” Judicial acknowledgment “that the unborn child is entitled to the law’s protection” has resulted in ordering blood transfusion necessary to save his life, over the cogent countervailing claims to the free exercise of religion. In a word, the unborn child is a person to be protected in his property rights and against negligence, and to be afforded the reach of equity’s affirmative arm for support and sustenance.⁴⁹

Although abortion law was virtually abolished by the Supreme Court in 1973, *Roe* did not touch assaults on the unborn child *outside the context of abortion*. *Roe* may have stifled an ongoing process of increasing state protection for unborn human life in the field of criminal and tort law,⁵⁰ but that process has progressively continued outside the immediate context of abortion despite *Roe*.⁵¹ The upshot of this progressive protection has been a gradual abolition of the artificial born alive rule and a growth in protection of the unborn child, even if stillborn, and without regard to the stage of gestation.

In tort law today, virtually all states allow suits for prenatal injuries for children later born alive. (Obviously, if the child is not born alive, the suit would be for wrongful death.) Today, at least thirty-six jurisdictions allow wrongful death actions for a stillborn child, while a dwindling minority of eight to ten states reject the cause of action.⁵² A majority of state courts have expressly or implicitly rejected viability as a limitation for liability for nonfatal prenatal injuries.⁵³ As recently as 1993, the Pennsylvania Supreme Court pointed out that “no jurisdiction accepts the . . . assertion that a child must be viable at the time of birth in order to maintain an action in wrongful death” (where the child is born alive and dies thereafter).⁵⁴

2. *Criminal Law*—Progressive development has continued in criminal law as well. At the time of *Roe*, several states treated the killing of an unborn child as a homicide at some stage of gestation without regard to live birth. The born alive rule, created as a bright line evidentiary rule in a time of primitive medicine, became illogical when medical science advanced to the point that the elements of homicide could be reliably demonstrated even if the child died before birth (stillborn). The born alive rule has been discarded by an increasing number of states at some stage of gestation. Today, more than half of the states treat the killing of an unborn human being as a form of homicide, even though not born alive (stillborn), at some stage of gestation. Eleven states, including Illinois and Minnesota, define (by statute) the killing of an unborn child as a form of homicide, regardless of the stage of pregnancy.⁵⁵ One state defines (by statute) the killing of an unborn human being after

⁴⁹David W. Louisell, *Biology, Law and Reason: Man as Self-Creator*, 16 *Am. J. Juris.* 1, 19-20 (1971).

⁵⁰Some courts concluded that *Roe* prevented protection of the unborn child even outside the context of abortion. See e.g., Bopp & Coleson, *The Right to Abortion: Anomalous, Absolute, and Ripe for Reversal*, 3 *B.Y.U. J. Pub. L.* at 256-57 (citing cases). But that erroneous understanding has been abandoned in recent years. See e.g., *People v. Davis*, 7 *Cal.4th* 797, 30 *Cal.Rptr.2d* 50 872 P.2d 591 (1994).

⁵¹See e.g., *People v. Davis*, 7 *Cal.4th* 797, 30 *Cal.Rptr.2d* 50 872 P.2d 591 (1994); *State v. Merrill*, 450 *N.W.2d* 318 (Minn. 1990), *cert. denied sub. nom. Merrill v. Minnesota*, 496 *U.S.* 931 (1990). For various surveys of the current status of legal developments protecting the unborn child in criminal and tort law, see Forsythe, 32 *Val. U.L. Rev.* at 494-501; Bopp & Coleson, *The Right to Abortion: Anomalous, Absolute, and Ripe for Reversal*, 3 *B.Y.U. J. Pub. L.* 247-261; Horan, Forsythe & Grant, 6 *St. Louis Pub. L. Rev.* at 307-309.

⁵²See generally, Sheldon R. Shapiro, *Annotation, Right to Maintain Action or to Recover Damages for Death of Unborn Child*, 84 *A.L.R.3d* 411 (1978 & Supp. 1997).

⁵³Paul B. Linton, *Planned Parenthood v. Casey: The Flight from Reason in the Supreme Court*, 13 *St. Louis U. Pub. L. Rev.* 15, 47-48 n.141 (1993) (citing 28 states).

⁵⁴*Hudak v. Georgy*, 634 *A.2d* 600, 602 (Pa. 1993).

⁵⁵*Ariz. Rev. Stat.* 13-1103(A)(5) (West 1989 & Supp. 1995); *Ill. Comp. Stat. ch. 720, 5/9-1.2, 5/9-2.1, 5/9-3.2* (1994); *Ind. Code Ann.* 35-42-1-6 (Burns 1994) (feticide); *La. Rev. Stat. Ann. tit. 14, 32.5-32.8* (read in conjunction with *tit. 14, 2(11)* (West 1996 Supp.); *Minn. Stat. Ann.* 609.266, 209.2661-609.2665, 609.268(1) (1987 & Supp. 1996); *Mo. Rev. Stat.* 1.205, 565.024 (Vernon 1996 Supp.) (see *State v. Knapp*, 843 *S.W.2d* 345 (Mo. 1992); *N.D. Cent. Code* 12.1-17.1-01 to 12.1-17.04 (1995 Supp.); *Ohio Sub. Senate Bill No. 239* (1996); *PA Senate Bill No. 45* (1997); *S.D. Cod. Laws Ann* 22-17-6 (1988); 22-16-1, 22-16-1.1, 22-16-4, 22-16-15, 22-16-20, 22-16-41, read in conjunction with 22-1-2(31), 22-1-2(50A) (1996 Supp.); *Utah Code Ann.* 76-5-201 (1995). Prosecutions under the Illinois law, without regard to time of gestation, are common. See e.g., Steven J. Stark, “Boyfriend, 21, is charged in pregnant teen’s slaying,” *Chicago Tribune*, Sunday, March 8, 1998, sec. 4, p. 3, col. 5 (defendant charged with “intentional homicide of an unborn child”).

eight to ten weeks gestation as a form of homicide.⁵⁶ Eight states define (by statute) the killing of an unborn child after quickening as a form of homicide.⁵⁷ Five states define (by statute or caselaw) the killing of an unborn human being after viability as a form of homicide.⁵⁸ Constitutional challenges to statutes of this type, include statutes applying throughout gestation, have been rejected in several decisions.⁵⁹

As medical science has developed, and the cause of the death of the unborn human being is more easily determined, the born alive rule has come under increasing criticism and has been increasingly rendered meaningless. It is important to remember that even under the application of the born alive rule, the killing of an early developing, human being was still counted as a homicide if the assault on the mother resulted in a miscarriage that produced expulsion from the womb and death after that expulsion, at any stage of development. In the course of things, the unborn human being might not survive the initial assault or the miscarriage, but if it did, it did not matter to the law of homicide how premature the human being was, as long as it survived expulsion from the womb and was observed outside.

By eliminating the born alive rule in the 20th century, state homicide law has abandoned the arbitrary matter of location (outside or inside) because location no longer matters to medical determination. This has allowed the law to focus on the *cause* of death at any stage of development, without regard to *location*. As a result, cases like the *Merrill* case in Minnesota have followed.⁶⁰ *Merrill* involved a double homicide, when a man killed his estranged girlfriend when she was pregnant with a 28-day-old embryonic human being, who died in the womb. The assailant was charged with a double homicide and that indictment was upheld on appeal. Many similar cases involving previable unborn human beings have arisen in Illinois, another state with a similar law that has abandoned the born alive rule without establishing arbitrary gestational limitations.

In California, because of the supreme court's May, 1994 decision in *People v. Davis*⁶¹ a charge of homicide can be brought for the killing of an unborn human being at any time after 8-10 weeks gestation. The court arrived at this result from a strict, biological reading of the legislative term, "fetus," even though the term "fetus" is commonly used to denote a developing human being at any stage of development.⁶²

These developments in homicide law continue. Recently, Indiana became the 26th state to treat the killing of an unborn human being as a homicide at some stage of gestation when it enacted a law, over the Governor's 1997 veto, to treat the killing of an unborn child as a homicide, whether born alive or not.⁶³ Because the publicized incidents that gave rise to the legislation involved the shooting of a pregnant woman carrying a presumably viable child, the legislation contained a viability limitation. In addition, Michigan enacted legislation to protect the unborn child ("embryo" and "fetus") at all stages of gestation. Legal protection of the unborn human being throughout gestation is a dynamic process that continues. Outside the context of abortion, there is a remarkable legal and legislative consensus across at least

⁵⁶ Cal. Pen Code 187(a) (1988). See *People v. Davis*, 7 Cal.4th 797, 30 Cal.Rptr.2d 50, 872 P.2d 591 (1994).

⁵⁷ Fla. Stat. Ann. 782.09 (West 1992); Ga. Code Ann. 16-5-80, 40-6-393.1 (Harrison 1994), 52-7-12.3 (Harrison 1996 Supp.); Mich. Comp. Laws Ann. 750.322 (West 1991) (limited by judicial decision to viability, *Larkin v. Cahalan*, 389 Mich. 533, 208 N.W.2d 176 (1973); Miss. Code Ann. 97-3-37 (1994); Nev. Rev. Stat. 200.210 (1995); Okla. Stat. Ann. tit. 21, 713 (West 1983); Wash. Rev. Code Ann. 9A.32.060(1)(b) (1988); Wis. Rev. Stat. 940.04(2)(a) (West 1996).

⁵⁸ Iowa Code Ann. 707.7 (West 1993) (as amended by H.F. 2109 (1996)); Commonwealth v. Cass, 392 Mass. 799, 467 N.E.2d 1324 (1984), Commonwealth v. Lawrence, 404 Mass. 378, 536 N.E.2d 571 (1989); *State v. Horne*, 282 S.C. 444, 319 S.E.2d 7093 (1984); Tenn. Code Ann. 39-13-201 (Michie 1991 & Supp. 1995); R.I. Gen. Laws 11-23-5 (Michie 1994).

⁵⁹ *People v. Davis*, 7 Cal.4th 797, 30 Cal.Rptr.2d 50, 872 P.2d 591 (1994); *Hughes v. State*, 868 P.2d 730 (Okla. Crim. App. 1994); *Brinkley v. State*, 253 Ga. 541, 322 S.E.2d 49 (1984); *Smith v. Newsome*, 815 F.2d 1386 (11th Cir. 1987); *People v. Ford*, 221 Ill.App.3d 354, 581 N.E.2d 1189 (1991); *People v. Campos*, 227 Ill.App.3d 434, 592 N.E.2d 83 (1992); *People v. Shum*, 117 Ill.2d 317, 512 N.E.2d 1183 (1987), cert. denied sub nom. *Shurn v. Illinois*, 484 U.S. 1079 (1988); *State v. Merrill*, 450 N.W.2d 318 (Minn. 1990), cert. denied, 496 U.S. 931 (1990); *State v. Bauer*, 471 N.W.2d 363 (Minn.App. 1991); *State v. Knapp*, 843 S.W.2d 345 (Mo. 1992); *State v. Black*, 188 Wis.2d 639, 526 N.W.2d 132 (1994).

⁶⁰ *State v. Merrill*, 450 N.W.2d 318 (Minn. 1990), cert. denied, 496 U.S. 931 (1990).

⁶¹ *People v. Davis*, 7 Cal. 4th 797, Cal. Rptr. 2d 50, 872 P. 2d 591 (1994).

⁶² See e.g., J.M. Tanner, *Fetus into Man: Physical Growth from Conception to Maturity* (Harvard University Press 1978) (where conception and fertilization are properly treated as equivalent, and "true foetal age" is counted as beginning with fertilization (p.38-39)).

⁶³ Indiana House Bill 1160.

thirty-eight states that the life of a human being is considered to begin at fertilization (conception).⁶⁴

II. THE LIMITS OF ROE V. WADE AND ITS PROGENY

A. *The Limits of the Supreme Court Privacy Cases Before Roe*

Whether human cloning is a constitutional right involves an application of, as Michael McConnell has phrased it, “the most fundamental question of modern constitutional theory: when, and under what conditions, may courts invalidate duly enacted state or federal laws on the basis of unenumerated constitutional rights?”⁶⁵ The Supreme Court’s 1973 decision in *Roe v. Wade* has spawned 25 years of litigation, legislation, scholarship, cultural change, and public discussion concerning sexual reproduction and the scope of a constitutional right to sexual reproduction. Proponents of a expansive right to sexual reproduction have given it various names and descriptions, among them “procreative liberty,” “a right of the couple to reproduce,” “a right to form a family.” Professor John A. Robertson, one of the foremost advocates of a broad “procreative liberty,” claims that “reproductive freedom” has traditionally been a right taken for granted. Of course, this begs a definition of “reproductive freedom.” “Procreative freedom” is too broad a description of what the Supreme Court has actually held to be constitutionally protected from popular, democratically-approved limits and constraints.

The Supreme Court’s substantive due process decisions of the twentieth century do not support a broad right to “procreative liberty” that encompasses using technology for non-coital, asexual reproduction like cloning. *Prince v. Massachusetts*⁶⁶ involved traditional family relationships. Two other cases relating to parenting rights are deeply based in the common law: *Meyer v. Nebraska*⁶⁷ dealt with the education of children, and *Pierce v. Society of Sisters*⁶⁸ concerned the decision of parents to send their child to a private school. *Skinner v. Oklahoma*⁶⁹ dealt with liberty against coerced sterilization of “habitual criminals,” a negative liberty that could be based in deeply-rooted, common law principles involving battery and informed consent. *Loving v. Virginia*⁷⁰ dealt with marriage, a union deeply based in Anglo-American law. *Eisenstadt v. Baird*⁷¹ involved the use of contraceptives and emphasized their use by individuals, not married couples.

In sum, it may be said that *Skinner* (a case sometimes referred to as involving “procreation” broadly⁷²) is to cloning as *Cruzan v. Director, Missouri Dept. of Health*⁷³ is to assisted suicide. Both *Skinner* and *Cruzan* involved negative liberties of refusing treatment that are based in concepts of battery and informed consent; they did not involve positive liberties to an activity or power. In this regard, it diminishes the strength of a “right” to cloning that cloning does not alleviate infertility, but rather circumvents it, and that cloning cannot be said to be therapeutic.

The substantive due process cases that preceded *Roe* in the area of family law and reproduction are distinguishable in a number of ways.⁷⁴ First and foremost, with the exception perhaps of *Eisenstadt v. Baird*, the rights recognized there have *historical antecedents deeply rooted in American law and were explicitly recognized as such*.⁷⁵ It is also important to point out that Justice Harlan’s opinion in *Poe v. Ullman* was limited to marital use of contraception. (Justice Souter’s concurrence in

⁶⁴ Paul Linton, 13 St. Louis U. Pub. L. Rev. at 120 (Appendix B, collecting legislation and caselaw from 38 states).

⁶⁵ Amicus Brief for Senator Orrin Hatch et al. at 1, *Vacco v. Quill*, 117 S.Ct. 2293 (1997) (No. 95-1858), 1996 WL 657755. See also Michael W. McConnell, *The Right to Die and the Jurisprudence of Tradition*, 1997 Utah L. Rev. 665 (1997).

⁶⁶ 321 U.S. 158 (1944).

⁶⁷ 262 U.S. 390 (1923).

⁶⁸ 268 U.S. 510 (1925).

⁶⁹ 316 U.S. 535 (1942).

⁷⁰ 388 U.S. 1 (1967).

⁷¹ 405 U.S. 438 (1972).

⁷² See e.g., Justice Stewart’s reference to *Skinner* as involving “procreation” in a footnote in *Harris v. McRae*, 448 U.S. at 312 n.18.

⁷³ 497 U.S. 261 (1990).

⁷⁴ *Pierce v. Society of Sisters*, 268 U.S. 510 (1925); *Meyer v. Nebraska*, 262 U.S. 390 (1923); *Skinner v. Oklahoma*, 316 U.S. 535 (1942); *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

⁷⁵ *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923) (“to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men”); *Pierce v. Society of Sisters*, 268 U.S. 510, 534-35 (1925) (“the liberty of parents and guardians to direct the upbringing and education of children under their control”, “engaged in a kind of undertaking... long regarded as useful and meritorious”); *Moore v. City of East Cleveland*, 431 U.S. 494, 503-04 (1977) (“the Constitution protects the sanctity of the family precisely because the institution of the family is deeply rooted in this Nation’s history and tradition”).

Washington v. Glucksberg ignores the limitations of *Poe*, enormously expands its implications and thereby seriously distorts Harlan's opinion.⁷⁶ Nothing in the substantive due process cases preceding *Roe* provides any basis for a right to non-coital, asexual reproduction.⁷⁷

Professor Robertson's vision of parenthood is the "wish to replicate themselves, transmit genes, gestate, and rear children biologically related to them."⁷⁸ Robertson posits a right to "produce a child for rearing that is genetically or gestationally related to one or both partners."⁷⁹ Entailed in such a right would be "discretion to create, freeze, donate, transfer and discard embryos, because these maneuvers are necessary to overcome coital infertility." He argues for "the right of persons to use technology in pursuing their reproductive goals"⁸⁰ and for "presumptive moral and legal protection for reproductive technologies that expand procreative options."⁸¹ But Robertson's argument is declaratory and conclusory, not reasoned: "If the moral right to reproduce presumptively protects coital reproduction, then it should protect noncoital reproduction as well."⁸²

Quite clearly, a constitutional right to cloning cannot be logically derived from the two sets of two sets of substantive due process cases that Professor Robertson posits as a basis for a right to non-coital reproduction.⁸³ The first line of cases involves contraception and abortion, both of which involve a person's physical integrity against a physical imposition by a third-party and a right to *avoid* procreation. These involve a right *not* to procreate, as Robertson points out. From these, Robertson states that a positive right to procreate by non-coital techniques exists, but without any reasoning: "This well-established right [not to procreate] implies the freedom not to exercise it and, hence, the freedom to procreate." The right to use contraception, as developed by American courts, may well assume a right not to use contraception, but this leads only to coital reproduction, nothing more.

The second line of cases involves rearing children, or the "assignment of rearing rights," in Robertson's words, from which he infers "a right to bring children into the world." Parental rights, however, are deeply rooted in American law and tradition and the common law, involving relationships between living parents and living children. There are several limitations on these rights that do not imply any right to non-coital, asexual reproduction. First, the parental relationship is founded in duty, not ownership. Second, these rights presume the existence of children from coital reproduction and nothing more. Third, parental rights are limited by the interests of the children, and while *Roe* establishes a right to end the life of a child conceived but not yet born, it says nothing about ending the life of children conceived *in vitro*. *Roe* involves a right to be free of the physical burden of pregnancy.

Hence, nothing in Supreme Court case law jumps the gap between coital and non-coital reproduction—to say nothing of the gap from sexual to asexual reproduction—and the reliance of the cases involving coital reproduction on physical integrity cannot be extended to the extracorporeal use of germ cells to achieve *in vitro* fertilization. Finally, it is apparent in Robertson's construction of his procreative liberty that the essence of this parental right is the exertion of parental will and desire, a notion of ownership, the imposition of personal will, a conditional love or care. It is exactly this notion that characterized the complete autonomy of the Roman father and was repudiated by the common law.

⁷⁶Michael W. McConnell, *The Right to Die and the Jurisprudence of Tradition*, 1997 Utah L. Rev. 665 (1997).

⁷⁷See also Marc Lappe, *Four reasons to step back from cloning*, Chicago Tribune, March 8, 2001, sec. 1, p. 21 ("No one has an inalienable right to reproduce, much less perpetuate her own genetic makeup, no matter how unique."); Lori Andrews, 11 Harv. J.L. & Tech. 643, 666 (1998) (quote); George Annas, *Human Cloning: A Choice or an Echo?*, 23 U. Dayton L. Rev. 247, 254 (1998) ("Asexual cloning by nuclear substitution represents such a discontinuity in the way humans reproduce . . . This discontinuity means that although the constitutional right not to reproduce would seem to apply with equal force to a right not to replicate, to the extent that there is a constitutional right to reproduce if one is able, no existing liberty doctrine would extend this right to replication by cloning."); George Annas, *Human Cloning: Should the United States Legislate Against It?*, A.B.A.J. at 80 (May 1997) ("Cloning is replication, not reproduction, and represents a difference in kind, not in degree, in the way humans continue the species.).

⁷⁸John A. Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* 32 (1994).

⁷⁹28 Jurimetrics Journal 285, 292 (1988).

⁸⁰John A. Robertson, *Children of Choice* at 42.

⁸¹John A. Robertson, *Children of Choice* at 220.

⁸²*Id.* at 32.

⁸³Robertson, 69 VA L. Rev. at 415.

B. The Limits of Roe's Right to "Terminate Pregnancy"

Roe v. Wade, properly understood on its own terms, dealt with a right to "terminate pregnancy" and nothing more.⁸⁴ It was entirely based on the physical impact of pregnancy on a woman and her desire to rid herself of the pregnancy.⁸⁵ To use Professor Robertson's words, *Roe* involved "the physical burdens of bearing and giving birth."⁸⁶ As the Court noted in *Harris v. McRae*, "the Court in *Wade* emphasized the fact that the woman's decision carries with it significant personal health implications—both physical and psychological."⁸⁷ *Roe* created a negative right to terminate a pregnancy without social (governmental) limits; it did not establish a positive liberty to procreation or a positive liberty in non-coital reproduction. *Roe* created a right to *avoid* procreation, not a right to procreate. This characterization was reaffirmed in *Carey v. Populations Services International*,⁸⁸ and *Planned Parenthood v. Casey*.⁸⁹ The central discussion of "terminating pregnancy" in *Casey* is concluded by a reference to "these considerations of the nature of the abortion right . . ."⁹⁰ Likewise, when the Court in *Eisenstadt v. Baird* refers to "the decision whether to bear or beget a child,"⁹¹ it was understood to refer to the literal physical burden of pregnancy.⁹² "Terminating pregnancy" is the concept of the *Roe* liberty held by Justice Blackmun himself.⁹³

Under the regime of *Roe v. Wade*, it is enough that legislation intervenes to protect human beings—the traditional function of the criminal law and homicide law. It is not necessary that the human beings be "persons" within the meaning of the 14th Amendment. Legislation does not need any other justification, if the exercise of legislative authority does not interfere with woman's right to abortion. The states can protect any extracorporeal human being under the homicide code. Protecting that extracorporeal embryo or human being does not interfere with the Court's limited abortion right. The right to "procreative liberty" is a negative right and does not extend to power over extracorporeal embryos or human beings.

The limits of *Roe* are seen as well in the abortion-funding line of cases. In *Maher v. Roe*,⁹⁴ the Court held that "the right protects the woman from unduly burdensome interference with her freedom to decide whether to terminate her pregnancy."⁹⁵ In *Harris v. McRae*,⁹⁶ the Supreme Court again referred, more than once, to the *Roe* liberty as "the freedom of a woman to decide whether to terminate a pregnancy."⁹⁷ The funding cases demonstrate that the states may "make a value judgment favoring childbirth over abortion" and "implement that judgment" by the use of public funding.

The *Roe* abortion liberty is also severely limited by the fact that it expressly and forcefully excludes men, even married men, from any right whatsoever in the abor-

⁸⁴ See 410 U.S. at 170 (Stewart, concurring) ("the right of a woman to decide whether or not to terminate her pregnancy").

⁸⁵ *Roe*, 410 U.S. at 150 (discussing the risk to the woman, state has interest in protecting the woman's own health and safety; 153 (detailing "detriment" to pregnant woman by "denying this choice"), 162 ("the rights of the pregnant woman at stake"). See also *Casey*, 112 S.Ct. at 2807 ("The mother who carries a child to full term is subject to anxieties, to physical constraints, to pain that only she must bear"), 2816 ("the urgent claims of the woman to retain the ultimate control over her destiny and her body").

⁸⁶ Robertson, 69 VA L. Rev. at 416.

⁸⁷ 448 U.S. at 316.

⁸⁸ 431 U.S. 678, 688 (1977) ("an individual's right to decide to prevent conception or terminate pregnancy . . .").

⁸⁹ 112 S.Ct. at 2804 ("the legitimate authority of the State respecting the termination of pregnancies by abortion procedures"), *Id.* (referring to "essential holding" of *Roe* as including "right of the woman to choose to have an abortion"), 2806 ("the profound moral and spiritual implications of terminating a pregnancy"), 2807 ("the woman's interest in terminating her pregnancy"), 2810 (describing *Roe* as "a rule . . . of personal autonomy and bodily integrity"), 2816 ("freedom to terminate her pregnancy"), 2816 ("the right of the woman to terminate her pregnancy"), 2816 ("the woman's liberty to determine whether to carry her pregnancy to full term"), 2816 ("a right to choose to terminate her pregnancy"), 2817 ("[t]he woman's right to terminate her pregnancy"), 2818 ("a right to choose to terminate or continue her pregnancy"), 2820 ("the right to decide whether to terminate a pregnancy").

⁹⁰ 112 S.Ct. at 2819.

⁹¹ 405 U.S. 438, 453 (1972).

⁹² See *Casey*, 112 S.Ct. at 2819 (quoting passage from *Eisenstadt*).

⁹³ See e.g., *Casey*, 112 S.Ct. at 2486-87 ("a woman's right to terminate her pregnancy") ("continue pregnancies they might otherwise terminate") ("the right to terminate pregnancies").

⁹⁴ 432 U.S. 464, 473-74 (1977) ("the right protects the woman from unduly burdensome interference with her freedom to decide whether to terminate her pregnancy").

⁹⁵ 432 U.S. at 473-74.

⁹⁶ 448 U.S. 297 (1980).

⁹⁷ 448 U.S. at 312. See also *Id.* at 316 ("the freedom of a woman to decide whether to terminate her pregnancy") (three times on the same page).

tion decision. The father of “the developing child” (as *Casey* used the phrase⁹⁸), even the woman’s husband, has no right to consent (*Danforth*) or even notice (*Casey*). Many efforts by men to intervene in and stop abortions have been summarily rejected by the courts.⁹⁹ Men have no legal right to be involved in abortion decision-making. Formally, the decision is the woman’s. *Roe* saw the decisionmaking as between the woman and her doctor only,¹⁰⁰ and, as the plurality stated in *Casey*, “what is at stake is the woman’s right to make the ultimate decision.”¹⁰¹ The plurality in *Casey* went on, at great length, describing the total exclusion of the father or spouse from decisionmaking.¹⁰² Legal commentators rejecting legal regulation of *in vitro* fertilization are inclined to wax eloquent over the involvement of “couples” in “decisions about whether and when to bear children” but fathers (and spouses) are strictly and absolutely excluded from the *Roe* framework and abortion decision making.¹⁰³

The limits of *Roe* are fairly admitted even by proponents of a broad right of non-coital procreation. Thus, such a familiar advocate as John Robertson states:

In the United States, the right to avoid reproduction by contraception and abortion is now firmly established. Whether single or married, adult or minor, a woman has a right to terminate pregnancy up to viability¹⁰⁴ and both men and women have the right to obtain and use contraceptives. The right to procreate—to bear, beget and rear children—has received less explicit legal recognition . . . [N]o cases (with the possible exception of *Skinner v. Oklahoma*) turn on the recognition of such a right. However, dicta in cases ranging from *Meyer v. Nebraska* to *Eisenstadt v. Baird* clearly show a strong presumption in favor of marital decisions to found a family . . . What then about married couples who cannot reproduce coitally? . . . The values and interests that undergird the right to coital reproduction clearly exist with the coitally infertile. Their interest in bearing, begetting or parenting offspring is as worthy of respect as that of the coitally fertile. It follows that restrictions on noncoital reproduction by an infertile married couple should be subject to the same rigorous scrutiny to which restrictions on coital reproduction would be subject.¹⁰⁵

Again, Robertson has noted the limits to *Roe* elsewhere, referring to “a woman’s decision not to conceive or bear a child.”

Even though the Court has eliminated most of the legal limitations on the right to avoid pregnancy, the freedom not to procreate is still circumscribed by a number of restrictions. One such restriction derives from the negative nature of constitutional protections, which shield individuals from state interference with their liberty but do not guarantee them the means to exercise those rights.¹⁰⁶

⁹⁸ 112 S.Ct. at 2817.

⁹⁹ See e.g., *Conn. v. Conn.*, 525 N.E.2d 612 (Ind. Ct. App.), *aff’d*, 526 N.E.2d 958 (Ind.), *cert. denied*, 488 U.S. 955 (1988); *Smith v. Doe*, 530 N.E.2d 331 (Ind. Ct. App. 1988), *cert. denied*, 492 U.S. 919 (1989).

¹⁰⁰ 410 U.S. at 156.

¹⁰¹ 112 S.Ct. at 2821.

¹⁰² 112 S.Ct. at 2826-31.

¹⁰³ See e.g., Lori Andrews, *The Legal Status of the Embryo*, 32 *Loyola L. Rev.* 357, 359 (1986).

¹⁰⁴ This misrepresents the scope of the *Roe-Casey* liberty. *Roe* did not limit the abortion liberty to viability. Instead, with the companion decision of *Doe v. Bolton*, 410 U.S. 179 (1973), *Roe* established a right to a “health” abortion throughout pregnancy (defined as “all factors—physical, emotional, psychological, familial, and the woman’s age—relevant to the well-being of the patient. All these factors may relate to health”). *Id.* at 192. Several federal courts have given such a broad reading to the “health” exception after viability. See e.g., *Women’s Med. Prof. Corp. v. Voinovich*, 130 F.3d 187 (6th Cir. 1997), *cert. denied*, 118 S.Ct. 1347 (1998) (Thomas, J., dissenting from the denial of *certiorari*); *American College of Obstetricians and Gynecologists v. Thornburgh*, 737 F.2d 283, 298-99 (3d Cir. 1984), *aff’d*, 476 U.S. 747 (1986); *Margaret S. v. Edwards*, 488 F.Supp. 181 (E.D. La. 1980); *Schulte v. Douglas*, 567 F.Supp. 522 (D.Neb. 1981), *aff’d per curiam, sub nom. Women’s Servs., P.C. v. Douglas*, 710 F.2d 465 (8th Cir. 1983). The breadth of this “health” exception after viability was not altered in the *Casey* decision. *Planned Parenthood v. Casey*, 505 U.S. 833, 846 (1992) (reaffirming “State’s power to restrict abortion after fetal viability, if the law contains exceptions for pregnancies which endanger a woman’s life or health”), *Id.* at 878 (reaffirming *Roe*’s holding “that subsequent to viability, the State . . . may . . . regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.”), *Id.* at 871 (“when the fetus is viable, prohibitions are permitted provided the life or health of the mother is not at stake”).

¹⁰⁵ John A. Robertson, *Decisional Authority over Embryos and Control of IVF Technology*, 28 *Jurimetrics J.* 285, 290 (1988).

¹⁰⁶ Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 *VA L. Rev.* 405, 405 n.3 (1983).

In sum, as one scholar has phrased it, “to characterize some or all of the cases on which the Court relies in reaffirming *Roe* [in *Casey*] as standing for an abstract right to ‘personal autonomy’ simply creates an artificial common denominator among a very disparate and largely unrelated group of cases while at the same time denying what makes abortion unique.”¹⁰⁷

The issue, though, is not coital versus noncoital as much as corporeal versus extracorporeal reproduction (occurring outside the living body). The negative liberty that has been recognized by the Supreme Court is grounded in personal physical integrity, and the Court has on several occasions explicitly disavowed a right to use one’s body in whatever way desired.¹⁰⁸ The “values and interests” of the “coitally infertile” may be conceded, but it does not follow that these may be pursued by whatever means or “techniques” possible. Some techniques may be legitimate, while others are wholly illegitimate. And it does not follow that any of the techniques are necessarily of a constitutional dimension that overrides other social and ethical judgments made by society through the democratic process. Still less is it clear that the judiciary is empowered to override the authority and decisions of society through the democratic process.

Robertson’s analysis begs all of these questions by focusing on one consideration to the exclusion of all others. Richard McCormick has mounted an insightful critique of Robertson’s utilitarian approach to the status of the human embryo and ethical defense of human cloning by blastomere separation (despite McCormick’s use of the term “pre-embryo” and his general agreement that a human embryo is not a person).¹⁰⁹ In McCormick’s words, Robertson’s defense is “breathtaking in the speed with which it subordinates every consideration to its [cloning by blastomere separation] usefulness in overcoming infertility. [Robertson’s] thesis can be summarized as follows: if it aids otherwise infertile couples to have children, it is ethically acceptable . . . anything that is useful for overcoming infertility is ethically acceptable.”¹¹⁰ McCormick points out that Robertson is trying to create a consensus, not protect an existing one.

The limits of *Roe* are apparent, as well, from the Joint Opinion in *Casey*, where the plurality of Justices O’Connor, Kennedy and Souter shifted the basic rationale of the abortion liberty from privacy to the sociological grounds of abortion as a backup for failed contraception and the “reliance interests” of Americans.¹¹¹ The Joint Opinion again put the emphasis on terminating pregnancy, a backup to contraception, not a positive liberty to “procreate” by any means, much less a liberty in extracorporeal reproduction.

It may be said that American law establishes a privacy interest in marital coital reproduction. But even this is limited to marriage. The precedents leading to *Roe* fairly establish this. Harlan’s specific emphasis in *Poe v. Ullman* was that the state statute in question criminalized *marital use* of contraception.¹¹² While there may be a right to the use of contraceptives, even by minors, there is still no established liberty in premarital or extramarital sexual relations.¹¹³

Roe itself identified abortion as unique and “inherently different from marital intimacy, or bedroom possession of obscene material, or marriage, or procreation, or education, with which Eisenstadt and Griswold, Stanley, Loving, Skinner, and Pierce and Meyer were respectively concerned.”¹¹⁴ The courts have not gone beyond *Roe*’s formulation since 1973. As *Casey* demonstrates, *Roe* and abortion have both

¹⁰⁷ Linton, 13 St. Louis U. Pub. L. Rev. at 31.

¹⁰⁸ *Roe*, 410 U.S. at 154 (“it is not clear to us that the claim asserted by some amici that one has an unlimited right to do with one’s body as one pleases bears a close relationship to the right of privacy previously articulated in the Court’s decisions”); *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (vaccination).

¹⁰⁹ Cf. Robertson, *The Question of Human Cloning*, 24 *Hastings Center Report* No. 2 at 6 (1994), with McCormick’s response, Richard A. McCormick, *Blastomere Separation: Some Concerns*, 24 *Hastings Center Report* No. 2 at 14 (1994).

¹¹⁰ McCormick, *supra* note 82, at 14.

¹¹¹ 112 S.Ct. at 2809 (“for two decades of economic and social developments, people have organized intimate relationships and made choices that define themselves and their places in society, in reliance on the availability of abortion in the event that contraception should fail”).

¹¹² 367 U.S. 497, 554-55 (Harlan, J., dissenting from dismissal on jurisdictional grounds). See also *Griswold v. Connecticut*, 381 U.S. 479, 499 (Harlan, J., concurring in the judgment).

¹¹³ Indeed, in *Eisenstadt v. Baird*, the Court implicitly acknowledged the state’s authority to prohibit “extramarital and premarital sexual relations.” 405 U.S. at 448. And *Eisenstadt* was based on the Equal Protection Clause, not the Due Process Clause. Likewise, *Carey v. Population Services Inter'l*, 431 U.S. 678 (1977), decided after *Roe*, did not create a right to premarital or extramarital sexual activity. 431 U.S. at 688 n.5, 694 & n.17. See also *Id.* at 702 (White, J., concurring in part and concurring in the judgment), *Id.* at 713 (Stevens, J., concurring in part and concurring in the judgment).

¹¹⁴ 410 U.S. at 159.

been treated as “sui generis.”¹¹⁵ In fact, the *Casey* plurality frankly stated that “abortion is a unique act.”¹¹⁶

No court has held that there is a constitutional right to *in vitro* fertilization. Two lower federal courts have struck down fetal experimentation statutes, but on vagueness grounds alone, while a third has upheld a fetal experimentation statute.¹¹⁷

The broader formulation of a positive liberty in “procreation” by various scholars is based on contemporary moral philosophy, rather than caselaw, or legal or constitutional history. Some would ground the procreative liberty and its scope on the subjectivity of the “choice” rather than physical integrity. For example, John Robertson has written that “[t]he personal importance of a decision or activity, rather than its secrecy from the gaze of others, determines its status as part of protected privacy (or liberty, to be more precise.)”¹¹⁸ The Supreme Court expressly rejected such a formulation in *Washington v. Glucksberg*.

C. Differentiating *Cruzan*, *Vacco*, *Glucksberg*

Proponents of an unlimited procreative autonomy have relied on the expansive language of autonomy in *Planned Parenthood v. Casey*,¹¹⁹ sometimes called the “mystery” passage. There, the plurality opinion stated: “At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.”¹²⁰ But it was aptly argued by scholars that this passage must be considered within the context of the plurality’s entire opinion and its emphasis on *stare decisis*.¹²¹ Within that context, the passage should be most accurately understood as rhetorical and not as prescriptive of any specific rights.

The scope of *Casey* was demonstrated to be narrow in the Supreme Court’s landmark decision in *Washington v. Glucksberg*,¹²² where the Court held that the Due Process Clause does not protect any right to assisted suicide. First, the Court in *Glucksberg* specified the two strict requirements of substantive due process. The Due Process Clause protects “those fundamental rights and liberties which are, objectively, ‘deeply rooted in this Nation’s history and tradition’ [cit. omit.] and ‘implicit in the concept of ordered liberty,’ such that ‘neither liberty nor justice would exist if they were sacrificed.’” And a “careful description” of “the asserted fundamental liberty interest” is required.¹²³ It must first be established that an asserted interest is fundamental so as to “avoid[] the need for complex balancing of interests in every case.”¹²⁴

Second, the Court specifically emphasized the limited nature of the passage from *Casey*. Referring to this passage, the Court stated:

By choosing this language, the Court’s opinion in *Casey* described, in a general way and in light of our prior cases, those personal activities and decisions that this Court has identified as so deeply rooted in our history and traditions, or so fundamental to our concept of constitutionally ordered liberty, that they are protected by the Fourteenth Amendment. The opinion moved from the recognition that liberty necessarily includes freedom of conscience and belief about ultimate considerations to the observation that ‘though the abortion decision may originate within the zone of conscience and belief, it is *more than a philosophical exercise*.’ [cit. omit.] That many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected [cit. omit.], and *Casey* did not suggest otherwise.¹²⁵

Two of the three Justices who joined the *Casey* plurality opinion joined this opinion in *Glucksberg* (O’Connor and Kennedy).

¹¹⁵ 112 S.Ct. at 2810.

¹¹⁶ *Id.* at 2807 (“the liberty of the woman is at stake in a sense unique to the human condition and so unique in the law”).

¹¹⁷ *Lifchez v. Hartigan*, 735 F.Supp. 1361 (N.D.Ill.), *aff’d*, 914 F.2d 260 (7th Cir. 1990), cert. denied, 498 U.S. 1069 (1991); *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986); *Jane L. v. Bangertner*, 794 F.Supp. 1537 (D. Utah 1992).

¹¹⁸ Robertson, 28 *Jurimetrics J.* at n.16.

¹¹⁹ 505 U.S. 833 (1992).

¹²⁰ 505 U.S. at 851.

¹²¹ See e.g., Yale Kamisar, *Against Assisted Suicide—Even a Very Limited Form*, 72 *U. Det. Mercy L. Rev.* 735, 765-68 (1995); Richard S. Myers, *An Analysis of the Constitutionality of Laws Banning Assisted Suicide from the Perspective of Catholic Moral Teaching*, 72 *U. Det. Mercy L. Rev.* 771, 777-78 (1995).

¹²² 117 S.Ct. 2258 (1997).

¹²³ 117 S.Ct. at 2268.

¹²⁴ *Id.* at 2268.

¹²⁵ 117 S.Ct. at 2271.

The Court in *Glucksberg* also reaffirmed the limits of *Cruzan v. Director, Missouri Dept of Health*.¹²⁶ The right recognized by the Supreme Court in *Cruzan* was a right to “refuse unwanted medical treatment,” not a “right to treatment” and not a “right to die.”¹²⁷ The right is properly seen as a right to refuse medical treatment, based in bodily integrity and the common law doctrine of informed consent, and not a right to “bodily expression.” As the Court stated in *Glucksberg*, “[t]he right assumed in *Cruzan* . . . was not simply deduced from abstract concepts of personal autonomy. Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation’s history and constitutional traditions.”¹²⁸

In addition, the Court stated in *Cruzan*, and reaffirmed in *Glucksberg*, that the states have an “unqualified interest in preservation of human life.”¹²⁹ As the Court stated in response to the suicide advocates’ argument in *Glucksberg* that the state’s interest in life only applies to “those who can still contribute to society and enjoy life”:

Washington, however, has rejected this sliding-scale approach and, through its assisted-suicide ban, insists that all persons’ lives, from beginning to end, regardless of physical or mental condition, are under the full protection of the law. [citing *United States v. Rutherford*, 442 U.S. 544, 558 (1979) (“ . . . Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise”)] As we have previously affirmed, the States ‘may properly decline to make judgments about the ‘quality’ of life that a particular individual may enjoy. [citing *Cruzan*, 497 U.S. at 282] This remains true, as *Cruzan* makes clear, even for those who are near death.¹³⁰

Although in *Glucksberg*, this interest applies to the end of life, there is no reason—outside the strict constraints of *Roe* and bodily pregnancy—that this unqualified interest does not apply equally to both ends, or all stages, of human life. Thus, just as the states can decline to “make judgments about the “quality” of life that a particular individual may enjoy,” and enjoin assisted suicide despite an individual “interest” in assisted suicide, so too the states may protect extracorporeal human embryos despite varying notions about “personhood” or the interests of infertile individuals.

Since *Roe*, defenders of the abortion liberty have sometimes shifted from the Due Process Clause to the Equal Protection Clause to sustain *Roe*.¹³¹ To the extent that this is persuasive, it cuts against any right to human cloning. And it is instructive that Justice O’Connor, at oral argument in *Vacco* and *Glucksberg*, emphasized that suicide (and death and dying) did not affect women uniquely but affected men and women equally. In this context, a ban on human cloning—and the protection of extracorporeal human embryos—would fall equally on women and men. A prohibition on somatic cell nuclear transfer applies equally to the cells of men and women. For these reasons, as well, *Roe* and its progeny could not encompass a right to human cloning or somatic cell nuclear transfer.

III. LEGAL LIMITS ON HUMAN CLONING

A. *The Interests in Human Cloning*

There are clear, compelling state interests that justify a ban on human cloning and outweigh any supposed “right” to human cloning. These can be grouped into three categories: preventing the extensive destructive of human life that human cloning would clearly involve, preventing injury to the child-to-be, and preventing the degradation of the parent-child relationship.

There are obvious utilitarian benefits to be gained from animal and plant cloning. The utilitarian considerations that are appropriate for plants and animals, however, cannot be extended to humans. To do so violates a basic principle of human rights—to treat human beings as ends and not as means.¹³²

¹²⁶ 497 U.S. 261 (1990).

¹²⁷ 117 S.Ct. at 2270.

¹²⁸ *Id.* at 2270.

¹²⁹ 117 S.Ct. at 2272 (quoting *Cruzan*, 497 U.S. at 282 and the Model Penal Code “The interests in the sanctity of life that are represented by the criminal homicide laws are threatened by one who expresses a willingness to participate in taking the life of an other”).

¹³⁰ 117 S.Ct. at 2272.

¹³¹ See e.g., Richard Posner, *Sex and Reason* 339-40 (1992) (noting such a shift).

¹³² See e.g., Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 7 (1979).

Perhaps the three most compelling reasons for human cloning research are the production of children for infertile couples, possible enhancement of the ability to do prenatal diagnosis and detect genetic defects in the embryo leading to eugenic abortion, and the knowledge derived from cloning embryos that may result in new therapies (such as transplantation) to treat disease.¹³³ Among the interests that might support human cloning, the NBAC referred to “important social values, such as protecting the widest possible sphere of personal choice, particularly in matters pertaining to procreation and child rearing, maintaining privacy and the freedom of scientific inquiry, and encouraging the possible development of new biomedical breakthroughs.”¹³⁴

One of the most commonly argued reasons for human cloning is infertility. Cloning will be a handmaiden to IVF. As Robertson states, “scientific zeal and profit motive combine with the desire of infertile couples for biologic offspring to create an enormous power to manipulate the earliest stages of human life in infertility centers across the country.”¹³⁵ Some couples undergoing IVF who “cannot produce enough viable embryos to initiate pregnancy” might arguably seek cloning by blastomere separation or somatic cell nuclear transfer.¹³⁶ Human cloning, it has been argued, is justified as just an “incremental step beyond what we are already doing with artificial insemination, in vitro fertilization, fertility enhancement drugs and genetic manipulation.”¹³⁷ While the anguish of infertile women and couples may be great, it does not logically follow that they may seek any means to counteract that infertility or seek any means to have a particular child to their liking. There is no “right” to a “perfect child,” as demonstrated by the long legal tradition against infanticide, or a right to perpetuate one’s lineage. It follows that there is no right to a genetically perfect or identical child. At some point, there are simply ethical limits to available solutions to infertility.

There are times when scientific knowledge is greatly desired but not morally obtainable. At those times, it is necessary to pursue other avenues or to wait. There are alternatives to cloning, and to embryo experimentation in general, such as obtaining stem cells from other sources, such as umbilical cord blood. Alternative avenues that are morally permissible must be pursued. A ban on human cloning would create appropriate incentives to invest in alternative areas of research, which—though perhaps more difficult or expensive—do exist.

B. The Interests Protected by Prohibiting Human Cloning

Many ethical objections have been leveled against human cloning by Leon R. Kass, a biochemist and bioethicist from the University of Chicago, and others. These include the following: (1) cloning creates confusion of identity and individuality, (2) cloning represents a giant step toward transforming procreation into manufacture, that is, toward the increasing depersonalization of the process of generation, the production of human children as artifacts, products of human will and design, (3) cloning represents a form of despotism of the cloners over the cloned and thus is a blatant violation of the inner meaning of parent-child relations, of what it means to have a child, and (4) any attempt to clone a human being would constitute an unethical experiment upon the resulting child because of the lack of any consent by the child produced.¹³⁸ The common law born alive rule provides a solid legal basis for these arguments: any human being injured before birth can claim injury after birth. There is congruence between the human entity before and after birth.

1. Preventing Experimentation On and Death of Unborn Human Beings—Human cloning, and the process of developing it, will inevitably involve creating, manipulating, and killing individual members of the human species, i.e., human beings.

¹³³ See e.g., Robert Edwards, Ethics and embryos: the case for experimentation, in Anthony Dyson & John Harris, *Experiments on Embryos* 42, 50 (1990); John Harris, Embryos and hedgehogs: on the moral status of the embryo, in Anthony Dyson & John Harris, *Experiments on Embryos* 75-76 (1990).

¹³⁴ National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission ii* (1997) (hereinafter NBAC Report).

¹³⁵ Robertson, *Hastings Center Rep.* at 7.

¹³⁶ Jerome P. Kassirer & Nadia A. Rosenthal, Should Human Cloning Research Be Off Limits?, 338 *New Eng. J. Med.* 905, 905 (1998).

¹³⁷ Laurence Tribe, Second Thoughts on Cloning, *New York Times*, Dec. 5, 1997, p. A23.

¹³⁸ See Kass, *The Wisdom of Repugnance: Why we should ban the cloning of humans*, *The New Republic*, June 2, 1997, at 17. See also Leon R. Kass, *The Wisdom of Repugnance*, 32 *Val. U.L. Rev.* 679. See also, Marc Lappe, Four reasons to step back from cloning, *Chicago Tribune*, March 8, 2001, sec. 1, p. 21 (“According to the original Nuremberg Code developed at the end of WWII to prevent future abuses of medical research subjects, every experimental subject should have the right to terminate his experiment. How would we ever get an acceptable consent from future generations?”).

(Killing is not a rhetorical word, simply the straight-forward use of the dictionary definition.¹³⁹ We may “discard” things, because things do not die, but we “kill” living beings by causing their death. The very use of the term “discard”—as is typical in most ethical discussions of embryo experimentation—reduces the living human embryo to a thing.) Congressional testimony and debates indicate that it is precisely the ambition of scientists to do research on such developing human entities, with the “disposal” of many or most. John Robertson vividly describes the casual treatment of *ex utero* embryos.¹⁴⁰

Cloning will inevitable involve non-therapeutic experimentation on, and killing of, human embryos.¹⁴¹ Several international codes of medical ethics avoid any distinction between human beings and persons by addressing the interests of “human beings” and “human subjects.” For example, the Nuremberg Code (1947) limited experimentation on the “human subject” by requiring that “voluntary consent” is “absolutely essential.” Experimentation is not permitted on “human subjects” without “legal capacity to give consent” and cannot be continued if “a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.”¹⁴² Likewise, the Declaration of Geneva [1948] declares: “I will maintain the utmost respect for human life from conception.” Similarly, the United Nations Declaration on the Child (November 20, 1959) states: “The child by reason of his physical and mental immaturity needs special safeguards and care, including appropriate legal protection before as well as after birth.” By these contemporary, authoritative ethical standards, human cloning cannot be justified.¹⁴³ This is most clearly true with intentionally cloning human beings for research without intending to implant them.

It is precisely the prerogative of society to give respect to the dignity of these developing human beings and to require that equal dignity and respect be given by other individuals. Anglo-American law has always treated human beings, and the human species as special, and uniquely protected it through homicide law.

2. *Preserving Human Freedom and Dignity*—It is obvious that human cloning by any means (by somatic cell nuclear transfer or blastomere separation) is intended to use unborn human beings, who would be treated as means, not ends, who would be evaluated and valued precisely because of their attributes. The NBAC referred to “a possibly diminished sense of individuality and personal autonomy.”¹⁴⁴

It would extend the degree of control over shaping human lives and in ways that are highly subjective. Clearly, human cloning is not therapeutic, either to the mother or the human being cloned, and is elective. Cloning is only the most recent and highly publicized example of the admonition that technology always involves the power of some people over other people.¹⁴⁵ As the Oxford scholar, C.S. Lewis has written, “For the power of Man to make himself what he pleases means . . . the power of some men to make other men what *they please*.”¹⁴⁶ Of course, education—to a greatly limited extent—has always involved a similar power. But, as C.S. Lewis points out, “in the older systems both the kind of man the teachers wished to produce and their motives for producing him were prescribed by the *Tao*—a norm to which the teachers themselves were subject and from which they claimed no liberty to depart. They did not cut men to some pattern they had chosen.”¹⁴⁷

Perhaps the most sympathetic case for cloning a human being—the genetic replacement of a lost child—shows instead the depersonalization of children. The notion that genetically cloning the child will replace the child suggests that children

¹³⁹ See e.g., Webster’s Ninth New Collegiate Dictionary 661 (1987) (“Kill merely states the fact of death caused by an agency in any manner.”); American Heritage Student Dictionary 546 (1994) (kill: “To cause the death of; deprive of life”).

¹⁴⁰ See e.g., John A. Robertson, The Question of Human Cloning, Hastings Ctr. Rep. Mar.-Apr. 1994 at 7. See also Margaret Talbot, A Desire to Duplicate, New York Times Magazine, February 4, 2001, at 140 (“Cloning mammals is a wildly inefficient process that can require hundreds of attempts both to create an embryo and to implant it successfully.”).

¹⁴¹ NBAC Report, supra note 134, at 63-64. See e.g., Marc Lappe, Four reasons to step back from cloning, Chicago Tribune, March 8, 2001, sec. 1, p. 21 (“Much of the more subtle damage in animal clones has shown up only one or more generations after the first one was cloned.”).

¹⁴² Warren Thomas Reich, ed., Encyclopedia of Bioethics 2763 (Rev. ed.) (vol. 5, Appendix).

¹⁴³ See e.g., Marc Lappe, Four reasons to step back from cloning, Chicago Tribune, March 8, 2001, sec. 1, p. 21 (“According to the original Nuremberg Code developed at the end of WWII to prevent future abuses of medical research subjects, every experimental subject should have the right to terminate his experiment. How would we ever get an acceptable consent from future generations?”).

¹⁴⁴ NBAC Report, supra note 134, at ii. See Kass, 32 Val. U.L. Rev at 694-95.

¹⁴⁵ See generally, Paul Ramsey, Fabricated Man: The Ethics of Genetic Control (1970); C.S. Lewis, The Abolition of Man (1950).

¹⁴⁶ C.S. Lewis, The Abolition of Man 72 (1950).

¹⁴⁷ Id. at 73-74.

are their genes. We know that children are at least their genes, but they are more than their genes. Children are not fungible and cannot simply be “replaced.”

3. *The Diminution of Parental Responsibility*—A third result of human cloning is a coarsening of the relationship between parents and cloned children. The NBAC referred to a “concern about a degradation in the quality of parenting and family life.”¹⁴⁸ With cloning, children will be manufactured in ways that are highly subjective and particular. Because of highly subjective criteria, cloned children will be conditionally accepted; in fact, if the conditions are not satisfied, they will most likely not be born at all—the embryos will be “discarded.” Such conditional acceptance treats children as commodities or possessions. Consequently, “family relations are necessarily diminished, turned into merely contractual relationships between autonomous individuals.”¹⁴⁹

As Leon Kass has testified:

Cloning also represents a giant step (not the first) toward transforming procreation into manufacture, children into artifacts and commodities, products of human will and design. Cloning, like other nontherapeutic genetic engineering, is a form of despotism, an attempt to make children in our image and to control in advance their future. It thus represents in blatant form a deep violation of the meaning of parent-child relations, of the meaning of procreatively saying yes to our own demise and “replacement.”¹⁵⁰

A resulting detachment between parent and child is not speculative. We see it already in sperm and egg donation, as exemplified by the California Court of Appeals’ decision in *Jaycee Buzzanca*.¹⁵¹ Buzzanca was conceived from anonymous sperm and egg donors and born in 1995 to a surrogate mother (with her husband’s consent), contracted by John and Luanne Buzzanca. The Buzzancas separated shortly after Jaycee was conceived and subsequently divorced. Luanne Buzzanca, who had custody of Jaycee since birth but had not adopted her, sued John Buzzanca for child support, and was “the only one of the six people who helped create her to claim parental rights.”¹⁵² A California Superior Court judge ruled that Jaycee had no legal parents, but the court of appeals reversed. Advocates for Jaycee argued that the court should focus on what is best for the child and not on the biological status of the Buzzancas, and the ACLU contended that the child has a “right to have parents” that overrules the lack of legal precedent in California. The way to give meaning to a “the child’s right to have parents,” however, is by preserving biological links and preventing detached, asexual reproduction through cloning, not by imposing parental responsibilities, after the fact, on people who do not have a biological link with the child. The California court of appeals explicitly urged the state legislature to address the situation through legislation because “[t]hese cases will not go away.”¹⁵³

Cloning would overturn the traditional rule of Anglo-American jurisprudence that limits parental authority over the life and health of the child. The protection of vulnerable human life is reflected in the common law’s clear repudiation of the absolute power of the Roman father over the life of the child and the common law’s elevation of legal protection for human life. Blackstone pointed out this contrast.¹⁵⁴ Justice James Wilson, one of the first associate justices of the Supreme Court, emphasized the common law protection for the unborn and newborn child:

I shall certainly be excused from adducing any formal arguments to evince, that life, and whatever is necessary for the safety of life, are the natural rights of man. Some things are so difficult; others are so plain, that they cannot be proved. It will be more to our purpose to show the anxiety, with which some legal systems spare and preserve human life; the levity and cruelty which others discover in destroying or sporting with it; and the inconsistency, with which, in others, it is, at some times, wantonly sacrificed, and, at other times, religiously guarded . . .

[I]n Sparta, if any infant, newly born, appeared, to those who were appointed to examine him, ill formed or unhealthy, he was, without any further ceremony, thrown into a gulph near mount Taygetus . . . At Athens, the parent was empow-

¹⁴⁸NBAC Report, supra note 134, at ii. See Kass, 32 Val. U. L. Rev at 697-98.

¹⁴⁹Allen Verhey, Theology after Dolly, Christian Century, March 19-26, 1997, at 285.

¹⁵⁰Leon Kass, supra note 134, at 21. A version of this testimony has been published as Leon R. Kass, The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans, 32 Val. U.L. Rev. 679 (1998).

¹⁵¹Buzzanca v. Buzzanca, 72 Cal. Rptr. 2d 280 (Cal. App. 1998).

¹⁵²Ann Davis, Artificial-Reproduction Arrangers Are Ruled Child’s Legal Parents, Wall Street Journal, March 11, 1998, at B2.

¹⁵³Buzzanca, 72 Cal. Rptr. 2d at 293.

¹⁵⁴1 Blackstone 440.

ered, when a child was born, to pronounce on its life or its death... [A]t Rome, the one held his life by the tenure of her father's pleasure...

With consistency, beautiful and undeviating, human life, from its commencement to its close, is protected by the common law. In the contemplation of law, life begins when the infant is first able to stir in the womb. By the law, life is protected not only from immediate destruction, but from every degree of actual violence, and, in some cases from every degree of danger...¹⁵⁵

Wilson concluded that "[t]he formidable power of a Roman father is unknown to the common law. But it vests in the parent such authority as is conducive to the advantage of the child."¹⁵⁶ This sentiment was apparently familiar to lawyers during the Founding era, because it is reflected as well in the legal training of John Quincy Adams, who observed that the common law "has restrained within proper bounds, even the sacred rights of parental authority, and shewn the cruelty, and the absurdity of abandoning an infant to destruction for any deformity in its bodily frame."¹⁵⁷ To paraphrase Justice Harlan, this is a tradition from which we have broken.

Based on the common law principle that parental authority must be consistent with the life and health of the child, states have limited parental control that threatens the life or health of the child. For example, parental beliefs against medical treatment can be overridden to preserve the life and health of the child. Parents may be held responsible for the death of the child if medical treatment is not provided. Based on this principle, the states have a related interest in limiting parental control over the genetic destiny of a child.

The interests against human cloning cannot be protected short of a prohibition on the practice. Once cloned, the embryo's genetic identity is formed and controlled and, while subject to further possible experimentation, it cannot be unaltered. Once cloned, it is not possible to effectively protect the life of the extracorporeal embryo. Requiring implantation is inconceivable, and placing them for "adoption" would entail freezing techniques carrying a high risk of death or injury. The only effective way to protect the human embryo is to prevent cloning altogether.

Each of these concerns independently justifies a ban on human cloning. Each supports state action outside the context of abortion to protect human life.

CONCLUSION

As the Professor Gilbert Meilaender testified to the National Bioethics Advisory Commission (NBAC) on human cloning, "sometimes we may only come to understand the nature of the road we are on when we have already traveled fairly far along it."¹⁵⁸ Human cloning is the logical outcome and most recent extension of 20 years of embryo experimentation and manipulation and may be the most subtle extension of that technique and philosophy in its denigration of the dignity of the human being. It proceeds on a cramped, artificial, and impersonal view of human beings and reflects the dehumanizing spirit of Aldous Huxley's *Brave New World*. The impersonal instinct that leads to controlling the genetic destiny of one's progeny comes from the same instinct that treats the human embryo as just a clump of cells. Hopefully, the publicity and analysis given to human cloning will illuminate and educate Americans on the entire misguided effort of human embryo experimentation and manipulation.

At important junctures in this century, scientists have recognized, as a basic tenet of medical ethics, that protection of the human being is more important than the interests of science or society. That is the essence of the Nuremberg Code, which reaffirmed limits on research on human subjects. As the 1975 Helsinki Declaration of the World Medical Association stated, "Concern for the interests of the subject must always prevail over the interest of science and society."¹⁵⁹ Twenty-seven years

¹⁵⁵ 2 The Works of James Wilson 596-97 (R.G. McCloskey ed. 1967). See also Adam Smith, *Lectures on Jurisprudence 172-75* (R. Meek, D. Raphael, P. Stein, eds. 1978) (Liberty Classics Reprint 1982) (quote).

¹⁵⁶ 2 Works of James Wilson at 604.

¹⁵⁷ 2 JQA, *Diary of John Quincy Adams* 193 (March 1786-December 1788) (entry of April 2, 1787).

¹⁵⁸ Reprinted as Gilbert Meilaender, "Begetting and Cloning," *First Things* 41, 43 (June/July 1997). See also Gilbert Meilaender, *Cloning in Protestant Perspective*, 32 *Val. U.L. Rev.* 707 (1998).

¹⁵⁹ Declaration of Helsinki, World Medical Association (1989), reprinted in 5 Warren T. Reich, *Encyclopedia of Bioethics* 2766 (Rev. ed. 1995). See also id at 2767 ("In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject."). See also Declaration of Geneva, World Medical Association (1948) ("I will maintain the utmost respect for human life from the time of conception."), reprinted in 5 Warren T. Reich, *Encyclopedia of Bioethics* 2646-47 (Rev. ed. 1995).

ago, Nobel Prize-winning biologist James Watson noted that ethical decisions about human cloning could not be left to science:

This is a matter far too important to be left solely in the hands of the scientific and medical communities. The belief that surrogate mothers and clonal babies are inevitable because science always moves forward, an attitude expressed to me recently by a scientific colleague, represents a form of *laissez-faire* nonsense dismally reminiscent of the creed that American business, if left to itself, will solve everybody's problems. Just as the success of a corporate body in making money need not set the human condition ahead, neither does every scientific advance automatically make our lives more "meaningful." No doubt the person whose experimental skill will eventually bring forth a clonal baby will be given wide notoriety. But the child who grows up knowing that the world wants another Picasso may view his creator in a different light.¹⁶⁰

It is necessary for society through civil government to establish limits. As Paul Ramsey pointed out, some scientific knowledge, however, interesting or valuable, cannot be obtained by moral means. When that happens, we must seek it by other means or wait until it can be obtained by appropriate means.

Roe v. Wade and its progeny created a woman's "liberty interest" in "terminating a pregnancy." The Supreme Court limited state protection of unborn human life only when balanced against the woman's personal abortion liberty. In that context, a physician is only an agent of the mother and has no personal constitutional liberty interest at stake. Outside that limited context, when the woman's interest in terminating pregnancy is not at stake, the states are free to protect the unborn human being from homicide at every stage of gestation, including fertilization, as some states have done. When extracorporeal human embryos are at stake, no woman is pregnant, and the considerations of *Roe* are absent. This state interest has a long tradition that is actively exercised by states today. Scientists and doctors, as third parties, have no personal constitutional liberty to deprive an unborn human being of life or dignity. No broader constitutional liberty in "procreation" encompasses a right to use technology to clone *in vitro* human embryos. Accordingly, the Constitution leaves broad authority to the representative branches to ban or regulate the practice of human cloning.

Mr. GREENWOOD. The Chair recognizes for 3 minutes for his opening statement, the gentleman from Ohio, Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman. I want to thank you for holding the hearing today on this important issue. We know that scientists have made tremendous strides in recent years with technologies that were the stuff of science fiction novels just a few years ago. Much of this research is very exciting and its potential heal the sick and to improve the quality of life of patients around the world.

I am hopeful that in the coming months, researchers will learn more about the unique properties of stem cells and what they can do for patients with Parkinson's Disease, Lou Gehrig's Syndrome and other diseases of the brain. Nearly every great scientific advance brings with it accompanying ethical issues which society must consider and resolve. Too often, I am afraid, that the resolution of these ethical issues tends to lag behind the rapid pace of scientific development. So I am pleased that the subcommittee is holding this hearing today so that we can hear some of the arguments for and against the prospect of human cloning.

I want to make one observation and then listen to the debate. It seems to me that research into human cloning is a great departure from other more traditional forms of medical research. Traditional medical research focuses on preventing disease, curing disease, slowing the progress of disease, lengthening of life or the easing of pain. We may have ethical disagreements about the methods used

¹⁶⁰James Watson, *Moving Toward the Clonal Man*, 227 *The Atlantic* 50, 53 (May, 1971).

to conduct this research, but I think we all agree that the goals of this type of research are laudable and good.

Research into human cloning has a vastly different goal, the copying of a human being. While there may be collateral medical benefits to cloning, I understand that the goal of those scientists who are attempting to clone humans are not related, the goal is not related to improving the health of individuals, but is rather about making copies of existing humans. Given this great departure from traditional research, I think that our debate should start not with questions of safety and efficacy, although these are very important, but with whether this pursuit is something that we as a society should permit to continue.

Again, I thank the Chair for holding this important hearing and I look forward to hearing the testimony of our witnesses and I relinquish the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for 3 minutes for his opening statement, the gentleman from Oklahoma, Mr. Largent.

Mr. LARGENT. Thank you, Mr. Chairman, for holding this important subcommittee hearing. I'm looking forward to hearing the testimony of our witnesses this afternoon and would just make a few brief remarks.

Human cloning represents the first footstep into a dark wilderness from which we may never emerge. University of Chicago professor, Leon Kass, has written that human cloning would be a fateful step toward "making man himself simply another one of the man-made things. Human nature becomes merely the last part of nature to succumb to the technological project which turns all of nature into raw material at human disposal."

In our vain quest for immortality, will we simply regard cloned babies as meaningless blobs of cells and tissue mass that we can dispose of without any burden on our conscience? The last century and a half is blood soaked with examples of what happens when men are subjugated to the will of other men. We know from our own Nation's experience that slavery not only chained the body of the slave, but it also hardened the heart of the slavemaster to unspeakable brutalities.

It was a small step for German physicians in the 1930's from believing that there was such a thing as a life not worth living to embrace the mass murder of their neighbors. If you had a chance in human history to prevent slavery, would you have taken it? If you had a chance to prevent genocide, would you have taken it? Congress has a chance to prevent the ills that will follow human cloning. Will we take that chance?

The future of the human race is the issue before us. I'm afraid that if human cloning proceeds as a mainstream scientific endeavor, that we may find out what C.S. Lewis meant when he observed that "man's conquest of nature would result in the abolition of man."

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for 3 minutes for the purposes of an opening statement, the gentleman from Louisiana, Mr. John.

Mr. JOHN. Thank you, Mr. Chairman. Thank you for holding this hearing to address, I think, the numerous and myriad issues around the science of human cloning and I'll be very brief in my remarks.

As you've heard from many of my other colleagues, the cloning of the sheep in Scotland occurred just a mere 4 years ago, but the speed in which medical research has produced findings that call us now to address the possible ramifications of human cloning. I think it is absolutely imperative that we have an open and in-depth debate in order to determine the most appropriate role that the Federal Government or should not play in regarding this complex issue as far as and related to legal and ethical matter.

Congress has made it clear that Federal tax dollars cannot be used in the promotion of human cloning research, however, as you've heard from some of my colleagues today and of course, we will hear from some of the panelists, it is only a matter of time, it will only be a matter of time before someone tries to clone, if it hasn't actually started to happen.

I believe it is imperative that we are fully aware of the potential ramifications of human cloning and what the causes beyond will be. Beyond the ethical and moral questions about whether we should even be performing cloning, the data available from the animal cloning shows that we have a very, very long way to go before we have a reliable source of information for safe human cloning. Simply put, I believe Congress and Americans, we must be responsible for the results of these actions or our actions and at this point the consequence of human cloning, I believe, are very unclear.

A few states, including my home State of Louisiana, have issued a ban on human cloning. Some of the other states have issued or is in the process of reviewing this. Also, many countries have already implemented laws limiting or prohibiting human cloning research and just to list a few of them, it may surprise you: Ireland, Israel, Italy, France, Argentina, Spain, are nations that have prohibited human cloning. Nations with current legislative process on the way are Korean, Canada, New Zealand and Russia.

So I think it is imperative that this U.S. Congress step up to the plate and responsibly respond to the scientific community. Therefore, I'm very anxious to hear from our distinguished and experienced panel here, their thoughts on the current scientific status of human cloning and the legal issues surrounding the individuality, the identity, reproduction rights and also privacy of this issue.

I think that the United States, if we fail to address the scientific questions facing us today, I think it will pale in comparison to the questions that we will face tomorrow.

I thank the chairman and I look forward to the testimony to follow.

Mr. GREENWOOD. The Chair thanks the gentleman and for purposes of an opening statement recognizes the gentleman from New Hampshire, Mr. Bass.

Mr. BASS. No opening statement.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for 3 minutes for purposes of his opening statement the gentleman from North Carolina, Mr Burr.

Mr. BURR. I thank the chairman. I won't take the full 3 minutes. I want to thank the chairman for this hearing. I want to thank the witnesses.

Clearly, there's been a lot said about the witnesses because they vary greatly. The fact is that we're a very diverse world and the Congress should welcome as many different views on a particular subject as they can find because I think it displays to the American people, (1) the reason that we're here; and (2) the urgency that many of us feel compelled to inject into this debate.

We've heard today the number of countries around the world that have banned human cloning, that the U.N. is ahead of the U.S., that the Catholic Church is ahead of the Congress. We've read quotes that deal with words like "abort spontaneously", "abnormality rates", "congenital defects", that deal with the cloning of animals and potentially the cloning of humans.

We have the experience of individuals who have participated in animal cloning. One such Michael Bishop, the President of Infogen where he said "that's still a scientific blackbox that we're trying to unravel. We won't be able to tell which embryos can grow to a calf and which cannot. We're getting there."

Where getting there? Where we are today is we have reached a point where I personally believe and I hope it's the belief of my colleagues, that when a male and female DNA don't meet, implantation in a woman's uterus should be banned. I hope, in fact, this committee will listen very carefully to the information our witnesses bring to us today, but I do desperately hope that that's the initiative that comes out of this and that we can pass it on to the relevant committees of this Congress to move legislation.

I thank the chairman and I yield back.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MICHIGAN

Mr. Chairman, the subject of today's hearing is enormously important.

Because of this significance, I am disappointed that we will not hear today from the premier voice in basic science, the National Institutes of Health (NIH). They are a valuable resource on the matters before us, even though NIH is barred from using federal funds for cloning humans.

I also urge caution as the Committee approaches this subject, because a clumsy, ideologically driven effort would chill or curtail some of the most important research being conducted in the life sciences. This research holds promise for so many who suffer from a number of diseases, including Parkinson's, diabetes, cancer, and Alzheimer's. I know that the biotechnology industry is concerned about this and I am glad they are here today.

Finally, Mr. Chairman, some may suggest that the Food and Drug Administration (FDA) lacks both the authority and the resources to police a ban on cloning. If we want FDA to do more, I ask, how? What personnel and what facilities should now become subject to FDA jurisdiction? How often, and under what standards, should anyone with the theoretical ability to clone a human be inspected? And where is FDA going to find the resources to take additional steps to police a ban on cloning? I don't see anything in the President's budget that would allow FDA to enhance its efforts to stop the cloning of humans. Would existing programs, such as new drug approvals and food safety, be adversely affected? If we place more obligations upon FDA without providing additional resources, then we will be at fault.

I urge the Committee to address this topic thoughtfully, carefully, and responsibly.

Mr. GREENWOOD. The Chair thanks the gentleman. The Chair now calls our witnesses and thanks the first panel of witnesses and thanks all of them for their patience.

I would call Dr. Thomas B. Okarma, Ph.D. and M.D. who is the President and CEO of Geron Corporation and is testifying on behalf of the Biotechnology Industry Organization. Also, Dr. Mark E. Westhusin, Ph.D., Associate Professor of Texas A&M University, College of Veterinary Medicine; Dr. Rudolph Jaenisch, Ph.D., Professor of Biology, Massachusetts Institute of Technology; Dr. Panos Michael Zavos, Ed.S., Ph.D., Founder, Director and Chief Andrologist, Andrology Institute of America; and Dr. Brigitte Boisselier, Scientific Director of Clonaid. Welcome, thank you for coming.

You are aware that the committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath.

Do you have any objections to testifying under oath? Very well.

The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel, if you desire to be advised by counsel during your testimony today.

I see no affirmative responses.

In that case, if you would please rise and raise your right hand, I will swear you in. Do you swear that the testimony you are about to give is the truth, the whole truth and nothing but the truth? Thank you.

[Witnesses sworn.]

Witnesses may be seated in the order in which I introduced them, we'll begin with Dr. Okarma. For the benefit of all of the witnesses, you probably have noticed these little black boxes on the table. When you begin your testimony, you'll see the green light. You have 5 minutes for your testimony. You'll get the yellow light at 2 minutes, that's your 2 minute warning and at the red light we would ask you to please quickly summarize and desist.

Dr. Okarma, you are recognized for 5 minutes.

STATEMENTS OF THOMAS B. OKARMA, PRESIDENT AND CEO, GERON CORPORATION; MARK E. WESTHUSIN, ASSOCIATE PROFESSOR OF TEXAS A&M UNIVERSITY, COLLEGE OF VETERINARY MEDICINE; RUDOLPH JAENISCH, PROFESSOR OF BIOLOGY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY; PANOS MICHAEL ZAVOS, FOUNDER, DIRECTOR AND CHIEF ANDROLOGIST, ANDROLOGY INSTITUTE OF AMERICA; AND BRIGITTE BOISSELIER, SCIENTIFIC DIRECTOR OF CLONAIID

Mr. OKARMA. Good afternoon. I am Tom Okarma, the President and Chief Executive Officer of Geron Corporation in Menlo Park, California. Geron is a biopharmaceutical company focused on commercializing therapeutic and diagnostic products for applications in oncology—

Mr. GREENWOOD. Dr. Okarma, could you pull the microphone a little closer to yourself?

Mr. OKARMA. Geron is a biopharmaceutical company focused on discovering and commercializing therapeutic and diagnostic prod-

ucts for applications in oncology, drug discovery and regenerative medicine.

I'm testifying today on behalf of my company and the Biotechnology Industry Organization known as 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.

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 technical and social questions.

That's why BIO wrote to President Bush last month 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. In fact, in most animals reproductive cloning has no better than a 3 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 thereafter. It is simply unacceptable to subject humans to those risks.

The Food and Drug Administration has publicly stated that it has jurisdiction over human reproductive cloning experiments and that it would not approve them. BIO supports that view.

It's critical, however, 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, so called therapeutic cloning. These techniques are integral to the production of breakthrough medicines, diagnostics and vaccines, to treat heart attacks, various cancers, Alzheimer's disease, diabetes, hepatitis and other diseases. This type of therapeutic cloning could also produce replacement skin, cartilage and bone for burn and accident victims and result in ways to regenerate retinal and spinal cord tissue.

My company, Geron, as well as many other companies and academic laboratories, use cloning technology for many beneficial purposes. Let me explain how we use it to develop products that could revolutionize medicine and improve the lives of people suffering from serious illnesses.

Many diseases result in the disruption of cellular function or destruction of tissue. Heart attacks, stroke 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.

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're learning how

to turn undifferentiated human pluripotent 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.

Let me conclude. In addition to the scientific obstacles, human reproductive cloning raises numerous ethical and social concerns. When the moratorium was imposed in 1997, scientists, ethicists and policymakers believed that the various ethical issues raised by human cloning had not been resolved. At the time, the National Bioethics Advisory Commission called human cloning morally unacceptable.

Mr. Chairman, that is still true today. Now only is there no consensus in our society about how to resolve the ethical concerns implicated by human reproductive cloning, these issues have not even been adequately discussed. In my personal view, reproductive cloning would devalue human beings by depriving them of their own uniqueness.

Mr. Chairman, human reproductive cloning remains unsafe. Moreover, the ethical issues it raises have not been fully debated throughout our society, therefore the voluntary moratorium on human reproductive cloning should remain in place and no Federal funds should be used for human reproductive cloning.

Thank you.

[The prepared statement of Thomas Okarma follows:]

PREPARED STATEMENT OF THOMAS OKARMA, PRESIDENT AND CEO OF 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 last month 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. 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 pos-

sible to humans. This underlines that this would be an extremely dangerous procedure.

It is simply unacceptable to subject humans to those risks.

The Food and Drug Administration (FDA) has publicly stated that it has jurisdiction over human reproductive cloning experiments and that it would not approve them. BIO supports that view.

Beneficial Uses of Cloning Technology—Therapeutic Cloning

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 heart attacks, various cancers, Alzheimer's, diabetes, hepatitis and other diseases. This type of therapeutic cloning 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.

My company, Geron, as well as many other companies and academic laboratories, use cloning technology for many beneficial purposes. Let me explain how we use it to develop products that could revolutionize medicine and improve the lives of people suffering from serious illnesses.

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.

Predictive Toxicology/Drug Discovery

Geron is also developing research tools to facilitate the safe development of new drugs. The use of normal, cloned human liver cells to test new drugs under development for certain toxic metabolites would reduce the danger of human clinical trials by eliminating such compounds before human testing. This process could streamline and make safer the drug development process, thereby reducing by several years drug development time, bringing drugs to patients sooner and with greater safety, and reduce the reliance upon animal testing.

Agriculture

Geron uses cloning technology for applications in agriculture as well. These include producing animals with desirable qualities such as disease resistance, longevity, or improved product quality. Animals can also be cloned to produce proteins for human therapeutic use such as human antibodies, allowing for large-scale production of vaccines.

Ethical Concerns of Reproductive Cloning

In addition to the scientific obstacles, human reproductive cloning raises numerous ethical and social concerns. When the moratorium was imposed in 1997, scientists, ethicists, and policy makers believed that the various ethical issues raised by human cloning had not been resolved. At the time, the National Bioethics Advisory Commission (NBAC) called human cloning "morally unacceptable."

Mr. Chairman, that is still true. Not only is there no consensus in our society about how to resolve the ethical concerns implicated by human reproductive cloning,

these issues have not yet even been adequately discussed. 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 without a full and fair discussion of these and other moral issues 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 have described today—that could lead to cures and treatments for some of our most deadly and disabling diseases.

Conclusion

Mr. Chairman, human reproductive cloning remains unsafe. Moreover, the ethical issues it raises have not been fully debated throughout our society. Therefore, the voluntary moratorium on human reproductive cloning should remain in place and no federal funds should be used for human reproductive cloning.

Thank you. I'd be happy to answer any questions.

Mr. GREENWOOD. Thank you, Dr. Okarma for your testimony.

Dr. Westhusin, you're recognized for 5 minutes.

STATEMENT OF MARK E. WESTHUSIN

Mr. WESTHUSIN. Thank you. Thank you for the opportunity to come here and visit about this issue. I start off by saying that I'm currently an Associate Professor at Texas A&M University and I've been working with animal cloning since 1987, so I've literally been involved with tens of thousands of nuclear transfer procedures and experiments in science that related to nuclear transfer and cloning all the way ranging from just studying and trying to understand developmental biology all the way up to actually producing live animals.

There are really just three points that I want to focus on. A lot of us know the benefits from cloning animals and therapeutic cloning of humans, but there are three points that really I would like to focus on. One is basically just the risks that are involved with cloning even animals that we have to deal with today. And I'll give you some examples of some data. I'd also like to talk a little bit about this idea that you could potentially screen for embryos or fetuses and pick out those that were abnormal and abort those. And then finally, I just might make a few comments on some ethical concerns.

But what I wanted to do is part is I'm just going to read from my testimony.

Although animals can be cloned by nuclear transfer using somatic cells as nucleus donors, the efficiency is still extremely low. In cattle where the majority of the work has been completed, problems with early embryonic development do not seem to be a factor affecting development. Material recognition is not a factor and in fact, you can produce a reasonable pregnancy rate if you go check animals at 35 days of gestation. The problem is that after 35 days of gestation or during the first trimester, approximately 90 percent of the pregnancies are lost or abort.

The most common developmental malformation observed to date is just problems with the placental development which leads to all kinds of other problems that include developmental abnormalities such as immature lungs, cardiovascular disease, pulmonary hypertension and a number of things that we've, in fact, documented.

I wanted to give you just some examples of just so you have an idea about the efficiency of this 4 or 5 different cases. In one case, we had a bull that we cloned that was 21 years old. We collected cells. We produced 26 blastocysts from those, transferred those into 11 recipients and got 6 pregnancies and 01 calf that went to term. When that calf went to term, we spent the first 2 to 3 weeks in intensive care with that calf, really trying to keep him alive. He developed also Type 1 dependent diabetes which we don't understand at all why that happened because you just don't see that in cattle and he also had some immune problems.

In a second case, we cloned a Charolais cow or attempted to do that. To cut to the chase we transferred 37 embryos into 13 recipients. Six of there were diagnosed pregnant at 30 days. Only four remained pregnant past 60 days. We got two calves, but both of them died, and died, obviously, due to complications related to the cloning.

In another case, we had a Brangus cow that we worked on. We produced 43 embryos in that case where we transferred embryos. We produced only three pregnancies and none of those went to term.

And the point that I want to bring out with that, by giving you some of these different examples, is that in not every case is every animal easily clonable. There are big differences between one animal might work better than another, but in every case they seemed to show these abnormalities.

I'm running out of time here, I'm sure, so I won't talk about the last part, but there's just case after case of this.

I wanted to show—these are just some slides that show these kinds of things I've talked about, so this just shows the efficiency where it dropped off dramatically. This is the gestation loss that we see between 30 and 90 days which is just horrendous and then these are some of the kinds of things that we see and so the top is the bull calf that we actually saved and he's in ICU and he's on respirator just to keep him alive and in the lower right is obviously one that didn't make it.

I wanted to talk to you about, you know, the one on the lower right and then relate it to those six clones. I guess one could almost think about too, what's going to happen if you get more than one?

This is another one that I think was every interesting that we studied a group of 13 pregnancies that went into the third trimester. From these, only 8 calves were born alive. Four were still-born. Three of the cows that actually were carrying the pregnancies also died within 7 days and then we ended up with actually six calves, but we had tremendous amount of loss.

Now I want to, and these are just some examples, I wanted to talk about the aberrant placentation so I'm running out of time here and the different things that we see. But I wanted to bring this up also and talk that there'd been some issues that one might be able to screen these embryos and really is not the case.

We're not going to be able to screen embryos for anything to tell whether they're abnormal or not. The reason is because if you look at the karyotype, for instance, of cloned embryos, they all have normal karyotypes and they have the normal number of genes. They also have aberrant gene expression of various genes and we don't

really have a clue what those genes are at this time. It could be any of 30,000 genes or more and we really don't have a clue. You can't do genetic analysis of 30,000 genes and you can't do pre-implantation diagnostics of PDG to try and determine if those genes are abnormally expressed. It's just something that can't be done. We don't have the technology available to do that yet and you couldn't do it on pre-implantation. The closest you could get to, as referred to is you could get to something like ultrasound, but at that case you're basically going say the fetus is dead, the calf is dead, it's dying, it has problems.

So this concept that you're going to be able to screen pregnancies and embryos, there's just no basis for that in terms of how we would actually be able to do it because the technology is simply not available.

I guess I'll quit there, since I've run out of my time.

[The prepared statement of Mark E. Westhusin follows:]

PREPARED STATEMENT OF MARK E. WESTHUSIN, ASSOCIATE PROFESSOR, COLLEGE OF VETERINARY MEDICINE, TEXAS A&M UNIVERSITY

Man has long been interested in nuclear transplantation both as a tool to study developmental biology and as a means for producing genetically identical animals. The basic technique involves the transfer of a nucleus from one cell to another cell which has had its own nucleus removed. For cloning animals this entails transferring the nucleus of a cell obtained from the individual to be cloned into an unfertilized ovum that has had its chromosomes removed. If successful, the transferred nucleus is re-programmed so to direct development of a new embryo that is genetically identical to the animal from which the cell was obtained. This embryo can then be transferred into a surrogate mother for gestation to term and birth of a clone.

In recent years, nuclear transplantation has been employed to clone a number of different animals. The most acclaimed example is of course the report by Wilmut et al (1997), which was the first to demonstrate cloning of adult mammals was possible. Nuclei of cultured mammary epithelial cells derived from an adult ewe were transferred into enucleated sheep ova, ultimately resulting in the birth of a cloned lamb (Dolly). The demonstration that adult cells could be used for cloning mammals sparked enormous new interest in exploring the potential of cloning animals. As a result, in just the past three years, cloned cattle, sheep, goats, pigs, and mice have been reported.

The potential benefits animal cloning will afford mankind are far-reaching, and undoubtedly, many more applications and benefits are yet to be imagined. A current utility includes the production of transgenic animals for use as living bioreactors to produce pharmaceuticals. Several products produced in milk of transgenic sheep and goats are already in clinical trials (Factor IX, P.P.L., Inc.; anti-thrombin III, Genzyme Inc.; and the estimated market value of pharmaceutical production in the milk of transgenic animals currently exceeds \$3 billion per year. A number of other products are targeted for production in milk from transgenic livestock including both nutraceuticals and vaccines. Genetic engineering animals for protein production in milk promises to result in a wide variety of products for human use, many of which will be less expensive and more effective. Other applications of cloning to produce transgenic animals include the production of livestock that are that are genetically resistant to devastating diseases such as those currently causing major concern throughout the world i.e. Mad Cow Disease and Foot and Mouth disease. Agricultural applications of animal cloning will result in increased quality and decreased costs for food and fiber. In addition, animal cloning provides for rapid genetic gain in animal breeding programs and could potentially have a great beneficial impact on the conservation, preservation and propagation of endangered species.

Anticipated future applications of cloning procedures are nothing short of phenomenal. These include such things as the production of human embryonic stem cells for tissue transplantation and/or gene therapy and treatments for mitochondrial diseases, just to name a few. Human cells could potentially be utilized as nuclear donors for transplantation into oocytes, resulting in cell lines that may be useful for human therapy to treat conditions such as Alzheimer's or Parkinson's disease.

With animals representing 5 different mammalian species now having been produced by somatic cell nuclear transfer, cloning has been proposed as a tool for assisted reproduction in humans i.e. a means for producing a human baby. Experiments from our laboratory and others provide strong evidence that the current procedures used for mammalian cloning are not safe and many times result in abnormal development. This can ultimately lead to death of the cloned offspring and the surrogate mother. Based on these observations and evidence from studies in mice which demonstrate incompatibilities between nucleus and cytoplasm from different strains, cloning as an approach to human assisted reproduction is at present both risky and extremely irresponsible.

Although animals can be cloned by nuclear transplantation using somatic cells as nucleus donors, the efficiency of the technique is still extremely low. In cattle where the majority of the work has been completed, problems with early embryonic development do not seem to be a major factor affecting the efficiency of cloning, as development rates to the blastocyst stage *in vitro* are similar to those of normal embryos produced by *in vitro* fertilization. Maternal recognition and the establishment of pregnancy as indicated by pregnancy rates at 35 days of gestation are also similar between normal embryos and those produced by nuclear transplantation. However, after 35 days of gestation, pregnancy loss is dramatic and very few fetuses survive to term. Approximately 90% of the pregnancies are lost and abort between days 35 and 90 of gestation (the first trimester). The most common developmental malformation observed to date is aberrant placentation. Of those calves that do survive, most exhibit placental edema and a reduced number of enlarged placentomes. These placental abnormalities pose serious health risks not only to the developing fetus and offspring but also to the surrogate mothers carrying the pregnancies. In several cases involving cattle, both the surrogate mother and the bovine fetuses have died during late gestation due to a variety of complicated health issues related to the abnormal pregnancy. Moreover, even if the cloned offspring survive to term, many of the resulting calves exhibit developmental abnormalities and die at birth or shortly thereafter, normally a result of cardiopulmonary abnormalities. In general, regardless of the species, only 1%-5% of cloned embryos survive to term.

In our laboratory we have utilized nuclear transfer to try and reproduce the genotypes of several different animals, selected for cloning based on their inherent genetic value. Results we have obtained to date are similar to those reported by other laboratories regardless of the species involved. The first case involved a Brahman steer named "Chance", known to be at least 21 years old. Adult fibroblasts were obtained from a skin biopsy and expanded in culture using standard methods for tissue culture prior to being frozen and stored in liquid nitrogen. When nuclear transfer was performed using the fibroblast cells derived from Chance, 28% of the fused couplets (53 of 190) developed into blastocysts in culture. Twenty-six of these were transferred into 11 recipient cows resulting in 6 pregnancies. Three of these continued to develop through 90 days of gestation but only one survived to term. "Second Chance" is now over a year old and appears normal and healthy for his age. However during the first week of life he required intensive monitoring and therapy to treat lung dysmaturity and pulmonary hypertension. At 7 days of age he was also diagnosed and treated for Type 1 insulin-dependent diabetes, which is extremely rare in cattle. He also lacked the expression of an important T-cell antigen CD45, indicating his immune system was in some way abnormal (Hill et al, 2000).

The second and third attempts at reproducing desired genotypes by cloning involved two middle-aged cows, one Brangus and one Charolais. These were selected based on being top performers in the herd. Fibroblasts were again obtained from skin biopsies. Development rate to the blastocyst stage following nuclear transfer and embryo culture averaged 16%. Thirty-seven blastocysts derived from the Charolais cow were transferred into 13 recipients. Six of these were diagnosed as pregnant at 30 days of gestation but only 4 remained pregnant through 60 days. One of these pregnancies was subsequently lost. In two cases the fetus was removed for research purposes. The final pregnancy was allowed to proceed to term resulting in twin heifers. However, both calves died between 7-10 days after birth due to complications related to the cloning procedure. Forty-three blastocysts derived from the Brangus cow were transferred into 14 recipients resulting in 3 pregnancies. However none of these survived past 90 days of gestation.

Our most recent attempt at cloning a specific animal has involved a deceased Black Angus bull previously shown to be naturally (genetically) resistant to Brucellosis. Of the oocyte-fibroblast couplets fused and cultured, 44% developed to the blastocyst stage. Thirty-nine blastocysts were transferred into 20 recipients resulting in 10 pregnancies at 35 days of gestation. One of these survived to approxi-

mately 150 days of gestation and was then lost. Another single pregnancy survived to term resulting in a healthy bull calf.

Prior to any attempt to use nuclear transplantation/cloning as a means of human assisted reproduction, it is imperative that many additional animal studies evaluating the safety of somatic cell cloning be carried out. These studies should also include efforts to evaluate the safety of applying nuclear transplantation procedures for treatment of human disease or infertility by manipulating oocyte cytoplasm and/or genetically modifying human cells prior to cloning. Proponents of human cloning as a means of assisted reproduction have pointed out that even with accepted practices of assisted reproduction such as in vitro fertilization, success rates are low and pregnancy losses higher than in natural reproduction. This is indeed the case, but hardly to the extent seen in cloning where only 1-5% of the procedures performed result in offspring, and a significant number of these either die at birth or require intensive care for several weeks to keep them alive.

Moreover, the claim that cloned embryos could be screened prior to embryo transfer so to select those that will develop normally is simply not a possibility at this time. Research conducted in our laboratory and several others now points very strongly to the fact that problems seen in cloned embryos/pregnancies are likely epigenetic effects brought on by the cloning techniques themselves and causing abnormal expression of important developmental genes. Techniques to evaluate for these abnormalities are simply not yet available and it will likely be years before such diagnostics do become available. Procedures to determine whether cloned embryos and fetuses appear to have normal and the right number of chromosomes are woefully inadequate as there is no indication to date that abnormal karyotypes are a problem i.e. chromosomes in cloned embryos appear normal. If one wanted to screen for abnormal gene expression, which of the tens of thousands of genes would one screen for? There is no solid data yet to point to one gene/cause for developmental failure. In addition, given the small size and few cells available, current techniques will not allow any type of adequate analyses of an embryo so to determine in fact that it is normal. At best, with ultrasound, one could determine that the fetus is dead, which based on animal studies is likely to be the situation in 90% of the cases during the first trimester of pregnancy.

Finally, even the apparently healthy animals that are produced by cloning should be studied and observed for a number of years to evaluate their long-term health status prior to any applications in humans. Considerable evidence has now been accumulated to suggest that insults occurring during the critical period of embryo and fetal development may have long-term effects on the health of offspring and resulting adults. Cloned animals produced to date have not yet lived long enough to evaluate this potential risk. Undoubtedly it would be a devastating case to produce cloned humans only to find out that they all developed serious disease/health problems and/or died during childhood or adolescence or even early in their adult life. At this point it is simply impossible to eliminate this potential disastrous outcome.

Ethical Concerns Involving Human Cloning:

I have previously been quoted in the popular press as saying that while there are enormous beneficial applications to cloning animals, "I have never met a human worth cloning." Although my wife may take some exception to this statement, I still stand behind it. In part, this is due to the fact that as human beings, none of us are perfect. Also, expectations of what a human clone would be or do are many times, exaggerated. Cloning animals by nuclear transplantation is simply a technology that can be used to produce another individual with the same genetic make up. What cloning absolutely is not, is a means of resurrection. I think it best we leave this business to God as we have enough problems to deal with just trying to be decent human beings. It is indeed extremely troubling to me however, that with the successful cloning of animals, many people in society still seem to have no understanding of the difference between "reproduction" and "resurrection". A significant number of requests for human cloning involve the utilization of cells from "beloved family members" that are in fact deceased. Undoubtedly, those requesting such services, whether they would admit it to themselves or not, in some way believe cloning is a form of resurrection, not reproduction. It is deeply concerning that individuals offering human cloning services could take advantage of highly emotional situations involving the death of a loved one by selling resurrection vs reproduction.

With time and education, society will eventually understand the difference between resurrection and reproduction. I will also predict that given the current state of various assisted reproduction techniques that are already being utilized by humans and readily accepted as ethical, such as in vitro fertilization and intracytoplasmic sperm injection, cloning by nuclear transplantation will eventually

also be thought of as simply another form of assisted reproduction, and individuals employing techniques of nuclear transplantation will not be accused of “playing God.” In short, I predict that humans will someday be cloned. When this happens, the sky will not fall and the world will not come to an end. Scenarios such as that seen in “The Boys from Brazil” and armies of clones will remain in the movies. The number of human babies that would ever be produced by cloning will be infinitesimally small compared to children born by natural reproduction, and will hardly be noticed. The person (s) that come into this world by way of cloning will be new and unique individuals. Moreover, I have confidence and a personal faith in God that they will be blessed with a unique spirit and soul. To think otherwise is to suspect that God hasn’t blessed the thousands of babies already born by other forms of assisted reproduction with a soul, and neither the tens-of-thousands of genetically identical twins that live in this world. This begs the question, what is it that really makes human cloning so (as it is often referred to) repugnant? Is it the word “clone” itself and/or the horrendous stories that have been written, or movies that have been made that always depict cloning as a terrible thing leading to a terrible outcome? Would it be impossible to write a story about human cloning that had a happy ending, or is it just the fact that it wouldn’t sell and therefore no profit would be gained? Surely it is not the fact that a clone would have a genetically identical copy, either still alive or deceased? How would this be that much different than an identical twin?

Consider the following scenario. A skin cell from a human male is inserted into an enucleated human ovum (nuclear transplantation) so to create a cloned human embryo. However, instead of transplanting this embryo into a surrogate mother, the embryo is placed into culture and treated in such a way that it develops into embryonic stem cells. Given the enormous and promising success that has been achieved in recent years involving the production of human embryonic stem cells, it is easily conceivable that in the not to distant future, these stem cells could then be directed in culture to undergo gametogenesis and develop into cell types that represent gametes (sperm and eggs) containing a haploid number of chromosomes (half of that in a normal somatic cell), and the genes will have been rearranged, as occurs during normal gamete development. Once this has occurred, two of the gamete cells could be selected and using nuclear transfer a second time, placed into another enucleated ovum resulting in a normal embryo that could then be transferred into a surrogate mother for development to term. While this scenario may be difficult for some to follow, here’s the punch line. It is entirely conceivable that a single cell originally derived from a single male, with the aid of technology, could be used to produce a new human baby. This new human being would not at all be a clone, because of the natural process of gene rearrangement that occurs during gamete development, and in fact, could turn out to be a girl!

If cloning a human being is unethical, would this procedure also be unethical even though the new baby would not be a clone at all but simply derived from an elaborate assisted reproductive technology? Given the state of currently accepted practices for treating human infertility, I doubt it, but with one caveat. It would certainly be considered highly unethical and completely irresponsible if 90% of the pregnancies resulted in abortions, the surrogate mother was put in serious health risk, and a significant portion of the offspring that resulted were developmentally abnormal and many died.

So we are back to square one. Is nuclear transfer to produce a human clone a reasonable thing to consider attempting at this time? In my opinion absolutely no! Ethical issues and moral issues aside, at present, cloning is just too risky, many times resulting in serious health problems and/or death the developing fetus, surrogate mother, and resulting offspring.

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Mr. GREENWOOD. Thank you, Mr. Westhusin. Thank you for your testimony. For the benefit of the members, we're not going to recess during this vote, but try to allow members to vote, go and vote and then return.

Next we'll turn to Dr. Rudolf Jaenisch.

Thank you for being here and we look forward to your testimony, sir.

STATEMENT OF RUDOLF JAENISCH

Mr. JAENISCH. I am Professor of Biology at MIT and the Whitehead Institute in Boston. It's clear from the five different species which have been cloned, you can make common phenotypes observed. The great, great majority of clones die very early, some die later. Some make it to birth and they are abnormal at birth. What are the abnormalities? They're very often overweight. They have large placentas and they die within minutes. They have heart problems, circulatory problems, they can't inflate their lungs, the immediate cause of death. Some live longer. They may die after days or after weeks. At autopsies one sees problems in the kidney, brain abnormalities, dysfunction of the immune system, you just heard it.

So some reach adulthood and appear normal, but they may not be. I believe there's probably not a normal clone around and I will come to why that is. So what is the problem?

We believe programming of the genome is the main problem, so let me explain what it is. When you take let's say a nucleus of the skin and try to make a clone out of this, then you have to look at the nucleus what it is. The nucleus of a skin expresses those genes which are important for skin function, let's say hair growth, but not those genes which are important for embryonic developments. Those genes are there, but they are silent. They're not needed any more. So what has to happen for cloning to succeed? The nucleus is transplanted into the old site and now this embryonic program has to be activated hundreds of critical genes and that's where things go wrong. This fails.

So I think it's very useful to compare this what happens in normal development. In normal development also reprogramming has to occur. It occurs during egg maturation and sperm maturation. These are very complex processes which take years or months in humans. So when the two gametes, the egg and the sperm come together at fertilization, they are poised, they are reprogrammed to activate the embryonic genes and then things go normal. That's how evolution designed gametogenesis.

Now what happens in clones? In clones, this nucleus comes in and now it's to reprogram its genome probably within minutes, at most hours, because the egg has to divide and that's where things go wrong. Most clones die.

It's very interesting in the way they die. We don't know exactly why, but we believe the ones, the majority of the ones that die very early because it cannot activate the key early genes. Others die later, because they did activate the early ones, but not the later ones. And the ones which go to birth, probably did those okay, but now the other problems are there which affect kidney, brain, whatever.

So in principle, I think any of the 30,000 genes we have is a target for reprogramming errors. So even apparently healthy adult clones may have subtle defects which are beyond to detect easily in an animal.

So let me come to what I mentioned before, these cloning activists have announced they can do embryo grading, genetic screening, quality control, so they imply they are able to employ routine diagnostic procedures which are used in the clinic to screen out bad and good clones. This is a false statement. They cannot do this. The routine prenatal tests are designed to take chromosomal operation or single gene defects, but they cannot and I really emphasize this, they cannot detect reprogramming errors because reprogramming errors do not involve gene changes. The genes are normal, the sequence has not changed. It's the state of the gene which argues it's either expressed or not. So I think this is a really false statement. So the argument by the activists again, they have 20 years' experience with IVF, so they're good in cultivating embryos, better than the embryo clonists, yes, that might be true. They might avoid physical damage to the egg of the nucleus, so they might get the first steps, better than we get in mice, but the basic problem, the basic biological problem has not changed a bit. That is reprogramming. It's the same thing so what they will do is they will produce more embryos which implant. They may get more out of it at the other end, but the ratio of normal, apparently normal to abnormal

clones will not change a bit by this. It's more efficient in the early stages.

So I agree, they probably can use ultrasound to detect malformed fetuses, sure, but this is not important because malformed fetuses will die anyway. The problem are the ones which are apparently normal, but are not and I really reemphasize there's no way to screen the available technology or with any technology in the foreseeable future to do that.

Now for summarizing from the experience with animals, we can clearly predict how a few cloned humans would look like. The great majority will be abnormal. Some may live, but they may be not normal. They may have subtle defects like in the brain. So, for example, Dolly, I believe is not normal. You don't need much brain to graze on the fields, so we really don't know, we have no tests to check that.

So what will we do with the abnormal clones when they are born? With animals, this is an easy thing, the animals will die. We can study them. We can learn something. What can we do with humans? They will be kept alive with medical intervention for probably not happy lives.

You can ask do I know this for sure? Of course, I don't know because humans have not been cloned. But five mammalian species, mice, goats, sheep, cows and pigs have been cloned. They're all mammals and humans are mammals. So I think it's a very safe prediction that this will happen.

Should we find out whether humans are more efficient, maybe than pigs or mice, I think the answer is very clear. We should not find out because humans are not guinea pigs. They're not experimental organisms and we're particularly at the stage when we haven't really solved the basic fundamental problems in animals.

So the conclusion is from the scientific point of view that it's inappropriate and irresponsible to attempt cloning at this point.

I want to make just a final point if I may which is the public, I'm afraid, may associate the activities of these cloning activists with serious stem cell research as it was mentioned before. This would be extremely unfortunate. You've heard the benefits of this research, so I want to make very clear what the differences between reproductive cloning, reproductive cloning and embryos implanted, the goal is a new person, to copy a person. And yes, embryo stem cell research, the embryo is never implanted, it grows in the petri dish. The embryo stem cell is derived from this, will always be manipulated in a petri dish and the problems obviously are very different here.

So I think there are very serious areas that these ill-conceived cloning attempts at humans would get mixed up with this very serious and potentially very beneficial research and I think this would be of great concern.

Thank you.

[The prepared statement of Rudolf Jaenisch follows:]

PREPARED STATEMENT OF RUDOLF JAENISCH, WHITEHEAD INSTITUTE FOR
BIOMEDICAL RESEARCH

Recently, cloning of humans by nuclear transplantation has been proposed. In this testimony I will focus on the scientific concerns about human cloning that have resulted from the experience with animal cloning.

1. To date, five mammalian species (sheep, mice, goats, cows and pigs) have been cloned, however, survival of the nuclear clones has been uniformly low. The great majority of all clones (of all five species) die either at various stages of embryonic development, at birth, or soon after birth. Most newborn clones are overweight and have an increased and dysfunctional placenta. Those that survive the immediate perinatal period may die within days or weeks after birth with defects such as kidney or brain abnormalities, or with a defective immune system. Even apparently healthy adult clones may have subtle defects that cannot be recognized in the animal.

2. The most likely cause of abnormal clone development is faulty reprogramming of the genome. This may lead to abnormal gene expression of any of the 30,000 genes residing in the animal.

3. Faulty reprogramming does not lead to chromosomal or genetic alterations of the genome, so methods that are used in routine prenatal screening to detect chromosomal or genetic abnormalities in a fetus cannot detect these reprogramming errors. There are no methods available now or in the foreseeable future to assess whether the genome of a cloned embryo has been correctly reprogrammed.

4. The experience with animal cloning allows us to predict with a high degree of confidence that few cloned humans will survive to birth and of those, the majority will be abnormal.

The arguments given in this outline have been summarized in more detail in an article by Jaenisch and Wilmut that will be published in Science magazine on March 30, 2001. A copy of the article will be available at the Committee meeting.

Mr. GREENWOOD. Dr. Jaenisch, thank you for compressing what would have been a fascinating 2 hour lecture into 5 minutes.

We are going to recess for just 10 minutes so the last of us can run over and make this vote and then we'll return to Dr. Zavos as soon as we reconvene.

[Brief recess.]

Mr. GREENWOOD. The hearing will come to order. I ask the guests to please be seated. Again, to the witnesses, thank you for your patience. You've been more than patient and now we turn to Dr. Zavos for his testimony. Let me particularly thank you because as you and I know, you had a very hectic weekend and I implored you to come and present your testimony today and you agreed. I thank you for that. And I recognize you for 5 minutes to present your testimony.

STATEMENT OF PANOS MICHAEL ZAVOS

Mr. ZAVOS. Thank you, Mr. Chairman, and I thank the committee for inviting me. I am Dr. Panos Zavos. I am a Professor Emeritus, University of Kentucky. I'm the Director of the Andrology Institute of America and I have other titles, of course, which—

Mr. GREENWOOD. Dr. Zavos, if you could just pull that microphone in. It's fairly directional, so if you could pull it in as close as possible and then maybe lift it up a little bit. Everyone is eager to hear your testimony.

Mr. ZAVOS. Can you hear me better now? Thank you. Over the last 25 years, I have been involved in the area of reproductive physiology andrology and assisted reproductive medicine. I have received extensive formal education by obtaining four college degrees in biology, chemistry, general physiology and reproductive physiology. I have published quite generously in the areas of reproductive medicine and reproductive physiology as well.

I'd like to say something about the current events in the ART market, that's the assisted reproductive technology market. With the advent of IVF and all other advances in assisted reproductive

technologies, we're able today to perform incredible maneuvers and offer the infertile couples options that give them hope for having a healthy child. Never before in the history of mankind have we ever been so lucky to treat the infertility epidemic so incredibly well with such high probabilities for success. We all know that when an infertile couple comes to us for treatment of infertility, they want two things. They want a child yesterday, if at all possible, and they want a healthy child.

In all the years that Professor Antinori and myself have been involved in the diagnosis and treatment of both male and female infertility, have we ever been involved in taking risks to humans. This same principle will remain in place as we venture into the development of new frontiers in infertility medicine. The current status of animal cloning, a variety of mammalian species have been cloned utilize somatic cell nuclear transfer, this we have heard before. These include sheep, cattle, mice, goats and pigs. As for implantation and prenatal chromosomal and genetic screening was not performed in any of the aforementioned animal cloning experiments, a small but significant proportion of the resulting offspring exhibited development abnormalities and/or perinatal death. To avoid the developmental abnormalities observed in the unscreened animal experiments, we proposed to conduct a variety of screening protocols on the nuclear transfer or transplant of embryos.

Comprehensive embryo screening, although expensive would ensure that only healthy developmentally normal embryos would be conceived. This is the fundamental aspect of the consortium's proposal as producing developmentally abnormal human children is clearly not ethically acceptable by us.

The current status of human cloning, although no one has claimed as yet that a human clone has been produced, the rumors that are out there indicates that cloning is just around the corner. And I think the 60 Minute footage that you just played for us, Mr. Chairman, indicate that very well.

The technology for cloning a human being exists and it almost exists in every high tech laboratory across the world today. There are 55 such IVF labs in New York City alone today. So the questions that we must and we should be answering today is or are, who should develop this technology and then furthermore, what quality controls will be necessary to be developed and/or applied in order to make this technology safe with minimal risks to those using it and most importantly, to those that will be born from such efforts?

Who should develop this technology? The human therapeutic cloning technology should be developed by a group of scientists and medical experts that understand this type of work and the seriousness of its development. Furthermore, such teams should be focused on this effort and work with leaders in government to see that this technology can be made safe and be disseminated properly.

As you know, Mr. Chairman, I have just returned from a great country from a visit to a great country, the country of Israel, where I have visited with the chief spiritual leader of Rabbi Kaduri and the President of Israel and others that obviously have given us a

great deal of support and a great deal of endorsement although obviously we're approaching those kinds of steps very cautiously.

What quality controls are necessary? As stated before, during animal experimentation with cloning, no implantation of prenatal chromosomal and genetic screening was performed in any of the animal cloning experiments which brought about small, but significant proportion of the resulting offspring exhibiting developmental abnormalities and/or perinatal death. All animal experiments carried out today were done with unscreened embryos. This, according to the CHTC principles is totally inhumane and irresponsible for those that carry those experiments and gave the world this horrible picture, an impression that cloning cannot be offered and made to be safe in humans.

On the contrary, this Consortium, in order to avoid the developmental abnormalities observed in the unscreened animal experiments wishes to develop and apply a variety of screening protocols and for that I am submitting as Exhibit 2 to this testimony a whole array of write ups for those kinds of screening tests that are in existence and we will be developing as we go along.

Also, I need to mention something for this committee to be aware of is that our Consortium has no intentions of developing this technology within the continental USA.

As a closing remark, I must say to you the following that those that say ban it, those would not be the Neil Armstrongs that would fly us to the moon and walk us on it. Those that stop it, those would not be the Columboes that would take the bold step to discovery America. Those that say do not do it, they would definitely not be the Steptoes and the Edwards that changed the world by their innovative technologies of IVF. We are talking, Mr. Chairman, about the development of a technology that can help people. We are talking about the development of a technology that can give an infertile and childless couple the right to reproduce and have a child and above all complete its life cycle. This is a human right and should not be taken away from people because someone or a group of people have doubts about its development. We have no intentions and I emphasize that, we have no intentions to step over dead bodies or deformed babies to accomplish this. We never did in the past and have no intentions of doing it while we attempt to develop this revolutionary and yet magnificent technology. Thank you.

[The prepared statement of Panos Michael Zavos follows:]

PREPARED STATEMENT OF PANOS MICHAEL ZAVOS, FOUNDER, ANDROLOGY INSTITUTE OF AMERICA

INTRODUCTION

Over the last 25 years I have been involved in the area of reproductive physiology, andrology, and assisted reproductive medicine. I have received extensive formal education by obtaining four College degrees in Biology, chemistry, general physiology and reproductive physiology. I have also received extensive training in the areas of gamete physiology, manipulation, cell culture and in-vitro gamete manipulation. I have been involved in the development of various technologies and products and I have published on those subjects quite extensively. I have developed technologies in gamete culture and manipulation, cryopreservation and others (See short biography; Exhibit 1).

Recently, I was involved with a scientific group in Yonago, Japan in the development of ROSNI during which immature spermatozoa (spermatids) were harvested

from the testes of infertile men and their nuclei were transferred into nucleated oocytes and electrofusion was applied and pregnancies were achieved. This clinical service is available to infertile couples all over the world.

I own several US patents and have developed products that are currently in use in ART centers throughout the world. Both my wife, who is an OB/GYN and REI board eligible (Director of KCRM and IVF) and my self as Director of the Andrology Institute of America are involved in the infertility market and we also own a company that markets infertility products throughout the world. In my family, we are totally dedicated towards the treatment of infertility and we regard our patients as our primary target for offering them the best infertility service available.

It is because of our total dedication and belief in those principles that I have decided along with Prof. Antinori to undertake the great effort and to offer our infertility patients that have exhausted all options available to them to bear a biological child of their own the option of human therapeutic cloning.

CURRENT EVENTS IN THE ART MARKET

With the advent of IVF and all the other advanced assisted reproductive technologies (ART) we are able today to perform incredible maneuvers and offer the infertility couple options that can give them hope for having a healthy child. Never before in the history of mankind have we been so lucky to treat the infertility epidemic so incredibly well and with such high probabilities for success. We all know that when our infertile couple comes for a visit they want two things:

1. A child, yesterday if possible, and
2. A healthy child.

These incredible developments in the ART market today are no pure accident but rather the end result of various forces that come into play. These come about because of the abilities and the freedom that scientists and clinicians have to develop such efforts and work together in organized groups such as ASRM, ESHRE MEFS and others throughout the world. I have been and continue to work with such groups because it is essential that those efforts should continue towards the development of safe and effective treatments for infertility diagnosis and treatment. In all the years that both Prof. Antinori and I have been involved in the diagnosis and treatment of both male and female infertility have we ever been involved in taking risks to humans. This same principle will remain in place as we venture into the development of new frontiers in the infertility medicine.

CURRENT STATUS OF ANIMAL CLONING

A variety of mammalian species have been cloned utilising S.C.N.T. (somatic cell nuclear transfer). These include sheep, cattle, mice, goats, and pigs. As pre-implantation and pre-natal chromosomal and genetic screening was not performed in any of the aforementioned animal cloning experiments, a small but significant proportion of the resulting offspring exhibited developmental abnormalities and/or perinatal death. On the 9th of March 2001 our international consortium of scientists announced that they intended to perform human S.C.N.T. to allow infertile couples have children. To avoid the developmental abnormalities observed in the unscreened animal experiments, we proposed to conduct a variety of screening protocols on the nuclear transplant embryos. Comprehensive screening, although expensive, would ensure that only healthy developmentally normal embryos would be conceived. This is a fundamental aspect of the Consortium's proposal, as producing developmentally abnormal human children is clearly not ethically acceptable. This report is a review of the scientific literature, results and protocols regarding somatic cell nuclear transfer (S.C.N.T.) and contemporary morphological, chromosomal and genetic screening procedures. It is anticipated that the Consortium will utilize a range of screening protocols similar to (if not the same as) those discussed in this report.

CURRENT STATUS OF HUMAN CLONING

Although no one has claimed as yet that a human clone has been produced, the rumors are that the development of cloning technology for application in humans may not be too far off. If one examines other events by studying historical data one can conclude that the development of human cloning is inevitable. In a recent report by 60 Minutes during which a group of scientists and others participated, it was concluded that the recent developments are in tune with the trends. Human cloning is around the corner and more accurately as I stated over and over, where it comes to human cloning "the genie is out of the bottle". The technology for cloning a human being exists and it almost exists in everyone IVF high tech laboratory across

the world. They are 55 such IVF labs in New York City alone. So the questions that we should be answering today are:

1. Who should develop this technology, and
2. What quality controls will be necessary to be developed and/or applied in order to make this technology safe with minimal risks to those using it and most importantly to those that will be born from such effort.

WHO SHOULD DEVELOP THIS TECHNOLOGY?

The human therapeutic cloning technology should be developed by a group of scientists and medical experts that understand this type of work and the seriousness for its development. Furthermore such team should be focused on this effort and work with leaders and governments to see that this technology can be made safe and be disseminated properly. This technology like others can have catastrophic ramifications if it is not developed properly and it is allowed to end in the hands of the exploiters and the "pushers". It is because of those possible developments that our government along with others joins in and participates in the constructive dialogue and have something to say about its development and dissemination rather than taking the attitude that "I don't want to play". I believe that our government recent attitude with similar situations has adopted the principle of establishing a dialogue with hostile groups and governments throughout the world and it did pay off great dividends. This is not to imply however that the CHTC is either hostile or has any hostile tendencies towards anyone or any government in the world.

WHAT QUALITY CONTROLS ARE NECESSARY?

As stated before, during animal experimentation with cloning no pre-implantation or pre-natal chromosomal and genetic screening was performed in any of the animal cloning experiments which brought about a small but significant proportion of the resulting offspring exhibited developmental abnormalities and/or perinatal death. This according to the CHTC principles is totally inhumane, and irresponsible for those that carried those experiments and gave the world this "horrible" picture and impression that cloning can not be offered and made to be safe in humans.

On the contrary this Consortium in order to avoid the developmental abnormalities observed in the unscreened animal experiments wishes to develop and apply a variety of screening protocols on the nuclear transplant embryos that could ensure that only healthy developmentally normal embryos would be transferred to produce only healthy children. This is a fundamental of this Consortiums proposal, as producing developmentally abnormal human children is clearly not ethically acceptable. The Consortium has developed such array of testing procedures and wishes to make them available to this Committee for review and as part of this testimony (See Exhibit 11).

For this committee's benefit, I would like to make the following comments before I proceed further:

1. Our Consortium (the Consortium for Human Therapeutic Cloning) has no intentions of developing this technology within the continental USA. I am saying this to you Mr. Chairman at this time so that this Committee will not have to worry about this Consortium breaking any rules, laws, or having to be legislated out of extinction by this Congress.
2. That name calling is not in our cards and those that do because they believe that they are better medically, scientifically or ethically they serve no constructive purpose by doing so and the public is not served in any positive fashion at all.
3. We have received several offers by people to pay to have them cloned to have their own biological child. Such offers are not accepted by us because we have no technology to offer to anyone. It is still at its experimental stage.

CLOSING REMARKS

Those that say ban it, those would not be the Neil Armstrongs that would fly us to the moon and walk us on it. Those that say stop it, those would not be the Columbus's that would take the bold step to discover America. Those that say don't do it, they would definitely not be the Steptoes and the Edwards that changed the world by their innovative technologies of IVF. Ironically, Mr. Chairman, those that say don't do it, they may be the ones, that enjoy the fruits of Professor Edwards and his team's efforts by doing IVF and getting compensated for. This is hypocritical and this has to stop. We are talking Mr. Chairman, about the development of a technology that can help people. We are talking about the development of a technology that can give an infertile and childless couple the right to reproduce and have a child and above all complete its life cycle. This is a human right and should

not be taken away from people, because someone or a group of people have doubts about its development. We have no intentions to step over dead bodies or deformed babies to accomplish this. We never did it in the past and have no intentions of doing it while we attempt to develop this revolutionary and yet magnificent technology.

Mr. GREENWOOD. Dr. Zavos, thank you for your testimony. We appreciate it.

Now we would turn to Dr. Brigitte Boisselier, and you are recognized, ma'am, for 5 minutes for your testimony.

STATEMENT OF BRIGITTE BOISSELIER

Ms. BOISSELIER. Thank you, Mr. Chairman. Thank you for this invitation. I represent Clonaid, as you know, and this is a private company based in the United States that sets its goal to produce the first human clone. I'd like to remind you that when we talk about the first human clone, we are talking about a baby, a very healthy one and that's what we want and that's what we will produce. By the same time, I'd like you to recognize that this baby should be treated as a human being and I've heard a lot of words like monster, a bunch of cells and things like that. This is terrible. We are talking about parents who would like to be called to have this baby and I will address that issue after.

But first of all, you talk about harms and I heard a lot about defects and that this has been in the press for weeks now. Based on scientific publication, I will give you a few figures. First of all, if you look at the publication regarding cattle cloning in the year 2000, if you look at the numbers that were published there, they have success rate, an average success rate between 15 and 20 percent. The usual success rate in in vitro fertilization clinics, the best ones, are between 30 and 40 percents, meaning that today, 15 to 20 percent implantation of calves, of embryos for cattle cloning are bringing perfectly healthy clone. This is very comfortable to the success rate of in vitro fertilization in human.

Now when we talk about the defects observed with the cows and you have seen all these pictures and so on, I'd like to tell you to look at the results of in vitro fertilization of cows because the same defects have been observed in in vitro fertilization. They do have a problem in imprinting of the embryos in cattle. It's not a problem of cloning, it's a problem of this species, the cattle.

We heard a lot about defects also on mice. The mice have also indeed some defects, but I'd like to remind you that mice are inbred from generation to generation they have been mating between sisters and brothers, so they don't have any gene diversity and that's why they are not resistant to any defect. We are not inbred, we are outbred. Human beings are more resistant to these kind of defects and will not lead to these outcomes. So I'd like you to consider these defects that have been sensational all over the press today as elements that should be considered for these species. They have been researched on in vitro fertilization of humans. We know how to deal with these embryo, human embryo today and we have enough knowledge to proceed since cloning is actually using the technology of in vitro fertilization.

Now I'd like to talk about benefits and about the people who would like to be cloned, who are they? They are homosexual couples. They are infertile couples. They are also parents who have

lost a child. And I'd like to read very quickly, if I have time, a letter from my partner, I have founded a company with this man. He is the father of a baby who died at the age of 10 months. And that's what he says. "Dear Chairman Greenwood, who am I and why do I support human cloning? I am a successful attorney, a former State Legislator, a current elected official, a husband, a son, a brother, but most importantly, I am a father. At the age of thirty-eight I was blessed with a perfect baby boy. My wife and I were not expecting this miracle; as a matter of fact, I never even considered having children. The day our son was born was both the happiest and saddest day of my life." And then he goes on and explains how he loved this child and he learned that his child had a random birth defect that had to go through surgery for his heart. And then, "when our son was 10½ months old my wife and I took our angel to a children's hospital to have his heart repaired. The doctors told us he had a 94 percent chance of full recovery. After 17 days of misery and struggle, with my wife and I, our family and friends sleeping on the floor beside our child, praying, crying, our hearts and souls dying, our sweet baby succumbed to the insult on his body and we lost him. We didn't know what to do and I couldn't accept that it was over for our child and for the first time in human history I/we didn't accept death as the end. Not since our Lord and Savior, Jesus Christ, spoke to Lazarus and told him to 'come forth' from the grave has a human been able to bridge the great gulf of death. I hoped and prayed that my son would be the first; I could do no less for him. He deserves a chance to live, to grow, to learn, to walk, to talk, go to school, to listen to music, to drive a car, to make a difference in this world; all these things he would never have the chance to do if this were the end, because of the failure of a heart operation with a 94 percent success rate. How could this be, how could a father accept this outcome? I decided then and there that I would never give up on my child. I would never stop until I could give his DNA—his genetic makeup a chance. I knew that we only had one chance, human cloning. To create a healthy duplicate, a twin of our son. I set out to make it happen. We saved the appropriate cells" and then he explained how we built that and how we met and how he will support that.

"I must withhold my identity until after the project is successful. However our commitment to human cloning and to duplicating our child is unlimited, whether in the United States or abroad, we will never quit or give up on our child. Hopefully 1 day we can all celebrate our family and friends, my wife and our son, Dr. Grigitte and the brave new world. Until then, I am respectfully, a father."

He mentioned a brave, new world and I'd like to finish this with just a remark about that. You mentioned that Brave New World novel and Huxley to me didn't despite cloning. He actually described how a State controlled science could produce controlled individuals who would think the same, act and behave the same. Thus, it's not cloning that might lead to social harms, but for a social structure that allow any form of enforced control over people thoughts and behavior by their rulers. These are the harms I am concerned about. The ones that I suffered from in France in my country of origin when I first declared that cloning was right. As

a result of this declaration, I was denied the right to work and the right to have custody of my younger child.

For all these reasons, and on behalf of the couples who have hopes, on behalf of the scientists who are told not to proceed, I'm respectfully asking you to secure two basic freedoms, the freedom of scientific inquiry and the freedom to make personal reproductive choices.

[The prepared statement of Brigitte Boisselier follows:]

PREPARED STATEMENT OF BRIGITTE BOISSELIER, DIRECTOR, CLONAIID

Ghairman Greenwood, how could a baby, not even born yet, have created so much hoop around the world and in this country in the past 4 years?

Since the day the announcement of his potential birth was made, all the possible unfavorable outcomes have been predicted:

- A shortened lifespan due to shorter telomeres
- A high-risk of birth defect
- A high-probability of not having a soul
- Plagued with insurmountable identity crises
- A difficult relationship with the "gene" parent
- The possibility of having been desired for reasons other than for him.

How could a baby generate so much fear, so much disgust, and so much aversion?

Why is he announced as a monster, and why are we, scientists at CLONAIID, regarded as monsters?

Why do people only talk about armies of clones, fading copies, and high-risks of defects when today, **there are hundreds of cloned mammals that are alive and perfectly healthy?**

The "YUK effect" and the "Defect Syndrome" are terms that are used as a deterrent and are the result of a collective fear that is constantly fed by movies, novels, and reports that are hungry for sensationalism. The fact of the matter is that every time a new theory or a new technique is introduced to the public it is always scrutinized with the same level of apprehension, following the so-called "precautionary principle". This was true for other reproductive methods, such as:

- artificial insemination
- in vitro fertilization
- the freezing of human embryos
- surrogate motherhood

All went through this same "condemnation" phase and, with time, have come to be accepted techniques.

So despite the fact that a large number of people curse this new technology and condemn cloning, using the same arguments that were used for previous techniques, despite the fact that they claim "this time it's different and it's gone too far", it is important for society to realize that it will happen soon regardless. The question is: where. Furthermore, most researchers agree that it will soon be common practice and likely to be an option at many fertility clinics.

The purpose of my being public about our activities at Clonaid is, and has always been, to prepare our society for this new science, and to welcome this little baby. It is, and has always been, about educating people and reminding them that, unlike nuclear weapons, this pro-life technology does not represent a threat to the survival of the Human race and that reproductive cloning is not a new drug nor does it involve any gene modification. **This technique just involves the creation of a new baby, the belated twin of an individual that has given full consent to the procedure.**

I think it is important for people to go past their emotions and examine the rationale behind such a practice.

In order to do so, let us examine the harms and the benefits of human cloning in relation to the people cloned, their families and our society.

BENEFITS

Benefits related to stem cell research and cloning for organ repair, organ growth, ageing studies, and cancer studies have been extensively reported, therefore, I will only concentrate on the benefits of reproductive cloning.

Who wants a cloned baby?

For the past few years, and particularly the past 6 to 8 months, CLONAIID has received thousands of requests from individuals or couples who are eagerly waiting

for the public announcement of our success. These individuals are homosexual couples, individuals without a partner, and mainly infertile couples who have been through all possible fertility methods and who cannot have a baby with their own genes except through the cloning method. These requests are not geographically concentrated, they come from every continent, every culture, and every religion. The desire to give birth to a child bearing our genes is probably written in our genes.

A huge amount of requests have also been expressed by people who have lost a child or a close relative. Every day, more and more people are calling and currently, we are working on cells of a baby who died at 10 months of age.

A letter from his father is attached to the present testimony. It calls to us all and tells us about his motivation, his commitment, and about mine and the one from scientists at Clonaid. We will do all that is humanely possible to bring the belated twin of this boy back to life and healthy. If it becomes impossible to do it in this country, Clonaid will go elsewhere. And if no country on this planet allows it, we will do it on a boat in international waters, and we know that the number of people willing to help us will grow exponentially once they realize that we are only trying to give birth to a baby.

Having the best of death.

The belated twin of a dead child will not replace the first one, but it will be one way to have this unique genetic code express itself again, a first step towards eternal life. Further steps are needed before we reach that level but this is one of the most probable outcome of this research.

POTENTIAL HARMS

Low success rates.

The success rate announced for Dolly was very poor: only one viable offspring for 29 implantations. However, for the past 4 years, success rates have greatly increased (as could be expected for a new technology) and the average success reported in the 2000 publications range from 15 to 20% for cattle as an example. This means that 15 to 20 % of the implanted embryos produced healthy offspring. We should recall that the best IVF clinics have a success rate of 30 to 40 %. We should also recall that, 22 years ago, the success rate for IVF techniques when it first started was less than 1%.

These numbers tell us that, in animal cloning, we have already reached a level of reproducibility that compares well with human IVF.

Possible Defects

The reported defects have been different depending on the species studied. In regards to mouse problems, we should remember that the ones that showed defects were inbred which means they don't have any genetic diversity in their genome...each individual human being, on the other hand, is outbred and has full genetic diversity which makes us very resistant to genetic defects and abnormalities... (inbred means: brother-sister mating for many generations which makes the two copies of all their genes the same, therefore no genetic diversity).

Regarding problems of large offspring observed in cattle, we should recall that the same defects have been observed in calves resulting from IVF. These defects have never been observed in humans born through IVF.

Those who are familiar with the human Assisted Reproductive Technologies (ART) and the progress that has been made in growing human embryos in culture in IVF clinics in the last 15 years, know that our knowledge of human reproduction is far more advanced than that of other mammals...

Clonaid scientists are well-trained and have been perfecting the egg enucleation and heteronuclear transfer which makes us very confident about the outcome of this endeavor.

Miscarriages and possible problems for surrogate mothers

Miscarriages are common in pregnancy resulting from IVF but also in natural reproduction and do not constitute any potential harm to the mothers.

Psychological problem for the cloned individual

All kinds of problems have been announced for the first test tube baby, Louisa Brown and she is so normal...

Identity crises or genetic identity, neither means nor entails personality identity. The belated twin will have his own identity... And hopefully will be told how precious life is since the alternate choice for him would be not to exist. What is best for them, to exist or not?

Too much pressure, too many expectations... Would the belated twin be expected to behave like his gene donor? Isn't this what's already done with children today in many families. Aren't they expected to perform as well as dad or even better than dad?

While we are spending time wondering about this child who is desired and will be loved and cherished, 13,000 other children are dying every day from starvation and abuse, sometimes in their own families... Which children should we be more concerned about?

Armies of clones

Armies are not created by individuals but by governments... Among the thousands of couples or individuals who requested to be cloned, none ever asked to get more than two clones.

Gene trade

While it is our basic freedom to reproduce our genes as we want, it is not acceptable to use the genes of someone who is alive and reproduce them without his consent. This is common sense and should be regulated.

Again, I should emphasize that no one ever came to Clonaid with cells of famous personalities asking to get a cloned baby with these genes... and Clonaid does its own sampling to prevent such abuses.

Looking at all these potential harms, I do not see why we should deny scientists the right to perform these practices nor why we should deny these parents from having the baby they have dreamed about for so long.

MYSTERIOUS OBJECTIONS

During the debate that have been conducted the past years, mysterious objections have been raised and they really need to be addressed.

Playing God, Hubris...

Depending on the cultures and religions, different approaches have been taken. While Christians, in their majority, believe that we shouldn't head in that direction, Buddhists have expressed no concerns and some Jewish Rabbis have declared that if God has given us the brain to imagine it, then this is how it's meant to be.

This last attitude is very close to Raelian's, who believe that life on Earth was the result of the creativity of advanced and brilliant scientists. These creators were mistaken for Gods in ancient times and today, we ourselves are on the verge of also becoming creators... or Gods. Is this hubris? I believe it is only a natural cycle of creations.

The same emotional objection was given for most new technologies...

Cloning is unnatural...

It must be painful for identical twins to hear that they are considered to be unnatural and, therefore, that their existence is morally undesirable. Centuries ago they were already feared and chased...

Human dignity

Both, the World Health Organization and the European Parliament, have stated that such cloning endeavor would be an offense to human dignity.

The definitions of human dignity offered by major ethics dictionaries didn't help to explain how cloning would be a violation.

If this means, as I understand it, that we shouldn't treat other people merely as means to an end but always as ends in themselves, then I assume it refers to the production of embryos that may or should not be implanted. This philosophical problem is not unique to human cloning but is also part of the debate regarding IVF and abortion.

If it refers to the parent's choice to have a cloned child, then I want to testify how conscious these parents-to-be are. In this process, they conceive their baby with care, patience, determination and the baby will be one of the most loved child. Can we say the same for all naturally conceived children today?

Selfishness...

I often hear comments such as: "These parents are selfish. They want to have a child with their genes while there are so many children to adopt", or "They want to have the belated twin of a dead son to ease their grief."

First of all, we should remember that life is the most wonderful gift.

Now, are we going to have to examine the reasons why parents are having a child, whatever the reproductive method is used? Do they want it instinctively or for other reasons such as: they feel like it, they want a heir, someone to take over their busi-

ness, someone to help them when they are old... There are all sorts of selfish reasons that can be involved in the decision to have a child, whatever technique is used.

What world do we want to live in??

In his novel "A Brave New World", Huxley didn't despise cloning. He actually described how a state controlled science could produce controlled individuals who would think the same, act and behave the same. Thus, it is not cloning that might lead to social harms but rather social structures that allow any form of reinforced control over people's thoughts and behaviors by their rulers. These are the harms I am concerned about, the ones that I suffered from in France, my country of origin, when I first declared that cloning was right. As a result of this declaration, I was denied the right to work and the right to keep the custody of my younger child...

For all these reasons, and on behalf of the couples who have hopes, on behalf of the scientists who are told not to proceed, I am respectfully asking you to secure two basic freedoms:

- The freedom of scientific enquiry
- The freedom to make personal reproduction choices.

Mr. GREENWOOD. Thank you for your testimony.

The Chair recognizes himself for 5 minutes. Before I do, as a matter of housekeeping, the letter recommended by Dr. Okarma, a letter written on the stationery of Biotechnology Organization, by Mr. Carl Feldbaum, will be entered into the record without objection.

Dr. Boisselier, first of all, let me comment to you that in a Brave New World as you describe it, the bravery would not be required of those who replicate others. The bravery would be required of the replica, who must live his or her life without a singular identity and that's what concerns me. You reference in your letter this father, who had the happiest and saddest day of his life when his child was born genetically defective. And then that child died in a surgical procedure that you said had about a 96 percent likelihood of succeeding. What concerns the members of this committee is that in order to use the DNA from that deceased child to replicate it, would be to use a procedure that we've already been told here is 96 to 97 percent ineffective, has a failure rate of 96 and 97 percent. It would seem to me that the odds are overwhelmingly in favor of the reality that were you to try to bring such a baby into existence, that you would give this poor couple yet another happiest and saddest day of their life as they witness the birth of yet another seriously ill child with serious birth defects. Now a question for you is how on earth is it that you and I would like Dr. Zavos respond to this and I would like Dr. Jaenisch to respond to this and any others on the panel that would like to. How on earth can you possibly screen this process so that you provide anything like the degree of certainty that we can expect from normal procreation that the child would be born healthy?

Ms. BOISSELIER. Of course, I understand your point and we will do all we can to proceed so that we can check these embryos.

Mr. GREENWOOD. The question is what can you do?

Ms. BOISSELIER. Yes. Today, it was mentioned that the preimplantation diagnosis that are known today are not sufficient. It's true, if we consider the results of cattle cloning, but I'm telling you it's a problem of cattle reproduction. They don't know how to imprint that—

Mr. GREENWOOD. How do you know that? You are a scientist. You use the scientific method. It seems to me that your assertion

requires some level of scientific support which I've not yet heard from you.

Ms. BOISSELIER. Okay, I'm just telling you what was published and what has been published by experts in this arena. So that's how I am—I'm just telling you what they published and that's completely available in the literature today. They do have the same problem in in vitro fertilization of cattle.

Now when you look at the knowledge we have today on human reproduction, we have enough knowledge on how to deal with embryo, how to screen viable embryos and I think Dr. Zavos will explain that to you too. In in vitro fertilization clinics, they do these kind of screening. It might not be enough for what you think is good. I believe that we have—the trained scientists that are on my team are well-trained to address these issues.

Mr. GREENWOOD. Dr. Zavos, would you respond? I'm sorry, I have limited time. I'd like Dr. Zavos to respond to the question.

Mr. ZAVOS. We do hear you, Mr. Chairman, that you do have concerns just as much as every member of this committee. We need to point out several things that the basic scientists on this panel pointed out that they worked with animals, different animal models with different genetic makeup and therefore the susceptibility of those animal models is different and also one of the scientists indicated that there was a species to species variation or animal to animal species variation, that some can take the heat and stay in the kitchen and some cannot. In other words, we can do cloning with some, but others we cannot. Therefore this genetic diversity brings a very important issue here, that we have no standards as such as Congressman Rush just indicated a while ago about the FDA when they introduce a new drug, they do use some standard procedures via which they can scrutinize that drug and use different animal models to scrutinize that, and as of today, none of the animal models that have been created and have been studied have been scrutinized enough in order to be standardized and can be used as projections or predictors of an IVF or a human cloning effort as such.

Now I need to point out here that we've been doing IVF and oocyte retrieval and embryo manipulation in this world for 23 years now. And they just started animal cloning research and embryo manipulation as such for only very few years and I know I worked as a full Professor at the University of Kentucky and I operated such an effort for 22 years in the Animal Science Department. Therefore, I am quite knowledgeable as to what the standards for the animal industry to either clone or do IVF or do embryo transfer or whatever that might be, versus my wife and operating an IVF laboratory today and IVF clinic, an infertility clinic, the Kentucky Center for Reproductive Medicine and IVF. We have a success rate of almost 50 plus percent per embryo transfer. Now that is a significant difference between the animal species and the human species, therefore, when we retrieve 5 to 10 million oocytes per year in the human and we've been doing that for 23 years, we have a track record that is second to none. And therefore those experiences cannot be diluted by just a few dead cattle out there in Texas that they have been obviously cloned or reproduced under almost nonsterile conditions and in the case of their embryo transfer, they

have never been scrutinized or screened properly in order for those embryos to be transferred in utero and expect a decent pregnancy to be established. So those are very serious concerns that we have when we talk about animal models versus the human species.

There is a significant difference between a mouse and a human. There is a significant difference between a cow and a woman.

Mr. GREENWOOD. I think that is the difference we're interested in here, as a matter of fact. Yes sir?

Mr. JAENISCH. I think there are really serious factual errors and serious misstatements in both of the speakers which have to be corrected and I'm surprised to hear this from a Professor of Biology.

So first of all, it is just not correct that you can do prenatal screening for chromosomal operations. Chromosomal operations are not the problem in cloning. A chromosomal operation may occur and is of no great concern because these embryos will die very early as they do in normal human reproduction.

This is really not the point. The point is reprogramming which is not a genetic change. The genes are normal. There's no change. I think it's very important for them to understand that. There's a basic difference between IVF, in vitro fertilization and cloning. In vitro fertilization, the sperm and the egg have gone through the reprogramming. There's no problem with that. So to compare now in vitro fertilization rates to be high or low with cloning, low or high, that means comparing like apples with oranges. It has no—it is not usefulness in this comparison.

Then it was said that mice are inbred and that's why cloning is a problem. Again, I want to correct, these are all factual errors. When you try to clone inbred mice, it doesn't work at all. But when you clone mice which are not inbred, they're called F-1 animals, they're very happy to clone. They have all these malformations and they're actually quite well to be cloned as with probably similar efficiencies as you see in cows.

Now then comes the species—so the idea would be well, there's species variation. Yes, there is, because we understand the in vitro development of embryos to a different extent in these different species. There are clear differences, but this is not the problem. The problem is the basic biological problem of reprogramming. All mammals in this problem is the same. I can really say this with quite some conviction. I am really sure about this.

And then finally, 15 to 20 percent success rate in cloning of cattle, I just wonder where these data come from and I think my neighbor can really address this. I think this is very obscure sources, probably, and of course 15 to 20 percent success. What do they call success? Abnormal cattle? They don't know whether they're normal. As I said before, I don't believe there's a single normal clone in existence. All clones have some subtle defects. If the defects are serious, they die early in development. If they're less serious they go to birth and die at birth. The ones which have less serious ones go later and die after week or 2 and then Dolly made it to adulthood. Dolly is not normal. Dolly is overweight. They don't know why it's overweight. Dolly may have other problems which are beyond our ability to analyze in an animal. We cannot animal as easily what the brain function is. We can only do this in humans unfortunately and they're socialized and go to school. Then we have

an abnormal person. So I think it's totally irresponsible and totally misleading to use scientific data which are plenty there and select certain data to make a statement which is false.

Mr. GREENWOOD. Dr. Westhusin?

Mr. WESTHUSIN. I'd like to make a few comments also. I can point you to another reference also where the success rate was 80 percent, 8 calves were born and then 4 of those died within a day after they were born. So you can pick out isolated cases where the efficiency of cloning is higher and you don't have these problems, but when you look over across the averages of all the papers and put them all together, it's an extremely serious problem.

The other issue that was brought up about in vitro fertilization, the whole basis and background of human in vitro fertilization, what they do today, was brought on by animal research and it suggests that they can produce humans with in vitro fertilization better than we can even with cattle, if we had an interest with it today, is ridiculous. We're much better at producing babies by in vitro fertilization in cattle using all the nonsterile techniques we must use to do it than they are in humans, our pregnancy rates are much higher, our development to blastocyst rates are much higher and we're a lot better at it than in humans and there's a whole industry in in vitro fertilization in cattle that has much better record than humans do.

The other issue is I don't quite follow the logic to say that of all these animals that have shown these different problems we can't use those as an example of the human because they don't represent good models of the human, so does that mean we don't use any example and we just jump out and go try it? I don't follow the logic of that thought process of trying to argue that these are not good animals or models and we can do better in humans because we're so much better in the techniques and the things we have. I just doesn't make any sense.

Mr. GREENWOOD. Thank you. Dr. Okarma.

Mr. OKARMA. I have little to add technically other than to confirm the comments you've heard from my two colleagues to the left. In my opinion there is serious misrepresentation of fact and a tenor of confidence that the data, in fact, in human IVF and embryonic screening do not support.

It is true that when couples with a known genetic defect desire to have children through IVF in limited cases where the genetic defect is absolutely known, samples of the embryos that are created by IVF can be obtained and screened for the presence or absence of that single abnormality, when it is known as there it is, but the notion that this technology is capable of screening all of our 30,000 genes is absolutely specious. And I too am surprised at these kinds of statements made from a former faculty person in biology.

Ms. DEGETTE. Mr. Chairman, if the chairman would yield, I'd like to ask unanimous consent, we clearly have some scientific disagreement on this panel. I'd like to ask unanimous consent if all of the doctors on the panel, they've all referred to studies, if they could present to the panel in writing their studies and the sources of their claims and where they came from. I think that would be helpful.

Mr. GREENWOOD. Without objection, we ask each of the witnesses to the extent that you have referred in your testimony or referred in your written comments, in your oral comments and can recall them and reference studies that would be helpful in our decision-making. We would be delighted to have you submit copies of those.

The Chair recognizes the ranking member, Mr. Deutsch for 5 minutes for his inquiry.

Mr. DEUTSCH. Thank you, Mr. Chairman, and obviously there is a great disagreement amongst the five of you and I think it's very helpful for us and also for our jobs in terms of trying to shape policy.

I'm going to ask you to do something somewhat unusual. If you would like to, just dialog each other, you know in terms of some of the statements that were made in terms of the efficacy of the safety of cloning directly. I mean I've heard 180 degree different opinions from the two people on the right and the three people on the left from our vantage point on this panel. I don't want to be confrontational, but I think people are making statements in a public setting, citing scientific data directly opposite each other. And I think one of the things that does is highlight the role that the FDA conceivably could play in terms of determining what is, in fact, best science. It's not just someone with a Ph.D. or an M.D. behind their name saying something, but some type of independent arbiter who doesn't have a vested interest, who has legal standards in which they have to be responsive to.

I don't know if anyone wants to take a response to that, but I'd be happy—it's kind of unusual, but I'd be happy to open it up that way.

Mr. WESTHUSIN. I'll ask a single question to Dr. Zavos and it's along this line of we've been talking about screening.

There are at least half a dozen papers out there now that are documenting probably at least 6 to 8, probably more genes because the work is just starting to be really, it's just coming to the forefront of trying to do genetic comparisons between cloned animals and normal animals at the blastocyst stage through the field stage, all the way up through development. There are at least probably 6 to 7 genes that have been compared to normal and have been shown to be abnormally expressed and what that means if you're going to measure those is you have to do gene expression analysis which can't be done on a single cell from a few embryos or you can't do a biopsy to do those kinds of things, so how would you propose that you would screen for those 6 or 7 genes and then how would you have the thought process to the idea that those were the only 6 or 7 genes that were important of the 30,000 that could possibly be screwed up in expression?

Mr. ZAVOS. I think you just mentioned the key word, possibly, and the "mays" that you're using in your statements obviously do obviously bring a great deal of dismay to me because I think that we need to understand here that those impossibilities that they're talking about are only impossibilities and I don't want to be too philosophical on answering his question but if Columbus, for instance, would just even think that the winds are too troublesome or Mr. Neil Armstrong would think for a moment that he may not be able to climb on the ladder back onto this shuttle to get back

to the world, back to this earthly world, I should say, he would probably never take that bold step to get there and come back. So those are possibilities.

Now as a scientist I have to ask my people, my scientific colleagues on the right here as to have they ever cloned a human clone embryo and have they ever been able to study that? I want to ask them that question because I think that if you've never been to the moon you can't talk about the life and the environment on the moon, that's why we went there, we found out and came back and we said all about it and we have written books about it. And this is the story that they're trying to extrapolate the animal modeling that they have done and I have to challenge them about the numbers and the standards that they have established because there are no standards. I know as a faculty for 22 years and claim to be a full professor with tenure, I know the pressures that exist on a college campus to produce a paper or two in order to get the promotions and the financial compensations that go there. And therefore, I need to ask them those kinds of questions because we can debate this issue all day long about those six genes they may be obviously in trouble and you need to screen for. Have they ever cloned a human embryo and have they scrutinized that human embryo?

Mr. DEUTSCH. Let me just interject and again I think at some level of science I think it's appropriate, but let me try to respond to what you said. I think two things and again, just to get a feel for it. I don't know if you would suggest that the first time NASA sends something to the moon it would be humans on a ship. Clearly before we sent Neil Armstrong to the moon, we had lunar exploration and even though a human had not been on a moon, clearly we had done a great deal of scientific or societally as the United States of America, we had done a great deal of scientific exploration of the moon and what to expect in that environment.

I think there's two issues that I see. One is just the practical issue. I think that there is a scientific standard that's out there. I don't think whether you say philosophy or not philosophy to throw that out.

Dr. Jaenisch, it seems you were struggling to respond, so I want to give you that opportunity to respond.

Mr. JAENISCH. I have a couple of responses to that. So one, I would like to know from Dr. Zavos whether he has cloned a human, what his experience. I would like to know that.

But let me say clearly that humans are not guinea pigs. So if you do experiments with humans, it's application, but it's not experimentation to find out science the thing you do with animals and it's clear in animals this has not been resolved and therefore it's just out of the question to my opinion and it's totally irresponsible to even attempt to consider doing these experiments with cloning.

So one thing I wanted to come to this letter back of this father. This didn't make any sense at all, because apparently this boy had a genetic defect, so they want to reclone this boy? Of course, the clone would have the same genetic defects and these parents would have in addition to the existing problem all the problems coming from cloning. This seems to be not a very attractive proposal and I think these parents are really misled badly by misstatements as

we heard which totally distort, I think, the scientific literature and I think there's an enormous body of experience and knowledge now which I think underscore what my colleagues to the right have said and myself included.

Mr. WESTHUSIN. I would also like to comment that one of the real misconceptions that I think and later on this afternoon I think some of the ethicists will be here to talk more about ethics and stuff, but one of the real issues that bothers me about this also is the concept of the difference between resurrection and reproduction. This is not resurrection. It is not resurrection. Okay? It's a reproductive technology and whether or not you want to say you know whatever side you take on it, it should take, it simply is another form of assisted reproductive technology and we can talk about the ethical issues aside as to whether we should be doing it, but you can think up scenarios that you could take single cells from single individuals and create people that weren't clones and you could create—figure out huge technologies of people that couldn't have children where you could take one cell from each side, there was a skin cell and do things in the laboratory to where they would not be clones, but you still wouldn't do that if 90 percent of the babies died, if it put the surrogate mothers in risk and if you have these potentials for developmental problems to begin with. There's a real ethical issue, I think, and a real danger that this can be thought of as resurrection when it absolutely is not and in fact, a clone wouldn't even be as similar as an identical twin because it would have a new mitochondrial genotype.

Ms. BOISSELIER. If I may answer to some of the questions there. First of all, it was not a genetic defect that this baby. It was a random birth defect and was proven not to be genetic from what I know and what is said and what his doctors said.

When you talk about the success rates, I'd like to remind all of us that when we started in vitro fertilization the success rate was 1 percent, okay? So also that's something that we should keep in mind and improving it to 50 percent. It means that there have been a lot of embryos that never went through these implantation pregnancies. So we should remember that.

I also think that we should know we could go on and on with pig and cow cloning and learn and refine the technique with those. It will not help for human cloning because this is completely different cells. Again, they are different species with different reproduction techniques involved in there. The techniques that have been described right for the mice is not the one that has been used that are proven interesting for the cows and so on. So they could refine that and finally do the right imprinting of the DNA to get a viable embryo and have something completely reproducible. It will not help for human clone because it's different media, different way to generate the embryo.

What I'm saying is that through this in vitro fertilization experiences that have been accumulated for 23, 24 years now, they learn how to really start an embryo, how to screen an embryo, how to see how an embryo is viable one or not just looking sometimes just at the microscope, it can tell well this one is not right. They had this kind of experience I'm talking about the experts in this technique and they will detect whether an embryo is not viable or not,

which is not true for cow which is not true for mice, because they don't have the same length of experience. So I'd like really for you to come to hear that.

Mr. ZAVOS. I'd like to make a comment just in reference to the comments that were made so far. The other day I was on Swiss TV debating a scientist from the home country and he obviously told me that here I am trying to clone mice of this particular subspecies and I'm having almost 99 percent failure. And he says to me what is your reaction about cloning humans with that kind of failure? And my reaction to those kinds of statements is that I cannot really justify for some of those people's incompetency in cloning animals, just because they simply enter the field and they've done a few animals and they've done a few observations with absolutely no controls and when you design an experiment you have controls and experimental procedures as well as experimental control and experimental groups of animals in order to study various aspects. Some of the studies that are done out there are very isolated. Let's just take Dolly, for instance, 277 enucleated oocytes.

Twenty-nine embryos were produced. All transferred in 13 recipient use, that's female sheet. One took and yielded Dolly. No other abnormalities from any of the other embryos that were or were not implanted. One Dolly was born and now we question Dolly's IQ. Now Dolly has since reproduced and obviously we may have to take him to Harvard or something in order to have an IQ and that is really somewhat of an insult to people's intelligence talking about that. That sheep only needs enough brain to graze and thank God, we know that much. I mean where do we go from here?

So you know, the questions that are appearing in this panel are beginning to deviate from the main theme here is that we are, we have a technology here that inevitably will be developed. Mr. Chairman, everybody has to understand and I think that 60 Minutes footage indicated very clearly today that the genie is out of the bottle.

What we need to be debating here is that how do we put this genie back in a bottle and disseminate securely and safely? We're not talking about America. We are not talking about Turkey or Greece or Israel or Italy. We're talking about the world. And the world needs to address this issue very, very seriously.

Mr. GREENWOOD. The gentleman's time has expired. We're going to turn to Mr. Whitfield. I would ask that perhaps in response to a question from Mr. Whitfield, if you have additional comments you want to make, the Chair has been way overboard in terms of the little red light here and really in respect for the other members needs to move forward.

Mr. Whitfield for 5 minutes.

Mr. WHITFIELD. Thank you, Mr. Chairman. Mr. Westhusin, I would like to give you a minute to respond.

Mr. WESTHUSIN. I just wanted to make a brief comment about that. If the criticism is that we're incompetent and people that are cloning animals have not done controlled experiments to do that, is Dr. Zavos proposing that we jump in and not do more controlled experiments with animals, but just jump straight to humans to do those controlled experiments?

Mr. ZAVOS. I have never indicated that.

Mr. WESTHUSIN. What else would it be besides experimentation?
 Mr. ZAVOS. I do have a plan and I'm not going to reveal it before this committee today.

Mr. WHITFIELD. Dr. Zavos, you were talking about these controls and so forth. Do you have the technology to screen for the 30,000 genes? Yes or no?

Mr. ZAVOS. Not for the 30,000, no.

Mr. WHITFIELD. So you don't have the technology. Are you currently a professor at the University of Kentucky?

Mr. ZAVOS. I'm sorry, what?

Mr. WHITFIELD. Are you currently a professor at the—

Mr. ZAVOS. I'm professor emeritus, up to 22 years of service at the University of Kentucky. .

Mr. WHITFIELD. And you made a comment and unless I misheard you that at your clinic, I thought you said that you maybe had a 50 percent success rate?

Mr. ZAVOS. That's correct, sir.

Mr. WHITFIELD. Because it's my understanding that generally the success rate at most IVF clinics is like 20 to only 25 percent.

Mr. ZAVOS. The CDC data from 1998 it's 30.8 percent.

Mr. WHITFIELD. So you're around—

Mr. ZAVOS. Above average, yes, way above average, yes, correct.

Mr. WHITFIELD. Let me ask you, why did you not participate in the national voluntary program through which IVF clinics report their success rates?

Mr. ZAVOS. Our clinic is only less than 2 years old and we have a certain gray period. First of all, I need for this panel to understand that we do not need by law or any other standards to report to SART, that's the Society of Assisted Reproductive Technologies. We chose not to do that for the first 2 years. We're in the process of becoming candidates for SART and we will be reporting, but for a young program like ours, we wanted to establish a track record before we begin that effort.

Mr. WHITFIELD. Have you ever cloned an animal yourself?

Mr. ZAVOS. No sir, I have not.

Mr. WHITFIELD. And have you been part of any group that has cloned an animal?

Mr. ZAVOS. No, I have not. I represent a consortium of experts from all over the world that obviously, this is not a man's show here. I'm not the one that is going to be doing this. We have scientists, we have a scientific group that will be going to work to do this and therefore we feel like this is a team effort and that's why I spoke about the various aspects of putting a lot of brains together in order to get there on that 60 Minutes footage.

Mr. WHITFIELD. You've indicated that you would not do this in the United States, is that correct?

Mr. ZAVOS. That's correct, sir.

Mr. WHITFIELD. Where would you do it?

Mr. ZAVOS. Well, we cannot disclose that. It's obviously for security purposes and other purposes, we do not wish to disclose that.

Mr. WHITFIELD. Dr. Boisselier? Now you have a doctorate degree in what?

Ms. BOISSELIER. In chemistry.

Mr. WHITFIELD. From which university?

Ms. BOISSELIER. University of Houston.

Mr. WHITFIELD. Houston.

Ms. BOISSELIER. And I had one in University of Dijon in France before.

Mr. WHITFIELD. Okay, now recent press reports have indicated that work is underway at one of your labs or at your lab that was started last October, is that correct?

Ms. BOISSELIER. Well, we got the funding in September. We tried to assemble all the equipment. We had about everything by the end of December and so the scientists have been working and refining the protocols since then.

Mr. WHITFIELD. And you claim that you have four scientific staffers, two biologists, one geneticist and one M.D., is that correct?

Ms. BOISSELIER. It is correct.

Mr. WHITFIELD. And they're there now, working now?

Ms. BOISSELIER. Yes. The M.D. is not full-time because we are not working on human cells.

Mr. WHITFIELD. And you claim that almost 200 people are willing to pay up to \$200,000 in order to participate, is that correct?

Ms. BOISSELIER. Actually, there are thousands of people who are willing to be called and I mentioned those because they are the ones who are really willing to be, even the first.

Mr. WHITFIELD. So is \$200,000 a realistic figure?

Ms. BOISSELIER. I don't know exactly the amount that will be asked because we decided, I know that this is put on the website, but I didn't correct that for a long time. We will set the price once we have a successful birth because we'll know then how much we had to invest and also how many customers we have and we will go through the usual thing of a financial of a company.

Mr. WHITFIELD. Now you've stated that this lab is in the United States, but you've also publicly stated that it's outside the United States. Where is it?

Ms. BOISSELIER. Well, I don't think I have said that it is outside of the United States. I think I started to say it was in the United States in September or late September, before I was saying I am not disclosing where it is. That was my answer.

Mr. WHITFIELD. So you're not disclosing where it is?

Ms. BOISSELIER. So today, I am saying it is in the United States. Before I was saying I'm not disclosing where it is, so I was saying no for every—

Mr. WHITFIELD. And it is your intention to proceed to clone a human being?

Ms. BOISSELIER. Yes, it is. And will do that if it is allowed in this country. Of course, if there are laws against it, because from what I know today, I'm not against the law or I'm not breaching any law in doing it here in the United States in certain states. I know that we have some states where there are laws against it. I'm not based in one of those.

Mr. WHITFIELD. I see my time has expired, Mr. Chairman.

Mr. GREENWOOD. The time of the gentleman has expired. The Chair recognizes the gentle lady from Colorado, Ms. DeGette for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. Now Ms. Boisselier, I'm sorry, Dr. Boisselier, I got your résumé off of the internet and

it looks to me that you are a biochemist with an emphasis on metals research. Would that be an accurate summary of your résumé?

Ms. BOISSELIER. Yes.

Ms. DEGETTE. So you yourself are not conducting this cell research I would assume?

Ms. BOISSELIER. You are right.

Ms. DEGETTE. Thank you. Instead, as I heard you tell Congressman Whitfield, you have some scientists working for you. Is that correct?

Ms. BOISSELIER. This is correct.

Ms. DEGETTE. Now are those folks biologists?

Ms. BOISSELIER. And they are biologists, geneticists and an M.D.

Ms. DEGETTE. Now many biologists do you have?

Ms. BOISSELIER. Two.

Ms. DEGETTE. Now many geneticists?

Ms. BOISSELIER. One.

Ms. DEGETTE. And how many M.D.s?

Ms. BOISSELIER. One.

Ms. DEGETTE. So you have four of those folks working for you?

Ms. BOISSELIER. Right.

Ms. DEGETTE. Can you please let me know who those folks are?

Ms. BOISSELIER. Now, I'm not able to disclose that.

Ms. DEGETTE. And why is that?

Ms. BOISSELIER. Because they don't want to go public now.

Ms. DEGETTE. And can you get, can you submit at least their qualifications to this committee in writing, are you willing to do that without disclosing their actual names? Obviously, we're quite concerned that people conducting this kind of genetic research might be qualified to do it.

Ms. BOISSELIER. Okay, I will certainly disclose that to you, but not in public here.

Ms. DEGETTE. Thank you. We can take it in writing in the committee.

Now let me ask you what exactly is the research that is being conducted by your organization?

Ms. BOISSELIER. The first main step that has to be very well done is the enucleation of the egg.

Ms. DEGETTE. And are you, in fact, enucleating the eggs now?

Ms. BOISSELIER. So they are enucleation of eggs that are performed.

Ms. DEGETTE. Is that happening now?

Ms. BOISSELIER. It's the training of these—

Ms. DEGETTE. Yes or no. Is that happening now?

Ms. BOISSELIER. Let me finish. It's actually done on cow eggs.

Ms. DEGETTE. Okay, so you're doing that with cow eggs now.

Ms. BOISSELIER. Right.

Ms. DEGETTE. What's the second step?

Ms. BOISSELIER. Sorry?

Ms. DEGETTE. What's the second step?

Ms. BOISSELIER. The second step is to do the enucleation of human eggs.

Ms. DEGETTE. And have you done that yet?

Ms. BOISSELIER. No.

Ms. DEGETTE. When do you expect to do that?

Ms. BOISSELIER. Soon.

Ms. DEGETTE. How soon?

Ms. BOISSELIER. When the answers that I have been asking to my scientists are clear with the enucleation of cow eggs.

Ms. DEGETTE. And what are those questions you're asking your scientists?

Ms. BOISSELIER. To show me that there is indeed absolutely a very good reproductive activity in the enucleation of the cow.

Ms. DEGETTE. Great. Now you had just said a few minutes ago that a cow is a different type of mammal than a human.

Ms. BOISSELIER. Yes.

Ms. DEGETTE. So how is it that you're doing the enucleations of the cows and you somehow think that this research will be positively affect your research on human cloning?

Ms. BOISSELIER. Because we know perfectly the difference between the enucleation of the cow eggs and the enucleation of the human eggs. These have been very well described.

Ms. DEGETTE. Why are you doing the cow eggs if you know they're different from the human eggs?

Ms. BOISSELIER. It's easy to answer. It's difficult and I will not sacrifice any human eggs in the practicing of this technology so what they are doing today is doing the practicing on cow eggs.

Ms. DEGETTE. Now you don't know that once you do the cow eggs that the human eggs will be the same because they're a different species?

Ms. BOISSELIER. Yes, I know. This is described. What I'm telling you—

Ms. DEGETTE. So what's going—

Ms. BOISSELIER. —When we're training them it's not on how to do it, it's on what is the protocol to do it because it's well described.

Ms. DEGETTE. Right, okay. I have a short time and I apologize. You don't know that when you begin enucleating human cells that there won't be terrible anomalies as we've seen with cows, sheeps and in fact every other mammal that has been cloned, do you?

You don't know that, do you?

Ms. BOISSELIER. Yes, it's not a problem of enucleation. You are associating enucleation with defect. It's not that.

Ms. DEGETTE. Once you start cloning human cells, you do not know that there will—that you will be safe from abnormalities, do you?

Ms. BOISSELIER. I have great confidence that there will not be any—

Ms. DEGETTE. None?

Ms. BOISSELIER. Because of what we know about that. There will be miscarriages—

Ms. DEGETTE. No, no. But what—

Ms. BOISSELIER. I'm saying that these are defects.

Ms. DEGETTE. These gentlemen over here have testified that it's not an issue of the in vitro fertilization being successful or not. But actually, and I'm not a doctor, but it's actually the genetic channels in the cells which are going to change after the cloning. And I don't see how, if there's never been and certainly if you folks have never cloned a cell, I don't see how you can be certain from that. So let me ask you just one more question—

Ms. BOISSELIER. Could I answer that question?

Ms. DEGETTE. Who's going to bear the financial responsibility for wrongful anomalies, abnormalities and births?

Ms. BOISSELIER. I will answer the previous question. You said that we don't know about the rate of success. You should know that when we do implantation of embryo in in vitro fertilization clinics, they have a lot of miscarriages.

Ms. DEGETTE. I'm not talking about miscarriages.

Ms. BOISSELIER. There will be the same—

Ms. DEGETTE. I'm talking about the cellular makeup.

Ms. BOISSELIER. That's defect. That's defect. When there is a miscarriage, there is a defect in the embryo.

Ms. DEGETTE. Right. But as we've seen with the other experiments, you can have a fetus carried to term and they still have genetic abnormalities.

Let me ask you one more question. When are you going to apply—I assume your researchers are planning to apply to the FDA for an IND for this human research, correct?

Ms. BOISSELIER. I've received a letter telling me to do that recently, yes.

Ms. DEGETTE. So are they going to apply?

Ms. BOISSELIER. I will check with my counsel.

Ms. DEGETTE. You don't know if they are?

Ms. BOISSELIER. I just don't know.

Ms. DEGETTE. Who did you get the letter from, the FDA?

Ms. BOISSELIER. The FDA.

Ms. DEGETTE. So you don't know whether you'll apply or not for doing this human cloning research?

Ms. BOISSELIER. I have to review the letters, of course.

Ms. DEGETTE. Do you think you do need to apply?

Ms. BOISSELIER. I will review the letter.

Ms. DEGETTE. When did you get the letter?

Ms. BOISSELIER. Yesterday, so I am sorry, I do not have the time to review that.

Ms. DEGETTE. Well, now here's what the FDA says and I'm quoting. "Clinical researchers in cloning technology to clone a human being is subject to FDA regulation under the PHS Act and the FD&C Act. Before such research could begin, the researcher must submit an IND request to FDA which FDA would review to determine if such research could proceed. FDA believes that there are major unresolved safety questions on the use of cloning technology to clone a human being and therefore would not permit any investigation to proceed at this time." So do you plan to follow that and apply or not?

Ms. BOISSELIER. I will ask my counsel.

Ms. DEGETTE. I just have a couple of quick questions for you, Dr. Zavos.

First of all, I'd like to ask you the same question that I asked the previous witness is let's say that you have genetic abnormalities resulting from the cloning. Who's going to bear the financial responsibility for those—

Mr. ZAVOS. Obviously, that's a hypothetical question and—

Ms. DEGETTE. So you don't feel there will be any genetic abnormalities either?

Mr. ZAVOS. No, no. We believe that there will be, but every precautionary measurement will be taken.

Ms. DEGETTE. Well, now you've heard the researchers to your right testify that in every mammal that we've done this research on, there have been significant genetic abnormalities as a result of the cloning technique.

Mr. ZAVOS. That's correct.

Ms. DEGETTE. Do you agree when we start cloning humans that there will be similar genetic abnormalities?

Mr. ZAVOS. The Consortium's effort will be to transfer only viable embryos into recipient mothers in order to achieve a healthy pregnancy.

Ms. DEGETTE. Well, I sure understand that's your hope, Doctor, but the problem that I've got is as these researchers have testified, in animal research the way the genetic development happens is even if the embryo seems to be genetically complete, there are mutations and that, in fact, there will be abnormalities. We haven't had any research in other mammals without abnormalities.

Mr. ZAVOS. That is correct. That's a new area of expertise and we need to learn, as we go along as to what the ramifications will be and therefore it is very important that as we obtain those embryos, human embryos we will scrutinize them appropriately—

Ms. DEGETTE. One last question and we've got to vote. Do you believe that those human cloning research experiments need FDA approval and do you believe they need FDA approval?

Mr. ZAVOS. Absolutely, I do.

Ms. DEGETTE. Thank you.

Mr. GREENWOOD. We do have a vote. We will recess the hearing until 3.

[Brief recess.]

Mr. GREENWOOD. We will come to order. Guests will please take their seats. The Chair recognizes the gentleman from Florida, Mr. Stearns for 5 minutes for inquiry.

Mr. STEARNS. Thank you, Mr. Chairman. I just wanted to go back I think to some earlier testimony in opening statements. As I understand it, an egg cell donated for cloning has its own mitochondria DNA which is different from the mitochondria DNA of the cell that provided the nucleus and therefore the clone will therefore not be truly identical. I'd like you just explain that. Give me a little bit understanding of what the implications of that are, Dr. Westhusin?

Mr. WESTHUSIN. We really don't know what the implications of it are. And there have only been about three studies that have actually been able to be controlled in such a way that you could track mitochondria that came from the cell that was donating the nucleus with mitochondria that came from the egg, the donor that donated the egg. So if you think about this process, normally a human being or any animal is going to get their mitochondria from their mother because the mitochondria comes from the egg, so if you think about that you collect an egg from an individual, for instance, in our case if we collect an egg from one species of cow, that may have a different mitochondrial genotype in that egg actually than the mitochondria from the cow maybe that we're interested in cloning and so you can actually set up experiments to try and track

the contribution of each one of those mitochondria, but in general, the egg takes that over. We don't really know the implications of that because you can end up with a heteroplasmic situation where you have some populations of mitochondria from both and then also you know we really don't know. I mean that's a whole area of research that needs to be explored.

Mr. ZAVOS. May I follow up on that?

Mr. STEARNS. Sure. Just for the sake of the members and the folks in the audience, mitochondria is defined as any of various round or long cellular organelles that are found outside the nucleus, produce energy for the cell through cellular respiration and are rich in fats, proteins and enzymes.

Mr. WESTHUSIN. It coats about 21 genes, 16.5 KB of DNA, compared to 30 what billion base peers, Rudy?

I'm trying to compare. It's a very small, in terms of its genetic component, it's very, very small.

Mr. STEARNS. Okay, but could I say because of that phenomena that when you clone an individual—if you tried to clone an individual—you would never get an identical clone because of those cells?

Mr. WESTHUSIN. As defined, right. It would not be the same as two genetically identical twins because genetically identical twins arose from the same egg where two clones might come from two completely different eggs with two different mitochondrial genotypes.

Mr. STEARNS. And without the research to understand the implication of that, that you have these different mitochondrial cells, we don't know what effect that has in the development for that DNA and therefore we don't know whether it's good or bad.

Mr. WESTHUSIN. And there are studies that suggest, there are studies that have been done in mice using the nuclear transfer procedure that, in fact, show there are—that can, in fact, have a significant effect.

So if you take nuclei—how shall I explain it—if you take pronuclei, it's not a cloning procedure. You're just swapping nuclei between embryos early on in development. What you find is there are going to be compatibilities between cytoplasm and the nucleus, there are mice studies that have shown that. And they don't develop.

Mr. STEARNS. Dr. Zavos, does that concern you at all that there's been no research on this and that the fact that these particular cells might provide the energy, they might provide the needed sustenance for this DNA which would make it survive?

Mr. ZAVOS. I am not sure that I really understand your question. Would you just please repeat it for me?

Mr. STEARNS. Yes, I'll take it through. An egg cell donated for cloning has its own mitochondrial DNA.

Mr. ZAVOS. Yes.

Mr. STEARNS. Which is different from the mitochondrial DNA of the cell that produced the nucleus. Are you with me to that point?

Mr. ZAVOS. Yes.

Mr. STEARNS. The clone therefore will never be truly identical. It appears to be no research on this to see the harmful effects when you make this attempt of cloning, the implications of that is on the

cloning process. And without that, I don't quite understand how you feel confident you can go ahead when there seems to be a lot of concern about it.

Mr. ZAVOS. Well, there's a lot of concern about other things as well, not just only that.

Mr. STEARNS. I know.

Mr. ZAVOS. There are two—there's data out there that—a variation between the two clones, it does exist because of simply of different variations in the environment that could bring about expression of DNA differently. In two identical clones, and George Seidel from Colorado State University back almost 10, 15 years ago when he was splitting embryos, he was able to show that in cows that that diversity could come about because of that.

Now as you may know, may not know, we do ooplasmic transfer today in the humans to treat deficiencies of eggs of patients that do not have adequate documentation of mitochondria. We can transfer mitochondria ooplasm from a fertile individual, fertile egg to a subfertile group of eggs in the human today and we are assuming that the DNA that is bound or associated with the mitochondria has no really any implications at all and that's why we're doing it.

It is done today in the human in IVF programs today, we do ooplasmic transfer.

Mr. STEARNS. Mr. Chairman, can I have just 30 additional seconds?

Mr. GREENWOOD. Without objection.

Mr. STEARNS. Dr. Zavos, would you transfer human nucleus into a non-human egg, do you think there's anything wrong with doing that?

Mr. ZAVOS. No.

Mr. STEARNS. There's nothing wrong with it?

Mr. ZAVOS. No, no, no. I wouldn't do that.

Mr. STEARNS. And why wouldn't you do that?

Mr. ZAVOS. Because that's obviously, I don't think there's a competency between the two that can—I think various scientists that done that already, where they transfer mice into cow eggs and what have you.

Mr. STEARNS. No, no, I mean a human nucleus.

Mr. ZAVOS. No, no. I wouldn't do that because that would be silly, mad science.

Mr. STEARNS. Dr. Boisselier, would that be acceptable to you, to transfer a human nucleus into a nonhuman egg?

Ms. BOISSELIER. No, I wouldn't do that.

Mr. STEARNS. Okay, thank you, Mr. Chairman.

Mr. GREENWOOD. The gentleman's time has expired. The Chair recognizes the gentleman from Illinois, Mr. Rush, for 5 minutes.

Mr. RUSH. I think that it's clear that we all appreciate many of the advances of the biotech industry has brought us and my question is how do we ensure that human cloning, that a human cloning ban does not interfere with the safe use of biotechnology by your company and others?

Mr. OKARMA. Thank you for that question. It is a very important issue to our company and to the field as a whole, so I think one needs to focus the language in such a ban to include very precisely

transfers to uteri, to a uterus of these kinds of recombined embryos with the intent of forming a live birth. That, for us, is the bright line that should not be crossed.

Mr. ZAVOS. Can I make a comment, Mr. Rush? I was very impressed, obviously, of your background and your ethical issues that you addressed here and I want to bring to this panel a discussion, some sort of a dimension here that everybody needs to understand.

What would be the ethical reaction of somebody if we would say that a 14-day embryo, a 14-day embryo that is used in stem cell research can be dismembered and be killed literally to harvest those stem cells and do research on those stem cells that's dismembered as a child. That 14-day embryo is a child by definition.

Okay, how can we afford to dismember that embryo and take it apart and take all those cells out of it and clone them or proliferate them and transfer them to treat somebody else's disease and it's morally or ethically incorrect to take a cloned embryo and implant it in a woman to give birth to a live child. If we're going to start discussing ethical issue, that ethical issue here really needs to be addressed as such.

Mr. RUSH. Dr. Jaenisch, would you care to comment?

Mr. JAENISCH. I think Dr. Zavos is mixing up things again. With the embryo stem cell work, it's clear that it never goes in the uterus. It's a blastocyst which develops into an embryonic stem cells and this is very different than an implanted embryo which is disrupted and used for other research. So I think this is very clear.

I would like to really raise the question, are those people ready to produce abnormal children and I think what I appear to hear from them, they are. They are ready to do this because there's just no way to pre-screen embryos and I really reemphasize this, to prescreen embryos for those defects. There's a misunderstanding also in the committee. I'd like to try to clarify this. Clones don't have genetic defects. They have reprogramming problems. And I would like to really reemphasize this important point because it's an analogy which I think is familiar to anyone in this room. If you write a text, this text, the words has spaces between them, there is punctuation, there are paragraphs, italics, it makes it easy to read. Now if you just follow my experiment, if you know totally the format of this text, taking all the spaces out between the words, taking all punctuation away, you will have a lot of problems reading the text. You cannot read it. This is exactly what I mean with reprogramming. The genes which are not expressed are in this reprogrammed format. They're not readable by the cell. The sequence has not changed. Information is exactly the same. So these genes which are expressed in the skin cell, the example I brought, the embryonic genes and the brain genes are not readable. Like the text, your informed of the text. These nucleus goes to the oocyte into the egg and now all the 30,000 genes in principle have to make readable this normally occurring string, egg maturation, sperm maturation which is short-cut in cloning. I think this is the really very important point, so when they say, on my left, they can prescreen the blastocysts on early embryo for false gene expression, this is again incorrect. Many of the genes that will be expressed in the genes normally in the brain. I've never expressed the blastocysts in the embryo. There's just no basis even to do this. You

have to look at the structure of those genes. You have to look, in principle, at all 30,000. So it's just utter—it's not correct what they're saying. They're misleading in a major way to the public that they say they could do this. So I think if they do this, they must be ready to produce abnormal children. I think this is rather distressing to me.

So then I would like to get one comment that Dr. Zavos made earlier that these colleagues on his right don't have experience with cloning. Is this correct? I have experience with reprogramming. I've been working on this for 20 years. That's what is fascinating to me because reprogramming is something which is important for normal development.

When the mice were cloned from this group in Honolulu, I right away arranged a collaboration with this Honolulu group.

Mr. RUSH. Dr. Jaenisch, my time is running out and I have a couple of questions I want to ask the others. I know you are very, very informed about this matter.

Ms. Boisselier, are you familiar with a magazine called Wired Magazine?

Ms. BOISSELIER. Yes.

Mr. RUSH. Do you recall doing an interview with Wired Magazine?

Ms. BOISSELIER. I'm sorry?

Mr. RUSH. Do you recall giving an interview to Wired Magazine or being quoted in a Wired Magazine?

Ms. BOISSELIER. Yes.

Mr. RUSH. I'm going to read from page 133. It says, "From Montreal, it takes about an hour by highway and country roads to reach a huge white barn painted with the word UFO Land. This is the home base for the Raelians. Clonaid's founders and religious believers who teach that advanced extraterrestrial beings called Elhouin landed in France in 1973 to meet aspiring race car driving Claude Varillion. They changed Varillion's name to Rael and told him that humans are clones of Elhouin and revealed that some day he will lead mankind into a blissful, techno-utopian future. Rael was to be the last prophet, the end of the line that includes Moses and Jesus, Mohammed and Buddha." Are those accurate comments?

Ms. BOISSELIER. Well, that's the comments of that Brian Alexander and I mean there is a religion that is called the Raelian religion and you have Rael here in this room and—

Mr. RUSH. Rael is in this room?

Ms. BOISSELIER. Yes, and I understand that he's a witness, so he will explain all of this to you. I am a Raelian and I hope that you will not discuss my religion because this is not the purpose of this hearing. I believe that we're talking about human cloning.

Mr. RUSH. I was just discussing something that was printed, published in a publication. I'm not in any way trying to—

Ms. BOISSELIER. But again, I guess—

Mr. RUSH. [continuing] lessen the impact of your religion.

Ms. BOISSELIER. Did you ask Dr. Zavos his religion?

Mr. RUSH. No.

Ms. BOISSELIER. It's true my religion—

Mr. RUSH. I didn't know this was your religion.

Ms. BOISSELIER. I don't know either.

Mr. RUSH. I'm asking about a comment that you made and that's my only purpose.

Ms. BOISSELIER. It's not a comment. It's a comment of Brian Alexander. This is where he met me.

Mr. RUSH. You made the comment in the Wired Magazine and it's accurate, is that correct?

Ms. BOISSELIER. I don't recall what he wrote about that, but what you read is a comment of Brian Alexander's—

Mr. RUSH. Let me ask you another question. Earlier, you indicated, I think, that there will not be any cloning done in the continental United States, is that right?

Ms. BOISSELIER. I don't understand your question. You mean am I doing this in United States? Is that what your question is?

Mr. RUSH. No, the question is in your earlier testimony—

Ms. BOISSELIER. Oh yes, with Brian Alexander, you mean. Yes, it's true we met end of August, beginning of September and at that time I didn't want to reveal where it was because we were talking with my partner at that time and I told him this is not—I said no to any State he mentioned, okay? I didn't want to reveal that. It's true that in November I started to say yes, it's in the United States.

Mr. RUSH. My question, Mr Chairman, my question is earlier in your testimony you indicated that there would not be any cloning by yourself or your organization conducted within the continental United States, is that right?

Ms. BOISSELIER. I'm sorry, I said it will be here in the United States.

Mr. RUSH. It will be here in the United States.

Ms. BOISSELIER. It will be if it's legal to do it here. So far it is legal as far as my counsel told me and I think I'm not breaching any law in doing it here.

Mr. GREENWOOD. Time of the gentlemen has expired.

Ms. BOISSELIER. There is something different—I'm sorry.

Mr. GREENWOOD. The time of the gentleman has expired. The Chair recognizes the gentleman from Oklahoma, Mr. Largent for 5 minutes.

Mr. LARGENT. Thank you. Dr. Boisselier, are you doing human cloning in the United States at this time?

Ms. BOISSELIER. We are in the process of doing it in the United States.

Mr. LARGENT. And are you seeking FDA approval to do that?

Ms. BOISSELIER. I received a letter from the FDA that came to the college I am teaching in yesterday or the day before. I don't remember. They gave me a letter that I will review with my counsel.

Mr. LARGENT. Okay. Dr. Zavos, is it your belief that it is possible to determine which embryos are destined to develop abnormally? Can you determine that today?

Mr. ZAVOS. Our team is working toward the development of very strict criteria that are currently available and we will be developing additional criteria in order to be able to screen what a viable embryo is which the definition of a viable embryo is something, an embryo that can be transferred in utero with the idea of implanting properly and giving birth to a healthy child.

Mr. LARGENT. So the answer is no, you cannot?

Mr. ZAVOS. Of course not, we haven't even done a clone embryo human clone embryo yet.

Mr. LARGENT. So if, in fact, you cannot do it, are you saying then that you will not do any human cloning until you can accurately determine abnormal embryos?

Mr. ZAVOS. Mr. Congressman, I think I stated at the very end of my statement that this Consortium will not step on dead bodies or deformed babies to get this accomplished and therefore I think that that statement defines exactly the answer that you're looking for.

Mr. LARGENT. So let me ask you this question, if you went forward believing that you had a method to screen abnormal embryos which Dr. Jaenisch says you cannot do—

Mr. ZAVOS. Well, that's his opinion.

Mr. LARGENT. I understand that. MIT carries a little weight up here.

Mr. ZAVOS. Yes, I know.

Mr. LARGENT. If, in fact, you went forward and created a child that was abnormal, would that stop your efforts?

Mr. ZAVOS. That's obviously not for me to make that decision, but for the Consortium. Bear in mind that I'm just a spokesman for a larger group of—

Mr. LARGENT. I understand. Would you advocate that for your Consortium?

Mr. ZAVOS. I would.

Mr. LARGENT. To say we need to stop?

Mr. ZAVOS. Yes, I would advocate for that. And the statement at the end of my presentation today just defines that. We don't intend to step on dead bodies or deformed babies to get there. And that pretty much really determines and defines that.

Mr. LARGENT. In January, Dr. Zavos, you and Dr. Severino stated in your intent to lead a project to clone a human being within the next 2 years.

Mr. ZAVOS. Eighteen to 24 months is to yield viable embryos for the purpose of transferring in utero to establish a pregnancy.

Mr. LARGENT. Where exactly will this project take place?

Mr. ZAVOS. I cannot disclose that. I think I have already stated to the committee that this is obviously, it's outside the continental USA, but I cannot tell you where that would be.

Mr. LARGENT. Okay, and—

Mr. ZAVOS. Can I just take one—about 10 seconds of your time, if I would. The people here are talking about the left and the right and we're not Republicans and Democrats, obviously. They could be on the right here, but on the left here, Dr. Boisselier and myself were not associated in any way, shape or form. Therefore, she represents a different group of people that she works with and I represent a Consortium for human therapeutic cloning and I just wanted for the record to be established as such and be very clear and vivid.

Mr. LARGENT. Dr. Zavos, let me ask you another question. When my colleague, Cliff Stearns asked you would you ever do a combination of a nonhuman egg with a human DNA or whatever, you said absolutely not, mad science.

Mr. ZAVOS. That's correct.

Mr. LARGENT. Why?

Mr. ZAVOS. Because by scientific standards it doesn't make sense.

Mr. LARGENT. Okay, but you agree that to a lot of people what you're proposing doesn't make sense either, so in other words, there could be more people that would be encouraged to do exactly what you said would be mad science because of the work you're doing. In other words, we kind of get on that proverbial slippery slope so that people would go there, maybe not you, but somebody would because you've taken the ball down the field a little bit. Somebody else might say why not? Why can't we do this?

Mr. ZAVOS. Mr. Largent, I think that we need to talk about this a bit because I think it is your responsibility of the government of the good old U.S.A. to take some precautionary measurements. I just finished coming back from Israel where I met with many, many figures including the President of Israel. Three weeks ago I was in Greece talking to the Greek government. I spoke to the Cypriot government where I have instructed the Cypriot government to establish guidelines and a committee to study for the employment of this type of technology and put the adequate restrictions that are necessary to employ this technology safely.

Mr. LARGENT. Right, okay. Dr. Zavos, let me just finish by saying I see my time is about to expire, is that you've been quoted as saying "ethics is a wonderful word."

Mr. ZAVOS. Yes.

Mr. LARGENT. "But we need to look beyond ethical issues here. It's not an ethical issue. It's a medical issue. We have a duty here."

And I would just say that it is the responsibility of Congress to look at this medical issue, but that we don't put the ethical issues antecedent or behind the ethical issues that we're facing and confronting here and we do have a responsibility to look at that and so anyway, I want to thank all of you for your testimony, it's been an enlightening panel and I yield back my time, Chairman.

Mr. GREENWOOD. The time of the gentleman has expired and all time for questioning this panel has expired, so we—

Mr. RUSH. Mr. Chairman, can I indulge the committee and ask just one burning question that I absolutely have?

Mr. GREENWOOD. The gentleman from Illinois asks unanimous consent for 40 seconds, without objection.

Mr. RUSH. Dr. Zavos, is the practice of human cloning, is that a medical practice, is that considered in the practice of medicine?

Mr. ZAVOS. If it becomes safe and reproducible, I think that it will become just like IVF was not in 1978, it was banned in the U.S.A. for 3 years until it became legal and it was employed properly in the U.S.A. Therefore, the future will tell. And of course, people like you have to make those kinds of decisions as we go along.

Mr. RUSH. So if it's not safe, considered safe, then it would not be a medical practice?

Mr. ZAVOS. Absolutely.

Mr. GREENWOOD. The time of the gentleman has expired.

Mr. RUSH. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair wishes to thank our witnesses in this panel. You have spent 3½ hours with us and we appreciate

that very much and you are excused. You are welcome to stay and listen to the other witnesses.

For the benefit of everyone, particularly those who have travel arrangements, our intention now is to take the second panel in sequence, the FDA and Bioethics panel beginning at 4. We expect to have them come up, testify, respond to questions by 4 o'clock and we'll bring the third and final panel up at 4 o'clock.

Gentlemen and lady, you are excused.

I would then call Dr. Kathryn C. Zoon, a Ph.D., Director of the Center for Biologics Evaluation and Research at the Food and Drug Administration and Dr. Thomas Murray, a Ph.D., National Bioethics Advisory Commission. Would you please come forward?

Dr. Zoon and Dr. Murray, thank you very much for your patience and thank you for joining us today. You are aware that the committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath. Do either of you have any objection to testifying under oath?

The Chair then advises you that under the rules of the House and the rules of the committee you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony? Neither of you do.

In that case, would you please rise and raise your right hands? Do you swear that the testimony you are about to give is the truth, the whole truth and nothing but the truth? Thank you very much.

[Witnesses sworn.]

You are welcome to begin and I believe that we will ask Dr. Zoon to start out and you are recognized, ma'am, for 5 minutes.

STATEMENTS OF KATHRYN C. ZOON, DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION; AND THOMAS H. MURRAY, NATIONAL BIOETHICS ADVISORY COMMISSION

Ms. ZOON. Thank you, Mr. Chairman. Mr. Chairman and members of the committee, I am Dr. Kathryn Zoon, Director of the Center for Biologics Evaluation and Research at the Food and Drug Administration. I can assure the members of this committee and the American public that FDA views the use of cloning technology to clone a human being as a cause for public health concern.

I appreciate the opportunity to discuss FDA's role with respect to this issue. I want you to know that because of the unresolved safety questions on the use of cloning technology to clone a human being, FDA would not permit it at this time.

Very recently, there have been numerous press articles on individuals and groups expressing interest in cloning a human being by the use of cloning technology. We have heard that people have incorrectly stated that there are no legal controls in place in the United States governing the use of cloning technology to clone a human being. My hope today is to clarify FDA's role in regulating the use of cloning technology to clone a human being and to discuss the significant scientific concerns regarding safety that would lead us to disallow any such activities at this time.

It is important to note that FDA's role in assessing the use of cloning technology to clone a human being is a scientific one. As recognized by the National Bioethics Advisory Commission, there

are additional unresolved issues including the broader, social and ethical implications of the use of cloning technology to clone a human being.

We have heard much today regarding the cloning of the sheep named Dolly and several other animal species, including cattle, pigs and mice. I will not repeat the science behind that because we have heard it today.

Again, though, I would like to remind the committee that it took 276 failed attempts before Dolly was born. The failure rate remains extremely high for the cloning of sheep and other mammals. Moreover, when live births occurred, there have been deaths and major abnormalities such as defective hearts, lungs and immune systems in the newborns and older animals. In addition, significant maternal safety risks including deaths have been observed. These facts raise serious concerns regarding the use of cloning technology to clone a human being.

With regard to FDA jurisdiction, the use of cloning technology, to clone a human being would be subject to both the biologics provision of the Public Health Service Act and the drug and device provisions of the Federal Food, Drug and Cosmetic Act. Before clinical research could begin, the sponsor must submit an investigational new drug application to the FDA which we would review to determine if such research could proceed. Again, I want to reemphasize that FDA believes that there are major unresolved safety questions on the use of cloning technology to clone a human being and therefore would not permit any such investigation to proceed at this time.

As part of our compliance strategy, in 1998, professional organizations, institutional review boards and several individuals professing an interest in using somatic cell nuclear transfer to clone a human being were notified of FDA's position.

FDA continues to communicate its jurisdiction with those that have expressed an intention to pursue the use of cloning technology to clone a human being. FDA continues to monitor information as it becomes available.

We can assure you that the Agency will continue to inform such individuals and entities of the laws and regulations governing such research and take appropriate enforcement action as warranted to protect the health and safety of the public.

Thank you.

[The prepared statement of Kathryn C. Zoon follows:]

PREPARED STATEMENT OF KATHRYN C. ZOON, DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Kathryn C. Zoon, Ph.D., Director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA or the Agency). I can assure the members of this Committee and the American public that FDA views the use of cloning technology to clone a human being as a cause for public health concern. I appreciate the opportunity to discuss FDA's role with respect to this issue. Because of unresolved safety questions on the use of cloning technology to clone a human being, FDA would not permit the use of cloning technology to clone a human being at this time.

Very recently, there have been numerous press articles on individuals and groups expressing interest in cloning a human being by cloning technology. We have heard

that people have incorrectly stated that there are no legal controls in place in the United States governing the use of cloning technology to clone a human being. My hope today is to clarify FDA's role in regulating the use of cloning technology to clone a human being and to discuss the significant scientific concerns regarding safety that would lead us at this time to disallow any such activities. It is important to note that FDA's role in assessing the use of cloning technology to clone a human being is a scientific one. As recognized by the National Bioethics Advisory Commission, there are additional unresolved issues including the broader social and ethical implications of the use of cloning technology to clone a human being. Because of the profound moral, ethical, and scientific issues, the Administration is unequivocally opposed to the cloning of human beings.

BACKGROUND

To give you a better understanding of cloning technology, the Statement for the Record submitted by Dr. Harold Varmus, then Director of the National Institutes of Health, to the House Committee on Commerce, Subcommittee on Health and Environment, (February 12, 1998 hearing, "Oversight Hearing Regarding Cloning: Legal, Medical, Ethical, and Social Issues") is helpful:

In order to understand this technology, it is necessary to briefly review normal sexual reproduction in mammals. . . Normally, an egg and sperm join to create a fertilized egg, which develops into an embryo and ultimately a newborn animal. In this situation, the progeny receives genetic material from both the mother and father.

In the Dolly experiment, a lamb was produced using the technology of somatic cell nuclear transfer. Unlike the normal process of sexual reproduction in which an egg and a sperm each contribute genetic material, somatic cell nuclear transfer is asexual. A somatic cell is any cell except the egg cells or sperm cells. Somatic cells contain the full complement of chromosomes. In contrast, an egg or a sperm contains half that number.

Somatic cell nuclear transfer is done in the following way . . . using sheep as an example. First a normal sheep egg cell is taken from a ewe and the nucleus (the cell structure containing the chromosomes) is removed, yielding an egg cell containing the nutrients and other energy producing materials that are essential for embryo development, but not the chromosomes. Next, a somatic cell is isolated—in the case of Dolly, a cell grown in cell culture from the mammary tissue of an adult sheep. Under certain conditions, the somatic cell (in this example, the mammary cell) is placed next to the egg from which the nucleus had been removed, an electrical stimulus is applied, and the two cells fuse. The result is a cell that contains the nutrient environment of an egg cell and genetic material only from the donated somatic cell. This is not sexual reproduction, since genetic material is derived from only one, not two, individuals. There is no sperm involved. The egg provides only the environment for growth. After a number of cell divisions, these cells are placed into the uterus of a sheep. In the case of Dolly, a lamb was born—an identical twin of the original donor, only born later.

This technology did not readily result in the birth of a lamb cloned from an adult sheep. It took 276 failed attempts before Dolly was born. Since the time of Dolly, additional animals have been cloned. However, the success rate remains low and numerous abnormalities in the offspring and safety risks to the mother have been observed. These facts raise serious concerns regarding the use of cloning technology to clone a human being.

FDA JURISDICTION

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

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

selected, pharmacologically treated, or otherwise altered in biological characteristics ex vivo to be administered to humans . . .”

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

Clinical research using cloning technology to clone a human being is subject to FDA regulation under the PHS Act and the FD&C Act. Before such research could begin, the researcher must submit an IND request to FDA, which FDA would review to determine if such research could proceed. FDA believes that there are major unresolved safety questions on the use of cloning technology to clone a human being and therefore would not permit any such investigation to proceed at this time.

The following briefly describes the established FDA process in overseeing clinical research. A researcher may not conduct a clinical study unless an IND is in effect. Sponsors are required to submit to FDA an IND describing the proposed research plan and other pertinent scientific information, to obtain authorization from an independent Institutional Review Board, and to obtain the informed consent from all participating individuals. The sponsor must wait at least 30 days after submitting its proposal to FDA before beginning any study. During this time, FDA may take action to prohibit a sponsor from conducting the study by placing the study on “clinical hold” for a variety of reasons, including but not limited to, situations where the Agency finds that “human subjects are or would be exposed to unreasonable and significant risk of illness or injury” or that “the IND does not contain sufficient information required . . . to assess the risks to subjects of the proposed studies.” (Title 21, *Code of Federal Regulations* § 312.42.)

Following the reports about the cloning of Dolly, the sheep, there were reports in the media that scientists were contemplating using cloning technology to clone human beings. FDA notified professional organizations, Institutional Review Boards, and several individuals professing an interest in using somatic cell nuclear transfer to clone a human being. This “Dear Colleague” letter, which is available on FDA’s website: www.fda.gov/oc/oha/irbletr.html reiterated FDA jurisdiction over the use of cloning technology to clone a human being. The letter notified researchers that clinical research could proceed only when an IND is in effect. The letter stated that until significant safety issues are appropriately addressed, FDA would not permit any such investigation to proceed. Since the 1998 “Dear Colleague” letter was issued, circumstances have not changed to warrant a change in FDA’s position.

FDA has further communicated regarding its jurisdiction with individuals or entities that expressed an intention to pursue the use of cloning technology to clone a human being. FDA continues to monitor information, as it becomes available, with regard to individuals or entities that express an intention to use cloning technology to clone a human being. We can assure you that the Agency will continue to inform such individuals and entities of the laws and regulations governing such research and take appropriate enforcement action as warranted to protect the health and safety of the public.

CONCLUSION

The Agency’s regulatory approach encourages research and innovation, while at the same time helping to ensure that safeguards are in place to protect the public from unreasonable risks that may be associated with clinical trials. Because of the unresolved safety questions pertaining to the use of cloning technology to clone a human being, FDA would not permit any such investigation to proceed at this time.

Mr. GREENWOOD. Thank you very much, Dr. Zoon.
Dr. Murray, please offer your testimony.

STATEMENT OF THOMAS H. MURRAY

Mr. MURRAY. Thank you very much, Mr. Chairman. I’m told that I should request that my statement be entered into the record.

Mr. GREENWOOD. And without objection, it will.

Mr. MURRAY. Thank you. I do that so that I don’t have to bore you by reading it, or at least not much of it and then instead try to give some comments inspired by what’s gone on already this afternoon.

My name is Dr. Thomas Murray. I'm a member of the National——

Mr. GREENWOOD. Dr. Murray, I forgot to tell you that your Congresswoman Connie Morella asked me to say hello.

Mr. MURRAY. Thank you very much. And she's actually in a different district, but she's a lovely person.

National Bioethics Advisory Commission, I'm a member of the Commission, but that's more or less a voluntary job in that all of us also have day jobs. The Commission was established by then President Clinton in 1995 to advise and to make recommendations to the President through the National Science and Technology Council on bioethics issues and their policy implications.

My fellow Commissioners on NBAC, as it's known, come from a variety of disciplines and backgrounds to include research scientists, religious scholars, physicians, lawyers, members of the public and others.

My day job is President of a place called the Hastings Center, a nonprofit, independent, nonpartisan research institute in Garrison, New York that addresses fundamental ethical issues in health and medicine, the biomedical sciences and the environment. I should note that at least I believe three of the people quoted in the members' own statements this morning on cloning including Leon Kass, Dr. Author Caplan right behind me at this time and Laurie Andrews are all fellows of the Hastings Center and I'm proud to see them represented on both sides of the debate.

I also serve on the Committee on Ethics of the American College of Obstetricians and Gynecologists and in my own work I do a lot of writing and thinking about parents and children and the ethical implications of reproductive technology, genetics and the like.

When Dolly's cloning was announced in February 1997, then President Clinton asked NBAC to review the legal and ethical issues associated with cloning technology and asked us to report in 90 days. I'll try to describe briefly what we said at that time and the process we followed. Since then, I should note that the Commission has issued three other reports with two more to be completed soon, one on research internationally, particularly in a developing world and another on the general oversight and protection of research on human subjects.

Now there's a saying in the field of bioethics, my field, that good ethics begins with good facts and I was pleased to see that this subcommittee apparently operates on the same presumption and that you started with a scientific panel. NBAC did too. It might be of interest to note that of the first eight witnesses, the first was a scientist and the following seven theologians representing four important religious traditions, traditions important both in the United States and around the world. We also invited ethicists, legal scholars and the general public. We commissioned a paper on issues related to cloning.

NBAC focused on a very specific issue. It seems precisely the one before this subcommittee, namely, where you would use genetic material, so called somatic cell nuclear transfer cloning, put it in another person's egg and try to create a child by cloning. We didn't look at other procedures like embryo splitting, nor did we look at the broader areas of embryo research. We were focused on trying

to create a child by cloning. That's what struck us as new and important for our deliberations.

Not surprisingly we found that this potential ability to clone human beings through this technique raised a host of complex scientific, religious, legal and ethical issues, some new, some old. It was noteworthy that we found a great diversity of views among religious scholars and indeed, even within the same religious traditions. We would find a range of views about cloning.

Although we didn't agree on all the ethical issues, after all, we were 18 individuals with different perspectives. We nonetheless concluded unanimously that given the state of the science any attempt to create a child using somatic cell nuclear cell technique we've been talking about today, whether in the public or private sector is uncertain in its outcome, unacceptably dangerous to the fetus and therefore morally unacceptable.

We've had no reason to retract that conclusion. Now we suggested a number of things, a moratorium, a voluntary moratorium to be bolstered and followed up with Federal legislation that would prohibit trying to create a child by cloning. We asked that if there would be legislation, it would be advisable to have a sunset period on it so that it could be revisited if and when the science changed. We also cautioned that any legislation written should be careful not to prohibit things that you don't want to prohibit it because scientists use the term cloning to refer to all kinds of things, including making copies of little snippets of DNA or copies of regular cells. All that in a lab is called cloning, so if you could prohibit all human cloning, you're going to criminalize a lot of what goes in laboratories today that's totally morally acceptable, no one would object to.

We urge international cooperation. In fact, as has already been mentioned a number of other nations have made statements as have some international groups.

I want to turn to some of my personal views now and I want to make it clear I do not at this point speak for the Commission, but for Tom Murray. As I think was made clear in the previous panel, the scientific literature, evidence that's accumulated since 1997 describing the cloning of non-human animals has only further illustrated the risks posed to any children that might be born as a result of this procedure as well as to any woman who would be asked to try to carry such a pregnancy. Researchers are only beginning to understand the causes of the abnormalities in cloned animals born in recent years.

Now imagine for a minute a new drug that caused abnormalities or neonatal deaths in half of the babies born to the woman treated with this new drug. Imagine further that the women itself, many of them suffered serious harm and then last imagine that the women who are given this drug were otherwise totally healthy. Would we be having a debate about the ethical acceptability of whether this drug should be distributed? Or would we condemn it resoundingly as unethical experimentation on human beings?

I think and I hope we would express moral outrage, but those are the very risks we're talking about today using cloning.

To create a human child by cloning at this time is a clear and unambiguous assault on worldwide ethical principles to protect

human subjects against irresponsible and morally outrageous conduct in the name of progress. Neil Armstrong's name was evoked. Neil Armstrong was an exhaustively trained adult volunteer. I wish he were here to give his own opinion about the use of his name in this cause, and the astonishingly arrogant claims, I believe, made in his name and to ask him whether he would have agreed to made his voyage, however historically important, over the damaged bodies of women and the broken bodies of children.

I also believe we need a vigorous public conversation about broader ethical issues raised by cloning, its impact on children and parents and the relationship between the two. The probably illusory control, people believe it and they offer over the traits of their offspring. I have fantasized that the best antidote to the enthusiastic support of cloning that exists out there, at least among some people would be if somebody actually did clone Michael Jordan and Michael II was totally uninterested in basketball and really wanted to be a good accountant. What makes Michael Jordan is in part his genes, but so much more than that, it is his drive, his fierce determination, his unexcelled competitiveness, not even just his physical gifts.

What is accomplished, I find myself asking, today by proclamation such as those made by Dr. Richard Seid, Dr. Zavos and the Raelians. Well, it seems to me two things are clearly accomplished. No. 1, you get enormous heaps of free publicity. This is good for business, if that's what you're after. No. 2, you provide false hope and possible exploitation of parents desperate in their grief over having lost a child. One more thing, if people are permitted to go ahead at this time is that we will have many dead fetuses, probably some damaged women and maybe, but maybe not a live born child or two who will almost certainly be born with severe abnormalities.

NBAC's recommendations are as relevant to the current discussion as they were when offered 4 years ago. I asked you take them under consideration and thank you for inviting me.

[The prepared statement of Thomas H. Murray follows:]

PREPARED STATEMENT OF THOMAS H. MURRAY, COMMISSIONER, NATIONAL BIOETHICS
ADVISORY COMMISSION

I want to begin by thanking Representative Greenwood for the invitation to speak to you today. My name is Dr. Thomas Murray, and I am a member of the National Bioethics Advisory Commission (NBAC). NBAC was established by President Clinton in 1995 to advise and make recommendations to the President through the National Science and Technology Council and to others on bioethics issues and their policy implications. My fellow commissioners on NBAC come from a variety of disciplines and backgrounds, and include research scientists, religious scholars, physicians, lawyers, and members of the public. My day job is as President of The Hastings Center in Garrison, New York, an independent non-partisan research institute that addresses fundamental ethical issues in the areas of health and medicine, the biomedical sciences, and the environment. I serve on the Committee on Ethics of the American College of Obstetricians and Gynecologists, and am the author of *The Worth of a Child*.

Upon the announcement of the cloning of Dolly the sheep in February of 1997, former President Clinton asked NBAC to review the legal and ethical issues associated with cloning technology and report back to him in ninety days. Today I will briefly describe NBAC's report and its recommendations. This report represents NBAC's assessment of these issues as we saw them in 1997. The Commission has since issued three other reports, with two more to be completed soon, on issues related to research with human subjects.

There is a saying in my field that “good ethics begins with good facts.” To that end, NBAC held three meetings, with testimony from scientists, theologians, ethicists, legal scholars, and the general public, and commissioned eight papers on different issues relating to cloning. NBAC focused on a very specific aspect of cloning, namely where genetic material would be transferred from the nucleus of a somatic cell of an existing human being to an enucleated human egg with the intention of creating a child. We did not revisit questions of human cloning by embryo-splitting or issues surrounding embryo research.

The Commission discovered that the potential ability to clone human beings through somatic cell nuclear transfer techniques raises a host of complex scientific, religious, legal, and ethical issues—some new, and some old. Especially noteworthy was the diversity of views that we heard among religious scholars, indeed even among those within the same religious tradition. Although we did not agree on all of the ethical issues surrounding the cloning of human beings, we nonetheless unanimously concluded that given the state of science, *any attempt to create a child using somatic cell nuclear transfer, whether in the public or private sector, is uncertain in its outcome, is unacceptably dangerous to the fetus, and therefore, morally unacceptable.*

In addition, NBAC made the following recommendations:

- The moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer should be continued. Non-federally funded entities should be asked to comply voluntarily with the intent of the federal moratorium. Professional and scientific societies should make it clear that such an act would be irresponsible, unethical, and unprofessional at this time.
- Federal legislation should be enacted to prohibit any attempt to create a child by somatic cell nuclear transfer. Such legislation should include a sunset clause to ensure that Congress reviews the issue after a specified time period, such as three to five years. Any state legislation should have a similar sunset clause. At some point prior to the expiration of the sunset period, an appropriate oversight body should evaluate and report on the current status of the technology and the ethical and social issues that cloning would raise.
- Any legislative or regulatory actions should be carefully written so as not to interfere with other important areas of research, such as cloning of human DNA and cell lines.
- If a legislative ban is not enacted or is lifted, clinical use of somatic cell nuclear transfer to create a child should be preceded by research subject to independent review and informed consent.
- The United States should cooperate with other nations and international organizations to enforce common aspects of their policies.
- The federal government and others should encourage continuing deliberation on these issues, in part to enable society to develop appropriate policies regarding cloning should the time come when present safety concerns have been addressed.

We hoped that the report would form a useful initial basis for ongoing deliberations and educational dialogues that we believe are essential. We also recommended that the federal government actively encourage public education in this area of science so that public deliberation is as informed as possible.

NBAC has not continued to debate human cloning issues, but we have been well aware of the continuing scientific developments and the ethical and policy discussions that have ensued in this country and abroad.

For example,

- In 1997, the G8 nations agreed at the Denver Summit on the “need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child.”
- With regard to our recommendation on federal legislation, it is worth noting that at least 14 countries, including the United Kingdom, Australia, and Israel, have existing legislation prohibiting cloning. Earlier this month, a Council of Europe protocol prohibiting cloning human beings went into effect.
- In this country, several states have proceeded to pass their own legislation regulating cloning. The NBAC staff surveyed state laws in 1999, at which time five states had enacted legislation to directly prohibit human cloning, and ten states had laws regulating research on embryos and fetuses that could also restrict cloning activities. Some of these laws are broader in scope than others, and I would recommend that Congress follow NBAC’s recommendation to craft a law that does not interfere with other areas of research.

In my personal view, the scientific literature since 1997 describing the cloning of non-human animals has only further illustrated the risks posed to the children that

might be born as a result of this technique as well as to the women who would carry these pregnancies to term. Researchers are only beginning to understand the causes of the abnormalities in cloned animals that have been born in recent years. Imagine a new drug that caused abnormalities or neonatal deaths in half of the babies born to women treated with it, and risks to the women as well. Imagine further that this drug was given to women who were otherwise healthy. Would there be any debate over the ethical acceptability of using this drug? Or would we condemn it resoundingly as unethical experimentation on human beings? I believe that we would express moral outrage. Yet these are the very risks encountered when we try to create a human child by cloning today.

I also believe that we need urgently a vigorous public conversation about the broader ethical issues raised by cloning: its impact on children and the parent-child relationship, the perhaps illusory control people may believe it offers over the traits of their offspring. I have wondered if the best antidote to the enthusiasm behind human cloning would be if someone were successful at cloning Michael Jordan—and Michael II, although he would begin to lose his hair at roughly the same age as his progenitor, had absolutely no interest in playing basketball but wanted desperately to become an accountant. What made Michael the First great was his fierce determination and unexcelled competitiveness, not merely his physical gifts.

NBAC's recommendations are as relevant to the current discussion on human cloning as they were when first offered four years ago. I would ask you to take them into consideration.

Thank you for the opportunity to speak to you, and I am happy to answer any questions that you may have.

Mr. GREENWOOD. Thank you, Dr. Murray.

The Chair recognizes himself for 5 minutes for inquiry.

Dr. Zoon, you were here, I believe, when Dr. Boisselier testified that she only received a letter from the FDA within the last day or two. Are you aware of that letter and when it was sent?

Ms. ZOON. Yes sir.

Mr. GREENWOOD. What can you tell us about that?

Ms. ZOON. I am aware that she had received the letter on Monday.

Mr. GREENWOOD. It would seem to this member that given the fact that FDA has asserted its jurisdiction, a claimed jurisdiction for the last 2 or 3 years—and given the notoriety of the Raelians in the American press—that such a letter would have been sent certainly long before the eve of this hearing.

Can you explain why that was not the case?

Ms. ZOON. Yes, the information regarding the Raelians first came to our attention at the end of last year when looking at a website and as a result of that, the Agency did start a process in which to find the various individuals associated with that website. As you know, as we have seen today, the 60 Minutes program raised additional information which FDA pursued. We were able to contact Dr. Boisselier and provide her with a letter giving her the instructions on what FDA's position was with regard to using cloning technology to clone a human being.

Mr. GREENWOOD. Dr. Boisselier said that when asked by a number of members of this panel whether she intended, her organization intended to clone a human being in the United States and whether they would comply with the dictates of that letter, she deferred responding until she spoke with her counsel. If the FDA were aware that her organization was embarking on human cloning somewhere in the United States, what would be the response of the FDA?

Ms. ZOON. FDA would look at this process with regard to our compliance strategies when dealing with such a claim and inves-

tigate it and do what we would normally do in a compliance action. We cannot reveal what we would do here today in public, but we would pursue this vigorously and take appropriate steps.

Mr. GREENWOOD. The strategy that you're not revealing here, one of the things that would, of course, be important to members of this committee is that such a strategy provides for a rapid enough response from the moment you became aware of where and when such cloning might take place or was about to take place, that we wouldn't be faced with a situation in which you have a cloned egg implanted in the uterus because my sense is that that would pose a fairly difficult enforcement situation.

Ms. ZOON. Yes. We would not wait until such action took place in order to—

Mr. GREENWOOD. So I would assume you would seek some sort of enforceable injunction?

Ms. ZOON. There are many mechanisms we would use for pursuing this. One would be to investigate this as a whole and get the appropriate information and find out as much as we can.

Mr. GREENWOOD. Suppose that you raided a clinic and found out that in fact, the cloning had taken place—whether that egg was or was not yet implanted in a uterus. Would you walk us through what you would anticipate might happen in terms of arrests, charges and penalties? What would be the most severe penalties under the current statute that such a person might confront?

Ms. ZOON. Clearly, it would depend on the circumstances of what FDA found. FDA has a number of actions it could take, depending on the nature of the violation. They would include for such a violation under the Public Health Service Act or such a misdemeanor under the Federal Food Drug and Cosmetic Act a penalty of I believe \$100,000 and up to 1 year in jail—

Mr. GREENWOOD. Are you aware whether anyone has ever been imprisoned under that section?

Ms. ZOON. I am not personally aware of anyone imprisoned—

Mr. GREENWOOD. Will you please get us the answer and respond in writing to the committee with that information?

Ms. ZOON. Yes sir.

[The following was received for the record:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
May 18, 2001

The Honorable JAMES C. GREENWOOD
Chairman, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce House of Representatives
Washington, D.C. 20515-6115

DEAR MR. CHAIRMAN:

Thank you for your interest in issues associated with human cloning. This is a follow-up to the March 28, 2001, hearing on "Issues Raised by Human Cloning Research." Dr. Kathryn Zoon appeared as a witness at that hearing for the Food and Drug Administration (FDA or the Agency).

At that hearing, you asked Dr. Zoon whether the government has prosecuted persons for criminal violations of the Public Health Service Act (PHSA).

The answer to your question is yes.

In general, after discovering evidence of a criminal violation related to a biological product, FDA may refer a matter to the Department of Justice (DOJ). On the basis of that evidence, it may be possible to charge a person with violating the PHSA, the Federal Food, Drug, and Cosmetic (FD&C) Act, and provisions of Title 18. How-

ever, it is not unusual for the government to decide to concentrate on only a few of those charges, and to decide not to bring charges under the PHSA.

A prosecutor makes such decisions for a variety of reasons, including the potential penalties associated with a criminal charge. For example, the maximum penalty that could be imposed on an individual for violating the PHSA is one year imprisonment and/or fine of up to \$100,000 (for a misdemeanor not resulting in death) or an alternative fine of twice the amount of gross pecuniary gain or loss. When the evidence supports it, government prosecutors frequently choose instead to bring felony charges under the FD&C Act and Title 18. The maximum penalty that could be imposed on an individual for a felony violation of the FD&C Act "with the intent to defraud and mislead" is three years imprisonment and/or a fine of up to \$250,000, or the alternative fine described above. The maximum penalty that could be imposed on an individual for violating Title 18 provisions, often charged in FDA cases such as obstruction of an agency proceeding, false statements, and mail and wire fraud, is five years imprisonment and/or a fine of up to \$250,000, or the alternative fine described above.

Because of these factors, in recent years few cases have resulted in convictions for violations of the PHSA. Older cases, in which the government successfully prosecuted violations of the PHSA, include the following:

1. *United States v. Southwestern Plasma Center, Inc., et al.* (M.D.Fla. 1976) (individual defendants sentenced to one year in prison on PHSA violations, to run concurrently with other charges);
2. *United States v. Westchester Blood Service, et al.* (S.D.N.Y. 1962) (individual defendants sentenced on PHSA violations to terms ranging from 60 to 90 days imprisonment, or to suspended sentences);
3. *United States v. Calise* (S.D.N.Y. 1962) (individual defendant received suspended sentence);
4. *United States v. Paterson Blood Bank, et al.* (D.N.J. 1963) (individual defendant sentenced on PHSA violations to nine months imprisonment).

FDA continues to refer cases concerning biological products to the Department of Justice, and the Department of Justice continues to prosecute those cases, generally under the FD&C Act felony provisions and Title 18. For example, on April 30, 2001, a defendant was sentenced to five-year probation with a five-year fine, after pleading guilty to making a false statement regarding the disposition of units of blood. *United States v. Petrik* (C.D.Ca. 2001). In connection with crimes committed by employees of the New York Blood Center viral testing laboratory, one defendant, convicted of misbranding and adulteration in violation of the FD&C Act, conspiracy, and false statements, was sentenced to 12 months and one day imprisonment. His co-defendant, convicted of conspiracy and false statements, was sentenced to six-months imprisonment. *United States v. Maniago and Gonzales* (S.D.N.Y. 1997).

Thank you again for your interest in this issue. If you have further questions, please let us know.

Sincerely,

MELINDA K. PLAISIER
Associate Commissioner for Legislation

cc: The Honorable Peter Deutsch
Ranking Minority Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Mr. GREENWOOD. Do you believe that it would be helpful to the FDA if the Congress made clearer its intent with regard to the law, and for instance, banned the creation of a human clone and increased the penalties?

Ms. ZOON. We would be happy to work with Congress and provide any technical advice that would be of assistance.

Mr. GREENWOOD. I thought that's what you might say.

The Chair recognizes the gentleman, Mr. Deutsch, for 5 minutes.

Mr. DEUTSCH. Thank you, Mr. Chairman, thank you both very much for being here and I guess listening through the last panel as well.

You heard testimony to the effect that there are people who are stating and people whose intentions seems to be to, in fact, do

human cloning, that they legally—there are no legal prohibitions to them doing that. You've obviously presented testimony directly contrary to that effect.

At this point in time what else are you doing to prevent it? What else, as a practical matter, what else are you doing?

Ms. ZOON. One of the things that—we've done several things since FDA established it had jurisdiction over this area since 1998 and one avenue we have chosen is to get letters out to numerous professional associations alerting them of FDA's jurisdiction in this area. We have also sent out letters to the institutional review boards alerting them if these activities go on that this is FDA's position and that we would have jurisdiction in this area. As I stated, any information that we get, or see in the press, or that comes to our attention from other sources—we actively follow-up on those issues.

Mr. DEUTSCH. Now again, I guess it's not so much from an FDA perspective that human cloning is illegal, but going on with the experimentation without going through your procedure is what the illegal aspect is, is that correct? It's not saying that human cloning in and of itself is described as illegal, but going through that experimentation without going through the FDA process is, in fact, what's illegal?

Ms. ZOON. The process is that if someone were to undertake experiments in which they were going to use cloning technology to clone a human being, even before they took their first steps, they would need to submit an IND, an investigational new drug—

Mr. DEUTSCH. I understand. And I guess what I say is that—I think that's a distinction which is worth really nothing because I think there's a consensus that I hear on this panel today, a total consensus, at least on this panel, if not the panel of the witnesses, that we should absolutely completely ban human cloning in the United States of America, period. And what you're saying, the only legal impediment that we're aware of right now is the impediment that they're not going through the FDA for experiments, not that human cloning is unacceptable in the United States of America, but if you want to go to human cloning, you have to go through this procedure and theoretically, if they were able to meet your standards, then, in fact, they could do it.

Again, I'm very serious, if they can meet the standards which clearly I think by any objective analysis it would be impossible that they can meet today, but if they were able to meet those standards next year, 2 years from now, you would be, in fact, compelled to allow them to do human cloning, is that not correct?

Ms. ZOON. The answer to your question is yes. Even though we don't believe that the scientific data supporting the safety would allow this to proceed, and I don't think even in the timeframe that you gave, I think there are issues not only—

Mr. DEUTSCH. I understand. But I just obviously presented a hypothetical to you.

Ms. ZOON. Right.

Mr. DEUTSCH. I think that's important for members to understand.

Ms. ZOON. Right.

Mr. DEUTSCH. Because there really is a debate going on which I think you sense from a member level about how to proceed with this and I think we've let the genie out of the bag in a sense that there really is a debate because I think there's a debate which both the chairman of the committee and myself would not want this hearing to be about stem cell research, but the reality is there is a debate about stem cell research and we don't want this hearing or human cloning to be about that. But I think if we're going to make sure that this doesn't occur in the United States of America, it would seem as if by definition we're going to have legislation. I would seem as if the FDA legally today can prevent it, in this sort of round about way, but maybe in a year or 2 years or 5 years will not be able to prevent human cloning from taking place in the United States of America if the research advances, if in fact, the types of things that clearly are not—there's no question today that the risks are unacceptable, I think by any objective scientific analysis. The percentage of embryos lost, the percentage of stillbirths, deaths, premature deaths, almost immediate deaths. There's no way you would ever prove human research in this type of statistic evidence. Impossible under any—I mean not even close. To give—I have some sense of your approval process, not even close.

But if scientific progress occurs that we can, in fact, do some of this embryo prescreening for 30,000 different genes, you would, in fact—and again, we're dialoguing, you would in fact be compelled to approve it.

Ms. ZOON. But if there were no safety issues identified and based on the scientific information, the FDA would then allow that IND to proceed.

Mr. DEUTSCH. Thank you very much. I see my time has expired.

Mr. GREENWOOD. The Chair recognizes the gentleman from Louisiana, the chairman of the committee, Mr. Tauzin.

Chairman TAUZIN. Thank you very much. Dr. Zoon, that is indeed a good place to start with your statement that absent safety concerns the FDA might allow this to proceed, right?

Ms. ZOON. Yes, based on our jurisdiction and our laws.

Chairman TAUZIN. Let's talk about your jurisdiction for a second. First of all, you've not gone through any rulemaking. The ordinary process in this kind of a matter might require well-established procedures to publish a proposed regulation in the Federal Register, to provide notice and opportunities for the public to comment. You've chosen to exercise jurisdiction through a letter to Dr. Seed in 1998, is that right?

Ms. ZOON. The FDA has had a history in the regulation of cellular products and it starts as far back as our regulation of blood and blood components and more recently in its rules with regard to the regulation of tissue which—

Chairman TAUZIN. Let's talk about the connection to this issue with those regulations. The Food, Drug and Cosmetic Act uses the term "drug" to define articles for the use and diagnosis, cure, mitigation, treatment or prevention of disease and articles other than food intended to affect the structure of any function of the body. These definitions are limited to articles. The ordinary meaning of an article is a piece of good. How is a cloned embryo a piece of goods under the FDA's jurisdiction?

Ms. ZOON. The product that the FDA is looking at here, what the FDA is regulating actually is the cells and the cellular components that would be used for the cloning technology—

Chairman TAUZIN. I would suggest that's a stretch. You did not exercise a similar jurisdiction in in vitro fertilization, did you not?

Ms. ZOON. What I would say is, sir, that we had jurisdiction over in vitro fertilization at the time when that went on. We did not exercise our regulation of that. And in fact, the FDA in 1997 proposed a tissue framework strategy which was a tiered approach based on risk.

Chairman TAUZIN. Here's my problem. My problem is that even if you've defined this tissue that's really a human being as an article under the Food and Drug and Cosmetic Act, it has to be an article that's intended, as I read the act, for the use and the diagnosis, cure, mitigation and treatment and prevention of disease and intended to affect the structure and function of the body.

Now the intended use of cloning materials is not to do any of those things, it's to produce a human being.

Ms. ZOON. There are several aspects of this and I can talk to several because we're talking about two acts—

Chairman TAUZIN. I'll ask you about the second act in a minute, but be brief because I have but limited time.

Ms. ZOON. Okay. The treatment here would be presumably infertility, in that case, and with the intention of producing a human baby. So that we believe that the cells and the cellular therapies and the components are the integral part—

Chairman TAUZIN. Now staff tells me and my reading of the act tells me this is a very tenuous hold on it and I'm deeply concerned about whether or not that would hold up in court. Under the PHS Act that section that you claim to have jurisdiction over, 351, applies to any virus, therapeutic serum, toxin, blood component or analogous product which would be applicable to the prevention, treatment or cure of diseases or injuries.

The FDA apparently claims that a cloned human embryo is an analogous product. How do you do that?

Ms. ZOON. Because many of the products we regulate are cellular therapies and in fact, in 1997, Congress changed the Act to—

Chairman TAUZIN. But a child is not a cellular—

Ms. ZOON. [continuing] include not only a disease, but also condition. I think that's important to point out.

Chairman TAUZIN. But you keep tying the jurisdiction, the jurisdiction over cellular products and I must tell you I have a grave concern as to whether or not the law would recognize jurisdiction over a whole human being because you have jurisdiction over bloods and toxins and cellular products. I'm concerned about that. I'm concerned enough to wonder why when Dr. Seed announces in the press that he's going to do this, you react immediately and send him a letter saying you need an IND, and yet when the Raelians in October announced that they're well-funded and prepared and 50 women have volunteered to carry these cloned embryos, they don't get a letter until Monday when this hearing is announced?

Why shouldn't that give us real cause to be concerned about how seriously the FDA is taking this issue?

Ms. ZOON. When we found out about the website, we started our investigations and——

Chairman TAUZIN. You sent Dr. Seed a letter within 2 months.

Ms. ZOON. Yes, because——

Chairman TAUZIN. The Raelian group says they have the money, the volunteers, they're going forward, no letter until Monday. Tell me, what was the delay all about?

Ms. ZOON. There are multiple parties involved with Clonaid which is the group and the agency was trying to identify——

Chairman TAUZIN. Did you have problems finding addresses?

Ms. ZOON. [continuing] where they were.

Chairman TAUZIN. We contacted them within an afternoon. When we decided we wanted them here, we simply used the phone directory and contacted them, got names, addresses and notified them we'd like them to be here. Why did the FDA have so much trouble finding addresses?

Ms. ZOON. Well, sir, we were investigating. I think the information and the increased visibility of these activities since the 60 Minutes show did, in fact, reveal different additional information that helped our investigators locate these folks.

Chairman TAUZIN. I just want you to know that when our staff using a phone directory can locate him in an afternoon and since October you can't send him a letter until this Monday, that it raises the level of our concern about the FDA's attention and serious regard for this issue.

I must tell you, Mr. Chairman, I'm deeply concerned about the tenuous nature of the FDA's assertion of jurisdiction here and I, like you, wonder what would happen if somebody started a project here in America challenging the FDA's jurisdiction and implanted cloned embryos in a whole group of volunteers as to what on earth you could or would do about it. And if anything, your testimony has raised our level of interest in legislating to a much higher degree.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The gentleman's time has expired. The Chair recognizes the gentleman from Illinois, Mr. Rush, for 5 minutes.

Mr. RUSH. Thank you, Mr. Chairman and Mr. Chairman, I think the chairman of the full committee had some very, very insightful points and I want to just kind of piggyback on some of his questioning.

Dr. Zoon, do you believe that the FDA's authority in this area needs to be strengthened through a more explicit statement of its jurisdiction, i.e., through legislation?

Ms. ZOON. Sir, I believe FDA does have jurisdiction over the scientific areas regarding using cloning technology for the purposes of creating a human being. If Congress would like to strengthen that, we'd be happy to work with you.

Mr. RUSH. Well, the chairman of the full committee mentioned situations before where your jurisdiction was question, for example, it brings to mind tobacco, the tobacco industry.

Do you think it is clear that the FDA has jurisdiction and authority over the regulation of human cloning and why and do you think that it would be defined well enough to withstand in an abbreviated time period court challenges? And I'm concerned because in the tobacco industry FDA was hauled into court for multiple

years and we certainly want to avoid the same type of situation if we are brought into court over the issue of cloning.

Do you feel as though you have jurisdiction, adequate jurisdiction and why and whether or not do you feel this jurisdiction is proper enough and strong enough and legal enough to withstand immediate challenges in court, in the courts?

Ms. ZOON. Based on FDA's analysis, we believe we do have jurisdiction. The issue you raise is would it stand up in court, if challenged. We believe we could make our position very strong. Would it guarantee we would prevail? I don't think I could give you that guarantee. I think the FDA could make a very good case.

Mr. RUSH. Well, in a statement, in a document rather attached to Mr. Wicker's statement and I think he's going to testify on the third panel, he remarks that FDA's regulation and I quote "are just fluff and have no real weight. They would not withstand any legal challenge. Ask any knowledgeable lawyer about that. Cloning is not a food, nor is it a drug."

In Mr. Eibert's testimony he remarks that "virtually every lawyer on both sides of this debate agrees that FDA has no such authority over cloning under current law."

Now you have disagreement already about the nature of your authority and whether or not your authority is strong enough. Can you respond to those comments?

Ms. ZOON. I would just say there's always disagreement. If the Chair would wish and if the Congressman would wish, Ms. Kate Cook, who is knowledgeable in the specifics of this, could come up to speak more. I'd be happy to have her come up here.

Mr. RUSH. Mr. Chairman?

Mr. GREENWOOD. I'm sorry, yes. I'm the new chairman. I'm not used to responding to that.

Mr. RUSH. I see. Mr. Chairman, she indicated that there's another witness that could be brought to answer some of these specific questions about—

Ms. ZOON. Jurisdiction and I'm asking permission if it's okay.

Mr. GREENWOOD. That person would have to be sworn in. The other option in the interest of time since there's a vote is perhaps the questions could be submitted in writing and responded to in writing.

Mr. RUSH. That would be good. I have one final question. If, in fact, cloning is not conducted, doesn't take place within the continental United States and it takes place on foreign territory, on foreign land, is there anything that the Congress could do to ensure that American services and/or products would not be—could not be utilized or that anyone would be prohibited from utilizing services and/or products, pharmaceuticals, anything that's manufactured here in the United States to promote cloning in other places?

Ms. ZOON. I think as far as FDA's jurisdiction in this area goes, we do have regulatory jurisdiction over various equipment and drugs that could be used in this procedure, but whether or not the agency could take action with regard to their export would very much depend on the situation, the type of equipment and drugs that are being exported and how they're labeled. So I think the answer to your question is right now, FDA would have some jurisdiction, but it would really depend very much on a number of factors.

Mr. GREENWOOD. The time of the gentleman has expired. The Chair recognizes the gentleman from Oklahoma for 5 minutes.

Mr. LARGENT. Thank you, Mr. Chairman. It was Benjamin Franklin, I believe, who plagiarized actually a phrase, a Latin phrase, *e pluribus unum* that we've adopted in this country which means out of many, one. I don't think this was what he was referring to when he adopted that phrase. Sometimes, but rarely, we are asked to address issues that can kind of shake the core of who you are as we catch glimpses of where this all may be leading us to and I think this is one of those areas. I think that this holy ground, frankly, that what we're talking about is not cellular products. What we're talking about is the creation of an eternal soul and I think it's best that we tread lightly on this and reverently.

My question is very simple and I'd like to ask you, Dr. Zoon and Dr. Murray, take off your FDA hat, take off your Federal Government hats and represent just you, as doctors, given your experience, your education, your families. Should Congress ban human cloning reproductive activity in this country, yes or no.

Dr. Zoon?

Ms. ZOON. I believe that Congress—

Mr. LARGENT. It's just a yes or no. Yes, we should or no, we shouldn't? This is your—you're not speaking for FDA now. I'm asking you to take that hat off and speak for yourself personally. Should we ban the topic of this hearing this morning in this country?

Ms. ZOON. My opinion on this is I do not think human cloning should proceed in this country at this time.

Mr. LARGENT. So that would be a no. Thank you. Dr. Murray?

Mr. MURRAY. I think it's a yes.

Mr. LARGENT. You're right. It is a yes. I got confused. Yes, we should ban it.

Mr. MURRAY. And Ben Franklin would be turned on his head, it would be many out of one. I think that's what cloning purports to do.

Speaking as a parent and husband and child and thinking about what we value in those relationships, I think human reproductive cloning at this time, it ought to be prohibited and I agree with the recommendation the President's Commission made in 1997, that there ought to be legislation to prohibit it and that the legislation ought to have a sunset clause so that we should come back and revisit this once there's been a wider public consideration of the larger moral issues.

Mr. LARGENT. Thank you, Dr. Murray. Thank you, Dr. Zoon.

Mr. GREENWOOD. I thank the gentleman for yielding. I thank the panel for testifying. I would suggest that Michael Jordan is probably a pretty good accountant as it is. And I call the next panel: Dr. Caplan, Director of the Center of Bioethics, University of Pennsylvania; Dr. Gregory Pence, Ph.D., Professor of Philosophy, School of Medicine and Humanities; Dr. Nigel M. De S. Cameron, Ph.D., Principal, Strategic Futures Group; Dr. Mark Donald Eibert, Esq., the law offices of Mark Eibert; Sharon Terry, M.A., Genetics Alliance, Inc.; Mr. Randolfe Wicker, Founder, Clone Rights United Front, Spokesman for the Human Cloning Foundation; Dr. Michael Soules, President of the American Society of Reproductive Medi-

cine; Mr. J.D. Hanson, Assistant General Secretary, General Board of Church and Society, the United Methodist Church; and Rael, leader of the Raelian Movement, United States Raelian Movement. Please come and for everyone's benefit, what we're going to do is swear in the witnesses. I'm going to ask Dr. Caplan to testify first, since he has to catch a train and then we're going to recess briefly so the last of us can vote.

I am going to ask all of the members, as the members are being seated, I address this question to you. You are aware that the committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath. Do any of you have objection to testifying under oath? Seeing no affirmative responses, I then advise you that under the rules of the House and the rules of committee you are entitled to be advised by counsel. Do any of you desire to be advised by counsel during your testimony? Again, seeing no affirmative responses, I would ask that you please rise, raise your right hand and I'll swear you in.

Do you swear that the testimony you are about to give is the truth, the whole truth and nothing but the truth?

Thank you very much, you may be seated.

[Witnesses sworn.]

The Chair recognizes Dr. Caplan for 5 minutes for his testimony.

STATEMENTS OF ARTHUR L. CAPLAN, DIRECTOR, CENTER OF BIOETHICS, UNIVERSITY OF PENNSYLVANIA; GREGORY PENCE, PROFESSOR OF PHILOSOPHY, SCHOOL OF MEDICINE AND HUMANITIES, UNIVERSITY OF ALABAMA AT BIRMINGHAM; NIGEL M. DE S. CAMERON, PRINCIPAL, STRATEGIC FUTURES GROUP; MARK D. EIBERT, THE LAW OFFICES OF MARK EIBERT; SHARON F. TERRY, GENETICS ALLIANCE, INC.; MICHAEL R. SOULES, PRESIDENT, AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE; RANDOLFE H. WICKER, FOUNDER, CLONE RIGHTS UNITED FRONT, SPOKESMAN FOR THE HUMAN CLONING FOUNDATION; JAYDE HANSON, ASSISTANT GENERAL SECRETARY, GENERAL BOARD OF CHURCH AND SOCIETY, THE UNITED METHODIST CHURCH; AND RAEI, LEADER, RAEIAN MOVEMENT

Mr. CAPLAN. Thank you, Mr. Chairman. I apologize for having to run out of here quickly and I'm going to penalize myself. I've submitted written testimony to the committee, tried to acknowledge the importance of this hearing and I know that the Chair has a personal interest in families and children that's longstanding and I think it's simply appropriate that this hearing be held now.

I would like to make four points, basically, if I can, about where we're at with respect to human cloning. It seems to me the evidence on safety ends the discussion. There should not be human cloning. It's not safe. The data from animals ends that discussion. No reputable person other than cults, cranks, kooks and capitalists seems to believe that the science is there to undertake human cloning. Whether it ever will be possible to clone a human being remains in some doubt. It may be that biology doesn't let us do what science fiction writers and Hollywood sometimes dreams about.

Be that as it may I think there are then some questions to be asked about cloning and the ethics of cloning that we haven't heard much about and I'll just introduce two points. I think No. 1, from where I come at this issue at, there are ethical issues separate from safety and I just want to introduce the two that I think are the most important. Some would argue that we should not outlaw, ban or restrict human cloning because it is a restriction on reproductive rights, on the ability of people to have children and that's not appropriate to do.

However, I would argue that that view is wrong, that reproductive rights do extend to being left alone, not interfered with, having a zone of privacy about one's behavior, but they don't extend to the entitlement to have a child or the entitlement to the means to have a child. There are many people in this world, I was once one of them who have no mate, who have no spouse, who would possibly want to reproduce and the government does not supply them, last time I looked with a wife, a mate, a concubine or some means to reproduce.

We all know that there are innovative ways to reproduce as well, sometimes you build families by adoption. The government deems in its wisdom appropriate that when a child is created and brought into this earth in a new type of environment that it will have some jurisdiction over who can do that, the means they must have, the abilities they must demonstrate.

In other words, it is not an inappropriate role for this Congress to legislate with respect to human reproduction if we're going to try and look out for the interest of children. The interest of children is the driving question that takes us outside of safety. If we're going to make children in new ways, using technology, if we're going to put them into situations that they've been in before, looking like others, if not being the same as others, if we're going to have them made asexually and be the products of single parents, it seems to me that government appropriately should be able to regulate this area.

Second point about the ethics of cloning. I said the driving interest should be in my opinion, is it good for the child and I believe that the jury is out on that. If you are made in the image of someone else, if you know things about how you will look and appear and what genetic risks you will carry with respect to health and disease, I would suggest your future may, it doesn't have to be, but it could be limited, restricted and your life made more miserable than it otherwise would have been had you been born by ordinary means and have your future open before you.

To put it simply, whether or not you are the same as the person who cloned you, many will treat you that way, whether or not you are the same as the person who clones you, you will look and age and succumb to certain genetic problems that have afflicted your parent and you may be able to have less of a life, less freedom, less opportunity to be who you want to be than we would normally say is appropriate for human beings. Those two reasons, I think, give us some reason to move toward perhaps saying that human cloning not only should not happen now, because it's not safe, that it should never happen because it's not good for the child.

I believe that there's another area of concern that people raised that I would just like to mention and that is well, why bother to regulate or legislate, how do we know that someone won't go on an island or in a distant land or somewhere and do this anyway?

I think, Mr. Chairman, that this committee despite the interest of the FDA in exercising its authority can send a clear message to the world by putting penalties in place that are severe and clear about what is wrong with human cloning that will be heard around the world in every nook and cranny, the premier scientific and technological Nation on the globe, if it says that human cloning is wrong, leave the decision to revisit that statement or not some time down the road will be heard everywhere.

Does it mean that no one will break the law? No. No more than having laws about speeding or killing or anything else mean that people won't do them, but it is very clear that the reception that will greet someone who tries to do this will be one of disapprobation and penalty. It seems to me that is exactly why this nation, since it is the world's science and technology leader, should make a clear national statement that human cloning is to be banned.

Last, I would like to conclude these remarks with a thought, if you will, about why it is that human cloning policy, I think, should be made here and not at the FDA or anywhere else. At the end of the day we are talking about human reproduction and I listened to the previous panel and some of the questions put to the FDA representative and I do believe that FDA has a role to play in regulating experimentation and the use of new biological materials. As the Chair knows I have another hat that I wear as the chairman of the advisory committee on Blood Safety and Availability. I deal with the FDA on those blood products and many of those substances trying to keep the blood supply safe. That's not what making people is about.

Congress should exercise its authority and say we understand the special nature, the respect, the special moral status that attends to human reproduction and we are going to put that under our ambit, not a bureaucracy, not a regulatory agency, but we representing the people of the United States are going to say clearly that certainly for now and I believe for the foreseeable future, human cloning is not only unsafe and ought not be pursued on scientific grounds, it is morally undesirable to do it, until we have a lot more clear evidence that it will be good for those made in that way.

Thank you.

[The prepared statement of Arthur L. Caplan follows:]

PREPARED STATEMENT OF ARTHUR L. CAPLAN, TRUSTEE PROFESSOR AND DIRECTOR,
CENTER FOR BIOETHICS, UNIVERSITY OF PENNSYLVANIA

Mr. Chairman it is an honor to have the opportunity to testify to this committee. I have long hoped that the Congress would hold hearings on the subject of human cloning and I am very pleased that Congressman Greenwood, who has long been a leader in protecting the interests of children and families, has deemed it important to do so.

Will Human Cloning Happen Any Time Soon?

This Committee has deemed it important to meet to discuss human cloning because there is a strong perception current in our society that human cloning will soon take place. This perception is fueled by four factors.

There has been progress in the cloning of animals with a number of species now having been cloned. This makes it seem as if we are moving rapidly and inexorably up the evolutionary ladder toward the cloning of human beings.

A number of groups and individuals have announced that they intend to try to create human clones. These announcements lend some urgency to the need to decide what the government should do about human cloning.

The media has contributed to the perception that human cloning will soon occur with a flurry of reports and stories, many feeding directly off one another and reinforcing one another about these pronouncements. The New York Times Magazine, Wired magazine and many other journals and television programs have stated that human cloning will happen in the very near future.

And, lastly, there is a very strong belief in our society that science and technology cannot be controlled. Senators, opinion leaders and editorialists have all been hard at work assuring the public that once the genie is out of the proverbial bottle there is no way to reign it back in. Cloning is the genie and Dolly was the bottle. Human cloning must be right behind.

I do believe that it is important to examine the need for regulations concerning human cloning. My view is that the Federal government should pass legislation declaring a complete moratorium on all cloning intended to create human beings. I think that this ban should be imposed until such time as the Food and Drug Administration is convinced that animal studies on many species including primates shows that human cloning is reasonably safe with a high degree of probability. I should add that I do not believe there is any reason for the government to take any action with respect to the cloning of cells, tissues or organs for medical and therapeutic purposes. But, my reasons for these opinions have nothing to do with the prospect of imminent human cloning. I do not believe the cloning of human beings is imminent.

While it is true that some animal species have been cloned the ability to successfully clone animals is severely limited. The failure rate among cloning attempts can best be described as embryonic and fetal carnage. Of the embryos that make it to birth many are born dead, many others are deformed and others still severely disabled. The only thing that work to date on animals convincingly shows is that the cloning of human beings at any time in the next few years would be completely immoral, unethical and barbaric human experimentation undertaken for no purpose other than publicity or to be the first to win a race that there is no need to hold—who can make the first human clone.

Not only does animal work not support the idea that human cloning is just around the corner neither do the pronouncements of any current group or individual. To date a collection of kooks, cranks, cultists and con-men have been the sole members of the club announcing that cloning will soon be used to make a human. No one and I mean no one who has any real expertise in cloning has made any such statement. No one and I mean no one with any real expertise in cloning believes that human cloning is imminent. The media has simply got the story wrong. Human cloning has been irresponsibly hyped using the pronouncements of persons who have no skills or abilities or track record with respect to cloning to fuel that hype.

In fact, it is just as likely that the successful cloning of a health human being will never occur as that it will. The biological problems inherent in using “old” DNA to make new organisms may not permit the creation of healthy human beings.

The Time For a Moratorium Is Now.

The fact that cloning will not be used any time soon to make human beings does not mean that this committee should not recommend that Congress enact legislation to insure that the inept and the irresponsible do not try. On the contrary the primitive nature of cloning technology is precisely why Congress must act. Congress should act to place a moratorium on cloning until the FDA is satisfied that animal work provides a reasonable basis for undertaking human trials. This will clearly send the simple message that until those who know what they are doing can show that they can clone animals with a reasonable success rate and which are healthy and vigorous attempts at human cloning will result in severe fines and time in prison.

There are those who will say that any effort at legislation is pointless since the bad guys will not obey the law and since you cannot reign in technology once it has emerged. Both arguments are simply poor arguments.

Of course bad people will break the law. But if we adopt the view that we will only pass laws that everyone will follow at all times then we will have no laws about anything. In one sense laws are made precisely because there are those who may seek to do immoral things. A tough law banning human cloning until the FDA states that the technique is safe makes it clear that there is a price to be paid and

a severe for breaking that law. By acting quickly to issue simple and clear regulations Congress also sends the message to the world that the world's premier scientific and technological society believes no one anywhere should undertake human cloning without much more research on animal and cell cloning. This message will ring loud and clear across the globe—even on the proverbial off-shore islands and remote jungle locations where so many seem convinced that cloning companies are or will soon begin operation.

Can the law really regulate technology? Of course it can. It already does. In human experimentation there is a complex set of laws that have worked to limit and restrict various kinds of inquiries for decades. In the United States embryo research and fetal tissue research have proceeded at a snail's pace. Work on xenografting has stalled due to regulatory and legal concerns about safety. The point being that science is no less amenable to control by society than any other human activity. What is needed is the will to steer and control science and technology—a will that has been all too often lacking in our society when it comes to genetics and reproductive technologies.

What Happens If Cloning Is Shown to Be Safe?

Not only will human cloning not occur soon if at all, it will never, even if it is shown to be safe³, become an important method for creating human beings. There are a number of reasons for my making this claim. The most important is that when it comes to reproduction human beings will prefer sex with another to spending a few hours and tens of thousands of dollars at a fertility clinic. If the choice is sex or a Petri dish bet on sex.

Those who favor allowing human cloning or who want to promote it argue that cloning may still help some people. Human cloning can be used to bring back deceased loved ones, to allow some of us to achieve immortality or to solve the chronic shortage of vital organs that results in so many otherwise preventable deaths.

Cloning can do none of these things. Cloning can no more bring back the dead than can owning a videotape of a deceased person. Genes do not control our minds and our thoughts. Clones are people made in an unusual manner. But they will have their own feelings, thoughts, free will and if you like—spirits or souls. Replicating a person's genes does not replicate the environment and the developmental that make the person who they are. It is simply impossible to step in the gene pool twice.

Evidence that having the same genes does not make us the same person is all around us. Human clones already exist. They are Even identical twins who have all their genes in common. Twins also are usually raised in a relatively common environment by the same parents. Yet they are not identical copies of one another. They do not have the same thoughts and feelings and do not make the same life-choices and plans.

Specially created human clones will have free will. Clones are simply people made in a never before seen way. But they are still people who will grow and develop. Bet on this—teenage human clones will not want to do or be what their parents wish they would any more than any other teenager born by more conventional means is or does exactly what their parents want them to do. So you cannot replace a lost child or loved one by cloning. Nor can you be immortal by cloning yourself any more than you can be literally immortal by having a child.

And making human clones will not solve the organ shortage. The clones will have every right to consent to having their organs removed, just as you and I do now despite the fact that someone may well need our kidney or a piece of our liver.

The most poignant claim made on behalf of cloning is that it will help the infertile have children. But the infertile can already have children through adoption, artificial insemination, and in vitro fertilization. Sterile men and women, gay men and single mothers have all had children using current techniques. Cloning would add another type of treatment for infertility but for nearly all of the infertile it would do nothing more than add a new option. It is not a breakthrough in the treatment of infertility.

Two Fundamental Problems with Human Cloning

Presume that cloning is safe. Presume too that very few people will want to clone themselves. Are there still any fundamental moral reasons why cloning a human being would be wrong?

One problem with cloning someone is that they will be made in the biological image of another person who has lived before them. They will know much about their appearance. This will lead others to have very strong expectations and reactions to them especially in an appearance conscious culture such as ours. The clone

may find that it is a terrible emotional burden to be a lookalike of someone who is twenty, thirty, fifty or eighty years older.

And others will have a hard time reacting to the commonality of appearance that clones will have with their parents. Some will see their former wife or husband reappear as they were in their youth. Some will find themselves puzzled over how to relate to a family member who looks like their mother but is actually a sister or a granddaughter.

In addition to these psychosocial issues cloning threatens to rob a person of their future. Because biology does dictate much about our health and many of our general capacities and abilities a clone will know much about what lies in store for them. A clone is the unconsenting subject of the most comprehensive genetic testing possible. While some may be able to adapt to this many other may find it more than they can bear. Even today many people when given the choice of knowing the results of a single genetic test prefer not to know for fear that the knowledge would make their lives hell. What would the impact be of not knowing one genetic test result but thousands of them on a child or young adult?

Cloning may be something that some persons choose to do. But government may still find that while it respects the rights of people to reproduce without interference it does not grant the right to people to use technologies that stand a high risk of creating people who are miserable or psychologically harmed. Cloning may simply not be good for humans, psychologically, emotionally or in terms of their own self-esteem and peace of mind.

So the day may come when Congress decides to convert a moratorium on human cloning into a ban on human cloning. Just as we severely restrict who it is that can serve as a foster parent or adoptive parent, just as we do not permit parents to do things to their children that traumatize them, Congress may decide that cloning is simply too risky a technology for making people.

But that day is far off. Today Congress should simply put cloning off-limits. The kooks and the cultists and the cranks and the con men can find otherways to prey on our fears. The media can strive to restore some balance to the public's anxiety about human cloning. Scientists can continue their efforts to use cloning to engineer cells and tissues and animals, which is where the real value of cloning lies and will always lie. And the ethicists and theologians and thought-leaders can strive to insure that our schools and religious institutions, and state legislatures and civic organizations are filled with spirited dialogue and debate about where we want human cloning to go if anywhere when and if it proves safe to try as a way to create a new member of our species.

Mr. GREENWOOD. Thank you, Mr. Caplan for your testimony and you are dismissed sir, for your transportation needs.

I have about 30 seconds to vote. This hearing will be recessed for 15 minutes.

[Brief recess.]

Mr. GREENWOOD. Again, with apologies to all concerned, the committee will reconvene and Dr. Pence, thank you for your patience throughout the afternoon. You are recognized to present your testimony, sir.

STATEMENT OF GREGORY PENCE

Mr. PENCE. Thank you, Mr. Chairman, for inviting me to testify today. I've been a proponent, philosophically, of human cloning when safe for about 3 years now and I have just a few points to make today.

One, I think the language is real important. I think to talk about the clone or the human clone, these are slightly negative phrases, almost question begging and kind of like referring to women as chicks. I would prefer talking about a delay twin or even better, a person originated by cloning, just so the language doesn't throw us.

I've taught and written about medical ethics for 25 years in the Medical School in Birmingham and so some of the philosophical issues here have a sense of deja-vu to me. In the early 1970's many people opposed test tube babies because of fear of harm to the fam-

ily, to children and to society. And some of the same critics on philosophical grounds, oppose human cloning today.

Today, we have over 100,000 American babies created through test tube technology or assisted reproduction and I'm glad that the philosophical objections weren't listened to 25 years ago, else those babies wouldn't exist today.

I also want to point out that 25 years ago 80 percent of Americans were against test tube babies and now the figure have reversed.

What can we learn from this experience? First, it was predicted that test tube babies would be regarded as products or as commodities by their parents. That, in fact, did not turn out to be true. Because of the effort and the costs that the parents went through, those babies today are probably some of the most loved babies around.

To me, there are two essential questions here. One, is it safe? And two, the more philosophical question, is it intrinsically wrong?

As for whether cloning is intrinsically wrong I believe that if 1 day it becomes safe, there will be nothing intrinsically wrong about this process. I believe it will be just another way of creating a family, just like in vitro fertilization and indeed it might be a way of creating a family and avoiding hereditary genetic disease.

Now to the question of safety. There's really two questions of safety. One is psychological harm and one physical harm. As far as psychological harm here, I think most of the criticisms that have been given are fairly speculative and stem from science fiction and pop psychology. It was also predicted that test tube babies would be harmed and there would be prejudice against them or they would be traumatized by being born in a test tube, all that, of course, turned out to be wrong. The only real requirement was the happiness of—the happiness of children is loving parents.

Now for the physical danger. I've always argued that children should not be originated by cloning until this process is as safe as sexual reproduction. Sexual reproduction has a rate of abnormalities of about 1 to 2 percent. Until about a year ago, the evidence was still, I think, up in the air that human cloning could be as safe as that. However, recently, the latest data and especially those unpublished data of Dr. Jaenisch was really one of the leaders in the field about molecular biology and the reprogramming and expression and Mark Westhusin is also a very recognized expert in animal cloning. These are fairly devastating, I think, about safety. So I think it is premature to proceed at attempts to originate humans by cloning now, but I would add this caveat. Four years ago, we thought it was a law of nature that once cells became differentiated they couldn't become undifferentiated. At first we thought Dolly was too old and then we learned that maybe she's too young. We thought we could only do a sheep, but couldn't do a frog or a cat, so the science is moving very rapidly and it might change a couple of years down the pike.

So the really interesting question is should we make this a Federal crime at this point? Having some experience in this field I remember that 20 years ago, Congress banned Federal funds from being used for embryonic research when it was concerned about test tube babies and other things. Over subsequent decades, sci-

entists tried to get this ban overturned, but it was very, very difficult to do so. I believe that if human cloning were similarly made into a Federal crime and the scientific evidence changed, it would be very, very difficult to undo.

To make an analogy here, we now know that bone marrow transplantation for breast cancer, many women went through this procedure. It was fairly horrible. Part of the data was based on fraudulent studies. Most of the data, I would say 96 percent of the data now says doing a bone marrow transplantation for breast cancer is not effective and shouldn't be done. But some physician might choose to go ahead and do that. Do we want to make that a Federal crime? Does every person who goes against the evidence in medicine, does that have to be a Federal crime?

Finally, philosophically, if government bans attempts at human cloning because of worries about developmental defects, I worry about the intrusion of the Federal Government in the private life. I'm not a legal scholar, but I'm not sure there's anything in the U.S. Constitution that gives the Federal Government as opposed to the State government the right to tell people how to originate children and why. Also, as a result of the human genome project, more and more fetuses are going to be tested for genetic diseases, more parents will learn their fetuses carry genetic defects. These are certain defects, not probable like in cloning. And it's important if some people decide to carry such fetuses to term. If the worthy aim is to prevent defects to children and the mighty power of the Federal Government is going to come in here, won't logical consistency force us to encourage or even require abortions of fetuses with such defects? Do we really want to open this door?

If the best interest of children is the moral criterion here for bringing in the Federal Government, then maybe we should make it a Federal crime to drink and smoke during pregnancy. You open a fairly big door here.

One final point. The reverse of this is also interesting. Let's suppose the scientific data really does change. Let's suppose that 1 day cloning is safer than sexual reproduction. Does that mean that we would ban sexual reproduction for the good of children?

Thank you.

[The prepared statement of Gregory Pence follows:]

PREPARED STATEMENT OF GREGORY PENCE, PROFESSOR OF PHILOSOPHY, SCHOOLS OF MEDICINE AND HUMANITIES, UNIVERSITY OF ALABAMA AT BIRMINGHAM

Thank you, Mr. Chairman, for inviting me to testify today. I believe that phrases such as "the clone" or "the human clone" are prejudicial, like "chick" or "queer" and should be avoided. I believe that the phrase "delayed twin" is much less question-begging.

Mr. Chairman, I have taught and written about medical ethics for nearly 25 years in the medical school in Birmingham. In the early 1970's, all bioethicists except Joseph Fletcher opposed "test tube babies" for fear of monsters, harm to families, and harm to the identity of the children created. Many of these same critics today oppose human cloning. Now over 100,000 American babies exist—200,000 worldwide—who would not have existed had these critics won. Back then, over 80% of Americans opposed test-tube babies; now the same percent of Americans support such efforts.

What can we learn from this experience? First, such babies were not viewed by their parents as the critics predicted, that is, as "commodities" or as "products." Instead, and because of the effort and cost that the parents endure, these children are very, very loved.

To me, the essential moral question is whether human cloning is intrinsically wrong. But how can a new way of creating a family be intrinsically wrong? How can a way of avoiding hereditary genetic disease be intrinsically wrong?

If it is not intrinsically wrong, then we must ask whether it is wrong for some other, associated reason, mainly, whether a child created by cloning would be *harmed*, psychologically or physically.

I believe that questions of psychological harm here are entirely speculative and stem from science fiction and pop psychology. I believe that how children are originated has little to do with their future mental health. The real requirement for the happiness of children is loving parents.

As for physical danger, I believe that children should not be originated by cloning until this process is as safe as sexual reproduction, which now has a roughly 1-2% rate of abnormalities. At the moment, Mr. Chairman, I believe it is premature to proceed with attempts to originate humans by cloning, but continuing research and advanced screening techniques for embryos may one day achieve safe results. Until then, I believe that families and physicians should be allowed to handle such matters without being subject to criminal penalties.

Over twenty years ago and partly in response to worries about assisted reproduction, Congress banned federal funds from being used for embryonic research. Over subsequent decades, many scientists tried to get this ban overturned, but it was very difficult to do so. If cloning were similarly banned or criminalized, it would be very difficult to ever undo such prohibitions—no matter what science later learned. Let us learn from the past and not repeat its mistakes. Let us leave such matters to physicians, scientists, and families, not to the federal government.

Finally, if government bans attempts at human cloning because of worries about developmental defects, will such a ban be the first step toward greater federal intrusions? As a result of the Human Genome Project, more fetuses will be tested for genetic diseases and more parents will learn that their fetuses carry genetic defects. Only instead of *probable* or *likely* genetic defects, these babies will have *certain* defects. Here it is important that some couples decide *not* to abort such fetuses and decide to carry them to term.

In this situation, and for the worthy aim of preventing such defects, will the same government be forced to encourage or even *require* abortions of such fetuses with genetic diseases? Doesn't the same goal and the same expansion of federal power justify both intrusions into reproductive freedom? If our moral criterion is the best interest of future children, how can government ban reproduction for *likely defects* but not for *certain defects*?

The reverse of this point is also interesting. If preventing defective children justifies federal intervention in the bedroom, and if cloning one day becomes *safer* than sexual reproduction, will cloning then be the *only* required way to have children—based on the good of future children?

Thank you, Mr. Chairman, for allowing me to testify today.

References:

Gregory E. Pence, *Re-Creating Medicine: Ethical Issues at the Frontiers of Medicine* (Rowman & Littlefield, Lanham, Md. 2001) (on the effects of the ban on federal funding of embryo research).

Gregory E. Pence, *Who's Afraid of Human Cloning?* Rowman & Littlefield, Lanham, Md. 1998) (on irrationalities about cloning humans).

Gregory Pence, *Classic Cases in Medical Ethics: Accounts of the Cases that Shaped Medical Ethics*, 3rd edition, McGraw-Hill, 2000 (on the history of assisted reproduction and past controversy).

Mr. GREENWOOD. Probably not.

Dr. Cameron.

STATEMENT OF NIGEL M. DE S. CAMERON

Mr. CAMERON. Thank you. I'm Nigel Cameron. I'm a consultant in bioethics. I serve as Executive Chair of the Center for Bioethics and Public Policy in London and also as Dean of the Wilberforce Forum in Reston, Virginia.

In human cloning we confront the quintessential question faced in bioethics as we address so many issues in which the promise for good and the promise for harm needs to be weighed by the human community. The means of human procreation itself, all of a sudden

lies in our hands. And we face a watershed as we address this question in the contest of public policy.

Now the field of bioethics, of course, is a meeting point for various disciplines of technology and science and medicine and policy and ethics and within the framework of the Hippocratic medical tradition, which is still widely acknowledged within our Judeo-Christian culture, the challenge is to make policy which will frame the values of the community as the values for bioscience.

It's been said that if it isn't possible for us to do this in the case of human cloning, it is very hard to say what issue we will be able to address effectively within the policy context.

Now I've been asked to talk about the international approaches to this question and then I shall offer one or two brief comments of my own.

Several nations, as has been noted, has enacted bans on human cloning, statutory bans, since the Dolly experiment and yet, it was in Germany in 1990 anticipating all of these developments that the most significant legislative move was made in that a statutory ban on human cloning was enacted in advance with a 5-year penalty of imprisonment in that one nation, of course, which has as we were reminded briefly in the movie, in 60 Minutes, which we were reminded, has had its own national experience of bioscience gone wrong.

Other nations have been noted. There's a bunch of nations around the world now, Ireland, Israel, Italy, France, Argentina, Colombia, Spain with legislative process in other nations including Canada.

But second, I want to draw attention to the one international treaty on bioethics, the European Convention on Biomedicine and Human Rights. I'm interested that this document has not been referred to yet. I was pleased that my thunder wouldn't be entirely stolen and there is a copy of the European Convention attached to my testimony.

The Convention adopted in 1997 appropriately 1 year after the announcement of Dolly, in the year of Dolly's announcement, open for signature then, seeks to bring together the issues in biomedicine and the European human rights tradition and international law. And sets them together in the title of the treaty which is one of the Council of Europe Treaty series. The Convention adopts the European principle of subsidiary in allowing a lot of freedom to the nations to interpret it and apply it, but the convention does ban human cloning. Specifically, intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited. That is the primary language of the treaty. As of today, 29 European states have signed the protocol and it actually came into force on March 1 of this year after ratification by the first five nations.

I have one or two brief closing comments. One, there's a fundamental need for development of public policy in our address to the issue of biosciences and this a question which has been referred to and we are way behind the curve and we need to address these questions urgently as a whole because, of course, this is one of the simpler questions being raised as the biosciences develop.

Second, one of the reasons for doing that, one reason why the biotech industry itself has an interest in policy is the need to develop public confidence in these technologies and so to avoid, for example, repetition of the European experience, with genetically modified food, where something akin to a peasants' revolt has led to handwritten signs in restaurants and shops all over Europe saying we don't stock GM food.

Third, the overriding significance of a single principle in this discussion, that of the dignity of the individual. It is this question which lies at the heart of every one of these questions and this question which makes this a priority question for public policy and not a matter simply for private commercial or other decision-making.

And then fourthly and finally, the significance of the need for international agreement. This has been referred to by various contributors and it's the one point at which I find myself in agreement with Dr. Zavos, that human dignity, like the world of bioscience, is indivisible and that if we cannot address these questions as a world community finally using the European Convention, using a current UNESCO process which parallels that Convention, then we shall finally be unable to address them as one human community.

Thank you, sir.

[The prepared statement of Nigel M. de S. Cameron follows:]

PREPARED STATEMENT OF NIGEL M. DE S. CAMERON, CONSULTANT IN BIOETHICS AND PUBLIC POLICY

In human cloning we confront the quintessential question of the new bioethics. The challenge it poses is emblematic of the new bioscience and its agenda, which offers both such promise for good, and such threat of harm, to the human community. The means of human procreation itself now suddenly lies in our own hands: nowhere is it clearer that we face a watershed for the human race.

The field of bioethics lies at the meeting-point of ethics with several disciplines, including science, technology, medicine, and policy. The challenge to policy is to maintain the priority of what is ethical, and therefore to assert the fundamental values of the human community as the context for these extraordinary new developments. It has been said that if it does not prove possible for us to do this in the case of human cloning, it is hard to have confidence in our capacity to address the thousand issues that are standing in line for attention, in the unfolding agenda of biotechnology. The distaste of the human community for cloning is almost universal. And the stakes could hardly be higher, since we are discussing experimentation on and the manufacture of human subjects.

I shall briefly outline some international policy approaches to human cloning, and then offer some observations.

National jurisdictions

In the four years since it was announced that Dolly the sheep had been cloned, many nations have taken steps to prevent the application of the somatic cell nuclear transfer technique, and in some cases other cloning techniques, to human beings. But they were anticipated in that one nation to which we should be most attentive in this debate, since its experience in the twentieth century offers the world a laboratory for misdirected science. In 1990 Germany enacted a statutory ban on cloning, with a penalty of five years imprisonment. German prescience stands in marked contrast to the reactive approaches of other jurisdictions, in which at every point science and technology have outstripped the policy process, in a pattern we may expect to see indefinitely repeated.

Several major nations have now enacted statutory cloning bans, or such enactment is in process. One of the most recent is Japan, which takes effect in June of this year, and carries a 10-year sentence for infringement, though no penalty for Japanese who travel abroad for the process—since a Japanese couple is said to be among those on Zavos and Antinori's list of clients, the responsible Japanese government minister is reported to be seeking an amendment to cover extraterritorial cloning involving Japanese nationals. Other nations that have banned cloning in-

clude Ireland, Israel, Italy, France, Argentina, Colombia, and Spain. Nations with current legislative process include Korea, Canada, New Zealand, and Russia.

The European Convention on Biomedicine and Human Rights

In 1997, appropriately the year of the Dolly announcement, the one international treaty on bioethics was opened to signature. The European Convention on Biomedicine and Human Rights seeks as its title suggests to set the questions being raised in biotechnology firmly in the context of the human rights tradition in European law, recognizing that the dignity of the individual is the prime question at issue. The Convention was the result of a lengthy consultative process—I myself attended one consultation in the late 1980s—and a product of the treaty process of the Council of Europe through the work of its bioethics advisory committee.

The Convention, while adopting the European principle of subsidiarity in recognizing diversity within its jurisdictions, adopts a series of key positions, including a ban on any profit from trade in body parts; a ban on germline gene therapy (therapy that affects subsequent generations); and a ban on the creation of human embryos for the purposes of research (while requiring protections for other, “spare,” embryos that are used for research purposes; in fact, the advisory committee originally recommended to the Council of Ministers a ban on all deleterious embryo research).

The Convention provides for the addition of subsequent protocols on fresh questions, and the first such protocol to be drafted bans human cloning. That protocol went into effect on March 1, after ratification by the requisite five signatories. It reads, in pertinent part,

Considering that the cloning of human beings may become a technical possibility... Considering... that the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine... Considering also the serious difficulties of a medical, psychological and social nature that such a deliberate biomedical practice might imply for the individuals involved...

Article 1

1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
2. For the purpose of this article, the term human being “genetically identical” to another human being means a human being sharing with another the same nuclear gene set.

As of today, 29 European states have signed the protocol, and it came into force on March 1 after ratification by the first five signatories. The full text of the treaty and the protocol are included as an attachment to this testimony.

Observations

Let me add four brief observations to be considered as we move to develop policy:

1. The need for policy in bioethics and the biosciences
2. The need to build public confidence
3. The overriding significance of the dignity of the individual
4. The importance of international agreement
5. **The need for policy in bioethics and the biosciences.** It is curious, and disturbing, that the development of policy—particularly here in the United States—has lagged far behind the development of technique and the growth of the commercial sector. In light of the detailed regulatory regimes—that have wide and bipartisan approval—operating through bodies such as the FDA, the USDA, and indeed the SEC, there is a powerful argument that the stakes here are the highest of all.
6. **The need to build public confidence.** This offers a powerful support to the development of policy, and is illustrated by a recent statement quoted from Carl Feldbaum, president of the Biotechnology Industry Organization (BIO), to the effect that “from the industry’s standpoint, attempting to clone humans is a lose-lose proposition,” since whether it succeeds or fails “it is likely to result in a backlash against mainstream biomedical research.” (The Record, Bergen Co., NJ, 2/18/01). This concern reflects the remarkable story of the popular European response to genetically modified (GM) foods, widely dubbed “Frankenfoods” in the European media, and largely rejected by European consumers. While the industry has not been in the forefront of demands for regulation, a strong argument can be made that its long-term interest vitally requires public confidence, and that such confidence needs expression and confirmation through the policy process. This offers a contrast to anti-science Luddism on the

one hand, and unrestrained exploitation on the other, and suggests a sound regulatory context for the biotechnology industry.

7. **The overriding significance of the dignity of the individual.** From one perspective this is such a statement of the obvious. Yet it actually states the central challenge confronting bioscience policy, since these unfolding developments will offer a stream of benefits to some individuals at potential cost to others. That is of course the central role for policy in a free society: to defend the individual against the encroachment of others, including the state itself. Questions such as access to genetic information (for insurance, employment, and other external purposes), germline gene therapy (in which we change the genetic inheritance of the next generation, a procedure summarily outlawed in the European Convention), and so-called “therapeutic” embryo experimentation (in which putative benefits to some are balanced against the destruction of individual embryos), offer samples of the decisions that await us.
8. **The importance of international agreement.** Plainly, there is value in setting policy within individual jurisdictions, and those states such as California, Louisiana, Michigan, and Rhode Island that have banned human cloning are to be commended for their initiative in asserting the common values of their citizens. The same is true of nations. But both human dignity, and the worlds of bioscience and the biotechnology industry, are indivisible, and there is urgency in the task of international agreement. This was well illustrated by the statement of Drs Zavos and Antinori that they intend to press ahead with the birth of a cloned human baby, and locate in an unnamed European country in which, one presumes, it is not illegal. The European Convention on Biomedicine and Human Rights offers a model; the present UNESCO process that has begun with a statement on the human genome offers a process.

Mr. GREENWOOD. Thank you.

Mr. Eibert?

STATEMENT OF MARK D. EIBERT

Mr. EIBERT. Thank you, Mr. Chairman. Sir, I am a patient advocate. I’m going to talk about the needs and the rights of infertility patients. Infertility affects about 12 million adult Americans. Medically, infertility is classified as a disease and legally, the Supreme Court and the EEOC have declared it a disability within the meaning of the Americans With Disabilities Act. Psychologically, infertility is a devastating condition. It interferes with one of the most powerful biological drives that every human being has. Being diagnosed as being incurably infertile is like having all of your children die and all of your grandchildren too.

Unfortunately, current reproductive medicine can only help less than half of infertility patients to have biologically related children. Among the millions that they cannot help are the many patients who cannot produce viable eggs or viable sperm. For many such Americans, cloning will soon provide the only way possible to have their own biologically related children and families.

Many people want to outlaw cloning as a treatment for infertility. The Constitution does not allow that. The Supreme Court has ruled many times that every American has a constitutional right to have biological children and to make all kinds of reproductive decisions without government interference. As the Supreme Court has said, “if the constitutional right of privacy means anything, it is the right of the individual to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision of whether to bear or beget a child.”

Some people like Mr. Caplan argue, oh, that only applies to sex. Disabled people who need medical help to have children don’t have the same reproductive freedom that healthy people do, but that isn’t true. Federal courts have struck down State laws to try to re-

strict IVF and similar high-tech reproductive technologies as violations of the constitutional right to have children.

It's not any particular means of reproduction that is constitutionally protected, it is the end, the right to have biological children and families and that is what the opponents of cloning are trying to deny to disabled Americans.

Other cases prohibit discriminatory laws that deny reproductive freedom to some people, but not others. For example, Oklahoma once had a law that required the sterilization of convicted criminals as part of a broader eugenics program designed to prevent the birth of seriously defective children, but the Supreme Court struck that law down, declaring that the right to have offspring was a fundamental constitutional right.

This case means that anyone who attempts to ban cloning will have to explain to the courts under a strict scrutiny standard why infertile people should have less of a right to have children and families than convicted criminals do. For infertile people who cannot have biological children any other way, anti-cloning laws are the practical equivalent of forced sterilization.

In short, the Federal Government simply does not have the constitutional authority to decide which Americans can and cannot have children or which children are likely to be perfect enough to be allowed to be born.

Today, the FDA claims to have statutory authority to regulate reproductive cloning. It's a pretty radical claim since America has never before had a Federal reproductive police. However, virtually every lawyer on both sides of this debate agrees that the FDA has no such authority under current law. I would be happy to tell you why during the question period.

Should Congress pass a new law giving the FDA control over reproductive cloning? If you do, what message would you be sending, that reproductive cloning is perfectly acceptable once it is safe or that chopping up human embryos for stem cell research, what many Members of Congress call cloned then killed, is acceptable while cloned then loved is not. Either way, Congress cannot delegate to the FDA powers that Congress does not have, like the power to control the reproduction of American citizens.

Finally, there is nobody in the world who cares more about having normal, healthy children than infertile patients and their doctors. Safety is what everyone wants above everything else and that is precisely why infertile people are overwhelmingly pro-choice on cloning. Cloning will happen very soon. It will either be done legally in fertility clinics that are already licensed and regulated by the states or it will be done in illegal underground clinics, similar to the old back alley abortion clinics of the 1960's. If the Federal Government denies infertility patients, all options except underground clinics, the most likely result will be thousands of dead and deformed children.

Mr. Chairman, the infertile population does not want the government to protect them from their own doctors. They want to be left alone to make their own private, reproductive, medical and family decisions free from government interference, just like healthy people do.

Thank you. I would ask that the article that I attached to my testimony which is much more detailed outlining what I just said be included in the record.

Mr. GREENWOOD. Without objection, it will be.
[The prepared statement of Mark D. Eibert follows:]

PREPARED STATEMENT OF MARK D. EIBERT

Mr. Chairman, I am a patient advocate. I speak for a group that is otherwise not represented at this hearing—the infertile population.

Infertility affects about 12 million adult Americans. Medically, infertility is classified as a disease. Legally, the Supreme Court has declared it a disability under the Americans with Disabilities Act.

And psychologically, infertility is a devastating condition. It interferes with one of the most powerful biological drives every human has. Being diagnosed as incurably infertile is like having all your children die, and *all* your grandchildren too.

Unfortunately, current reproductive medicine can only help less than half of infertility patients to have biologically related children. Among the millions they cannot help are the many patients who cannot produce viable eggs or viable sperm. For many such Americans, cloning will soon provide the *only way possible* to have their own biological children.

Many people want to outlaw cloning as a treatment for infertility. But the Constitution won't allow that. The Supreme Court has ruled many times that every American has a constitutional right to *have* biological children, and to make all kinds of reproductive decisions without government interference. As the Supreme Court has said, "if the [constitutional] right of privacy means anything, it is the right of the *individual* . . . to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."¹

Some people argue, "oh, that only applies to sex. Disabled people who need medical help to have children don't have the same right to reproductive freedom as healthy people." But that's not true. Federal courts have struck down state laws that tried to restrict IVF and similar reproductive technologies as violations of the constitutional right to have children.² It is not the *means* of reproduction that is constitutionally protected, it is the *end*—the right to have children and families. That's what the opponents of cloning are trying to deny to disabled Americans.

Other cases prohibit discriminatory laws that deny reproductive freedom to some people but not others. For example, Oklahoma once had a law that required the sterilization of convicted criminals, as part of a broader eugenics program designed to prevent the birth of seriously defective children. But the Supreme Court struck that law down, declaring that the right to "have offspring" was a fundamental constitutional right.³ This case means that anyone who attempts to ban cloning will have to explain to the courts why infertile people should have less of a right to have children and families than convicted criminals do. For infertile people who can't have biological children any other way, anti-cloning laws are the practical equivalent of forced sterilization.

In short, the federal government simply does not have the constitutional authority to decide which Americans can and cannot have children, or which children are likely to be "perfect" enough to be born.

Today the FDA *claims* to have statutory authority to regulate reproductive cloning—a pretty radical claim, since America has never before had a Federal Reproductive Police. However, virtually every lawyer on both sides of this debate agrees that the FDA has no such authority under current law. I would be happy to tell you why during the question period.

Should Congress pass a new law giving the FDA control over reproductive cloning? If you do, what message would you be sending? That reproductive cloning is perfectly acceptable once it is safe? Or that chopping up human embryos for stem cell research—what many members of Congress call "clone then kill"—is acceptable,

¹ *Eisenstadt v. Baird*, 405 U.S. 438 (1971).

² As one federal court put it, "within the cluster of constitutionally protected choices that includes the right to . . . contraceptives, there must be included . . . the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy." *Lifchez v. Hartigan*, 735 F.Supp. 1361 (N.D. Ill.), *affirmed*, 914 F.2d 260 (7TH Cir. 1990), *cert. denied*, 111 S.Ct. 787 (1991).

³ *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

while “clone then love” is not? But either way, Congress cannot delegate to the FDA powers that Congress itself does not have—like the power to control reproduction.

Finally, there is nobody in the world who cares more about having normal, healthy children than infertile patients and their doctors. Safety is what everyone wants above everything else. That is why infertile people are *pro-choice* on cloning. Cloning *will* happen very soon. It will either be done legally in fertility clinics that are already licensed and regulated by the states, or it will be done in illegal underground clinics, like the old back alley abortion clinics. If the federal government denies patients all options *except* underground clinics, the result will be thousands of dead and deformed children.

Mr. Chairman, the infertile population does not want the government to “protect” them from their own doctors. They want to be left alone to make their own private reproductive, medical and family decisions free from government interference, just like healthy people do.

Thank you. I would be happy to take your questions.

HUMAN CLONING: MYTHS, MEDICAL BENEFITS AND CONSTITUTIONAL RIGHTS

This article is adapted from a speech and multimedia presentation on cloning given by Mark D. Eibert, Esq., at the annual joint meeting of the San Bernardino County Medical Society, the Riverside County Medical Society, and the San Bernardino County Bar Association, on September 23, 1999. It is being reprinted by the permission of the author, who retains all right in it. Copyright 1999 by Mark D. Eibert.

Tonight I'm going to discuss three topics. The first is what cloning is, how it's done, what is going on in cloning today, and most importantly, what cloning is not. The second is the potential medical benefits of cloning, especially in the treatment of infertility and the prevention of genetic diseases and defects. My third topic is the current state of the law on cloning, and what constitutional questions those laws raise, especially with respect to reproductive and scientific freedom.

What Cloning Is And How It Is Done.

Cloning is a method of producing a baby—whether animal or human—that has almost the same genetic makeup as its parent. In very simple terms, it works like this.

You take an egg, and remove the nucleus, thereby removing nearly all of the egg's DNA or genes. You throw that nucleus away, because you don't need it any more.

Then, you take a nucleus from a cell belonging to the adult parent. (Ian Wilmut used a mammary cell—that's why he named his sheep “Dolly” after Dolly Parton.)

You insert this cell nucleus into the egg, either by fusing the adult cell with the enucleated egg, or by a more sophisticated nuclear transfer.

You then stimulate the reconstructed egg, either electrically or chemically, to trick it into behaving like a fertilized egg—into dividing and becoming an embryo. The embryo is then cultured, and when it reaches the appropriate stage, you transfer it to the uterus of a surrogate mother. There it follows the usual course of any embryo. It becomes a fetus, gestates for the usual time, and is then born in the usual way, looking and acting just like any other newborn of its species. That's how Dolly the sheep was created.

Today Dolly is a normal, healthy sheep, who has had four lambs of her own, one single lamb followed by a set of triplets, all the result of ordinary sexual reproduction.

Now you may have heard that Dolly was born already the age of the sheep that she was cloned from—which is six years old. This assertion is based on an experiment that attempted to measure Dolly's “telomeres”—structures within cells that become shorter with each cell division. But that experiment has been widely criticized for technical reasons (it seems that the telomere measurements were within both the margin of error of the study and the normal variation for sheep), and also because on the same day that Ian Wilmut announced the “telomere problem,” the company he works for announced that it had found the solution to the problem—a substance called telomerase.

There is a more fundamental reason not to worry about Dolly's telomeres. If Dolly were really born 6 years old, then she was 9 years old when she had her triplets. Since virtually all Poll Dorset sheep are dead by the age of 9, that would make her the “fertile octogenarian” of sheep. I don't think so. Not only does Dolly show no signs of premature aging, she is doing things—like having triplets—that would be impossible if she were prematurely aged. The truth is that Dolly is a healthy young sheep.

Now, I hate to start with badly outdated science, but before I tell you where cloning is today I need to dispel one of the great cloning myths. People seem to al-

most universally believe that because it took “277 tries” to make Dolly, that means there were 276 miscarriages or deformed or dead lambs along the road to Dolly. The Washington Post reported exactly that shortly after Dolly was born, and we’ve been reading it in the newspapers ever since. But that’s not true. What really happened is this:

Dr. Wilmut started with 277 reconstructed eggs—eggs that had their nucleus removed and were then fused with an adult cell. That’s what the number 277 refers to.

The eggs were then cultured in sheep oviducts, and of the 277, only 29 divided and became embryos. All 29 embryos were transferred to the uteruses of 13 sheep—some got one, some got two, and some got three.

When Wilmut later performed an ultrasound, he learned that only one of the 13 sheep had become pregnant. That pregnancy proceeded normally and produced Dolly. There were no dead or deformed lambs, no miscarriages, and no discarded embryos in this particular experiment.

More importantly, let’s put this in perspective—the perspective of fertility treatments involving in vitro fertilization (IVF).

IVF doctors and the federal government measure the success rate of IVF clinics by the ratio of live births to uterine transfers. IVF with humans began in 1978, but it wasn’t until 1990, after 12 years of worldwide human clinical practice, that the average success rate for IVF in humans got to be as good as one live birth out of 13 uterine transfers the Dolly success rate. (Today the average IVF success rate is about one out of four, but it took 20 years of human clinical practice and research to get it there).

And in the year Dolly was conceived, 1995, the largest IVF clinic in my area, the San Francisco Bay Area, was creating thirty human embryos for every one that made it to the delivery room, compared with 29 for the Dolly experiment.

The only part of the Dolly experiment that was out of line with IVF success rates of either today or the recent past was the large number of eggs it took. It was very inefficient.

Where Cloning Technology Is Today (September 1999).

But the second cloning experiment to be reported in a peer review journal, the cloning of 50 mice in Hawaii, had an efficiency rate (measured by number of eggs per live birth) that was ten times higher than the Dolly experiment.

The third published adult cell cloning experiment, using cows in Japan, was seventeen times more efficient than the Dolly experiment in terms of the number of eggs needed to get each live birth. Furthermore, if you go back to the measurement of success that IVF clinics use—live births per uterine transfer—the Japanese transferred two embryos into each of 5 cows and ended up with 8 calves—all five cows gave birth to at least one calf, which is better than any IVF clinic in the world can do today.

And cloning has continued with a variety of other species, like goats and pigs. There are now literally hundreds of animals in the world who were conceived through adult cell cloning.

Most importantly, scientists are already using cloning technology to create cloned human embryos. The first cloned human embryo was created by a pair of IVF doctors at a fertility clinic in South Korea. They used the egg and body cells of an infertile woman patient. Unfortunately, they only allowed the embryo to reach the two-cell stage before stopping the experiment.

In addition, a biotechnology company on the East Coast is currently mass producing cloned human embryos for medical research on stem cells. According to BBC-TV, they are producing them in batches of 600 at a time. They use cow eggs to hold the human DNA, but the cloned embryos they produce are quite human.

I’m not saying that cloning is sufficiently developed and safe enough for human clinical use right now. It probably isn’t—not just yet. Nor do I advocate trying it before there is evidence of reasonable safety from animal studies.

What I am saying is that cloning is not nearly as dangerous as the press makes it out to be—in fact, when compared with early IVF success rates, the current success rates with cloning look very promising indeed. I’m also saying that the process is improving very rapidly. And most of the scientists involved in cloning research that I talk to report that their success rates are steadily increasing, and that they’re optimistic that improvements in efficiency and safety will continue with more research, just as you would expect with any new treatment—just as occurred with IVF and heart transplants, for example.

In other words, if “safety” is your main argument against cloning, you’d better have a backup, because if the current trend of research continues, that may not be an issue for very much longer.

What Cloning Is Not—The “Xerox Copy” Myth.

If you’ve been watching television and movies and reading popular fiction for the last 30 years, you’ve learned a lot about cloning. Unfortunately, almost everything you learned about cloning was scientifically false.

For example, in “The Boys From Brazil,” starring Gregory Peck as the evil cloning expert Dr. Joseph Mengele, you learned—or thought you learned—that cloning could be used to “replicate” Adolph Hitler, and the Third Reich along with him—unless the good guys could stop him in time. They did stop him, but it was a real cliff-hanger.

In less serious movies like “Multiplicity” with Michael Keaton, you learned—or thought you learned—that “clones” would be “xerox copies” of the original person, born fully grown and with all the memories and feelings of the original—but if you copied one too many times, it was like making a xerox of a xerox of a xerox, and you might end up with a fuzzy copy, like Michael Keaton number four, the gibbering idiot.

But the problem with these and other cloning fiction is that the whole idea of cloning as copying or replicating people is just plain false. Even the National Bioethics Advisory Commission, which is no friend of cloning, admits that the vision of cloning portrayed by popular fiction is “based on gross misunderstandings of human biology and psychology.” Let me explain some of the reasons why.

Yes, children conceived with the aid of cloning technology will be genetic twins—or almost genetic twins—of the person who is the cell donor. But we already have 1.5 million genetic twins walking around the United States. We call them “identical twins” but it would be just as accurate to call them naturally occurring clones.

We know a lot about these natural clones. An entire branch of academia is devoted to the study of identical twins. There is a “Twin Studies” department at Cal State Fullerton, another at the University of Minnesota. Physicians, psychologists, sociologists, people who study family relationships, all just love to study twins. And the one thing we know for sure after decades of research is that so-called identical twins are not identical.

Physically, twins have different fingerprints and different organic brain structures, among many other examples.

Intellectually, twins have different IQ’s—a recent analysis of 212 separate studies of twins concluded that genes are only responsible for about 48% of a person’s IQ.

And of course, twins have different personalities. If you have ever known “identical” twins you that each member of the pair is a separate and different person. That’s why the law and society and everyone who knows twins treat them as unique individuals.

And children conceived with the aid of cloning technology will be even more different from their genetic parents than natural twins are.

Most of their genes will come from the adult cell donor. However, a small percentage of the child’s genes will come from the mitochondria of the egg donated for the procedure. This mitochondrial DNA primarily affects how cells process energy. Thus, the child will have almost—but not quite—the same genes as the adult cell donor.

The child will grow in a different uterus. Uterine environment has an enormous impact on many different aspects of fetal development. That’s why doctors tell you not to smoke and drink during pregnancy, for example.

Most importantly, these children will be born into different families, have different parents and siblings, go to different schools, have different friends, have different experiences from the day they are born, be raised in a different culture—surfing the web rather than watching “Leave it to Beaver” after school, for example. The nurture part of the nature versus nurture equation will be completely different.

But even that’s not all.

I have a beautiful calico cat named Tribble. What if I used cloning technology to give Tribble kittens—what would they look like?

Interestingly, they would not look like Tribble. Like all calicos, Tribble has patches and splotches of different colored fur—black, orange and white. If I cloned Tribble, the kitten would also have patches of different colored fur—but they wouldn’t be the same size or shape or location as they are on Tribble. Where Tribble has a mostly black back with a few patches of orange fur, her cloned kitten might have a mostly orange back with patches of black. Instead of a face that was half black and half orange, like Tribble, the cloned kitten’s face might be all one color. And so on.

The reason for that is a phenomenon known as “random inactivation of the X chromosome.”

Chromosomes are structures that carry genes. The X chromosome of a cat, for example, has about 5,000 genes on it. Male mammals—humans and tomtomcats—have one X chromosome and one Y chromosome. Female humans and cats have two X

chromosomes—they inherited one from their mother and the other from their father, so the genes on the two X chromosomes are all different.

What happens when you have two sets of blueprints for the same 5,000 genetic traits in the same mammal? Which one gets used? Well, nature decides in a very fair way. Randomly. In every cell in Tribble's body, one of the two X chromosomes is switched off. And which of the two is switched off—the one from mom or the one from dad—is completely random.

What genes are on the X chromosome? Well in cats, the genes that determine fur color are among those located on the X chromosome. The reason that the patches and splotches of color on a calico's coat look random is because they are random, thanks to random inactivation of the X chromosome. In other words, you can make a million clones of Tribble, and not one of them will look exactly like Tribble, or exactly like any of the other Tribble clones. Although it wouldn't be as visual and dramatic, the same principle would apply to humans.

A related concept, called gene expression, would also apply equally to male and female "clones." Basically, two identical twins could have the same gene, but they might express that genetic trait differently—or one might not express it at all. That's because whether and how a specific genetic trait or characteristic is expressed depends on very complex interactions both among genes and between genes and the environment. People who have all the same genes can and do turn out differently, even with respect to genetic traits.

In other words, every "clone" is different.

My final example is Chang and Eng Bunker. They were the original "Siamese Twins," what we now call conjoined twins. They were joined at the chest, and they shared one liver between them.

Chang and Eng were identical twins, with identical nuclear and mitochondrial DNA. They grew in the same uterine environment. They were born at the same moment. They had the same parents and family. And from the moment they were born, they had as close to the same experiences—as close to the same nurture in the nature versus nurture sense—as any two humans could possibly have. When they got married, they even married sisters.

In spite of all that, Chang and Eng turned out to have radically different personalities.

Chang was an alcoholic, a moody introvert who hated people and was verbally and physically abusive.

Eng was a lifelong teetotaler, an extrovert who loved parties and children and was generally liked by everyone who knew him—everyone who could stand being around Chang long enough to get to know him.

But enough examples. The point I'm trying to make is this: anybody who thinks their child conceived through cloning technology is going to be a little copy of himself is going to be hugely disappointed. You can't copy or replicate a human. That is scientifically impossible, even with cloning.

The truth is this: children conceived with the aid of cloning technology will be ordinary children who will grow up to be unique individuals, just like everyone else.

Once you understand that scientific fact, over 90 percent of the arguments—including most of the "ethical" arguments—against human cloning evaporate like fog when the sun comes up.

Of course you can't replicate Hitler, or an army of Arnold Schwarzeneger soldiers, or a factory full of compliant zombie workers. Cloning by itself has no more potential to do those things than IVF does.

Nor are the children going to be burdened or restricted by how they were conceived. These children will not be freaks leading second-hand lives; they will be unique individuals who have as much of an open future as anyone does. And there is no scientifically valid reason for these children to think of themselves as mere copies, or to be treated like copies by anyone else, or to be psychologically harmed by such an absurd thought.

Medical Uses Of Cloning.

Now we're ready to answer the next question: who in their right mind would want to be "cloned"?

Now that you understand that cloning has nothing to do with copying people, you can eliminate dictators, narcissists, megalomaniacs, ruthless employers, people who want to bring Hitler or Christ or Elvis back to life, and so on. There's nothing in cloning for them. People like that will find cloning totally useless.

The only thing cloning is really good for is building families, families composed of genetically related but unique individuals—a lot like the families we have now.

And the largest group of people who would be interested in that, once the technology is reasonably safe, is infertile people. About 10 to 15 percent of the population is infertile—physically unable to have children.

Medically, infertility is classified as a disease, according to the American Society for Reproductive Medicine and the American College of Obstetricians and Gynecologists.

Legally, infertility is a disability—the kind that entitles people to protection from discrimination under the Americans with Disabilities Act. That's based on both a recent U.S. Supreme Court case called *Bragdon v. Abbott* and on a recent decision of the EEOC in New York.

Psychologically, infertility is a devastating condition. It frustrates a basic and very powerful biological drive, one that is an intimate part of the will to survive. One analogy that you hear over and over again from infertile people is that learning that you are incurably infertile is not like having your child die. It's like having all your children die, and all your grandchildren as well. Infertile people are so motivated to find a cure that many of them spend year after year undergoing painful and expensive treatments that are not covered by health insurance and that, for many of them, have a very low chance of success.

Now everybody knows that in vitro fertilization (IVF) is one way that infertility is treated. The first so-called "test tube baby," Louise Brown, was born in 1978. She's a college student now.

But IVF doesn't work for everyone. For a 21 year old woman who's infertile because of blocked fallopian tubes, IVF will probably be a miracle cure. But for a woman who can't produce viable eggs or a man who can't produce viable sperm, IVF isn't much help. To get a good embryo out of the dish, you have to put good ingredients into the dish. There are literally millions of women who can't produce viable eggs no matter how big a dose of fertility drugs you give them—that's why they're infertile.

What makes cloning so revolutionary as an infertility treatment is that it does not require the patient to produce viable eggs or viable sperm. If they can spare a few cells scraped from the inside of their cheek, they can have genetically related children.

Now for a little historical footnote: twenty years ago, when the idea of IVF was first being discussed, most people had a strong visceral reaction against the idea of "manufacturing babies in test tubes." At first they thought it was weird and disgusting and it reminded them of "Frankenstein." And there was a debate about whether so-called "test-tube babies" should be outlawed.

All the same arguments now used against cloning were used against IVF. IVF would be "unsafe," the babies would be born deformed or with birth defects, they would be psychologically harmed when they found out that they were only "test-tube babies" rather than "real" babies, family structures and relationships would be radically altered, and so on. Part of the reason the arguments were the same is that the people making them were the same—some of the current leaders of the anti-cloning movement were also leaders of the movement to outlaw IVF 20 years ago. And before Louise Brown was born, 85 percent of the American public agreed with them and thought that IVF should be outlawed, which is about the same percentage that think cloning should be outlawed today. If you know your history, this cloning debate is just what Yogi Berra called "déjà vu all over again."

But then along came Louise Brown, the world's first "test-tube baby," whose face graced the front pages of almost every newspaper in the world for awhile. People looked at those pictures and said "that just looks like an ordinary baby, ten fingers, ten toes, mom is grinning from ear to ear—what's so terrible about that?" And the movement to outlaw IVF faded away.

Today it's 21 years later. The public has forgotten its horror and now accepts IVF, which so far has brought children, families and happiness to over 150,000 disabled couples. And we now know that all the arguments against IVF were wrong. The same thing will happen with cloning. And it will happen a lot sooner than most people expect.

The second biggest group of people who will be interested in the use of cloning to create children is people who know, from family history or genetic testing or counseling, that they have a high risk of producing children with serious genetic diseases or defects.

As explained by Dr. Lee Silver in his excellent book "Remaking Eden: Cloning and Beyond in a Brave New World", the vast majority of genetic diseases and defects are caused one of two ways. The first is errors that occur during meiosis, which is part of the process of sexual reproduction. These types of errors cause problems like Down Syndrome.

The second major way to get a serious genetic disease is by inheriting it from a parent who is a carrier. That's how children get born with such serious and often lethal conditions as Tay Sachs disease, sickle cell anemia, cystic fibrosis, hemophilia, and so on—there's a long list of horrors.

Cloning should make all of these kinds of diseases and defects extremely rare, if not impossible. There is no reduction of genetic material in cloning, so there is no opportunity for the kinds of errors that cause Down Syndrome to occur.

And a child conceived with the aid of cloning technology shouldn't get a genetic disease that his genetic parent didn't have—if the parent is a carrier the child will be a carrier too, but he typically won't actually get the disease.

For a lot of people who are at risk of having seriously ill or defective children, cloning technology may soon be a safer way to have children, and a more certain way of having normal, healthy children, than sex is.

So-called "reproductive cloning" isn't the only medical use of the technology. There are also some exciting and important medical uses that don't require the production of whole human beings.

For example, cloning could be used to create embryonic stem cells, which could be used to make tissues, and perhaps even organs, for transplant. Not only would this relieve the serious shortage of tissues and organs for transplant, but if you use cells from the patient who needs the tissue or organ, you could virtually eliminate the danger that the patient's body would reject it. Examples would include creating bone marrow for transplants for leukemia victims, islet cells to return to the pancreas of a diabetic, heart or liver tissue to repair the damage caused by heart attacks or hepatitis, healthy skin for grafts to burn victims, and so on.

Cloning can also be used to create animals that excrete therapeutic human proteins, like insulin, in their milk. You do this by inserting selected human genes into animal embryos during the process of cloning, thereby turning cows into walking drug factories providing an endless supply of cheap and plentiful human medicines. This is already being done.

Cloning may even help to find a cure for cancer by teaching us how to reprogram cells. Cancer cells grow uncontrollably; perhaps they could be reprogrammed.

These are just a few examples of the many exciting medical breakthroughs that should be possible with cloning technology.

Cloning and the Constitution—The State of the Law.

Now let's talk about law. What is the current state of the law about human cloning?

First of all, by Executive Order signed by President Clinton, you can't use federal funds for human cloning research. But since there's already a ban on the use of federal funds for embryo research, that doesn't add very much—it was a purely political gesture.

Beyond that, human cloning is currently illegal in three—and only three—states. California is one of the three, with a moratorium on using cloning to create a child that automatically expires after five years (about 3 years from now). In the meantime, the penalty for using cloning to create a child in California is a fine of up to \$1 million for an organization and \$250,000 for an individual—it's not at all clear that the fine wouldn't apply to the patient as well as the doctors involved—and the doctor could lose his medical license. Rhode island has a similar law, also with a five year sunset clause. Michigan has an even more radical law, which permanently outlaws not just the conception of children, but also the creation of cloned embryos for laboratory research on, say, curing diseases. The penalty is up to 10 years in prison, and that applies whether you are a laboratory researcher trying to cure cancer, a doctor helping an infertile patient, or an infertile woman who uses cloning to have children.

Human cloning is legal in the other 47 states. It's also legal in most countries, Western Europe being the major exception.

And there is no federal law on cloning. Last year, Congress debated various anti-cloning bills, but they got bogged down in a debate over abortion and couldn't agree on a law. The Republicans wanted a Michigan-style law forbidding the creation of all cloned human embryos. The Democrats filibustered that because it would end almost all cloning research and prevent the technology from being used for all the important non-reproductive medical purposes I mentioned. They proposed a law more like California's, but the Republicans wouldn't go along with it because they thought it was the moral equivalent of abortion—"clone then kill" they called it. Of course, both sides wanted to outlaw "clone then love," but because they couldn't agree on the "clone then kill" issue they fought themselves to a standstill and no law got passed. And now it seems very unlikely that they will be able to agree on a federal law anytime in the foreseeable future.

The last piece to the legal puzzle is kind of confusing. When it became clear that Congress couldn't agree on a law, the Food and Drug Administration announced that it had authority to regulate cloning. Not to ban it exactly, but to make researchers go through a lot of hoops to prove to the FDA that cloning is safe and effective before they use it on patients.

What's confusing is that nothing in the Food, Drug and Cosmetics Act or any other piece of relevant legislation gives the FDA jurisdiction over cloning or anything that could even arguably include cloning. As most doctors know, the FDA has no authority to regulate the practice of medicine, and as one of the most vehemently anti-cloning members of Congress (Rep. Ron Ehlers) put it, "it's hard to argue that a cloning procedure is a drug." Moreover, the FDA has for years totally ignored reproductive medicine, including procedures like ICSI and cytoplasm transfer that have a lot in common with cloning.

So far, I have yet to find a lawyer on either side of this debate who thinks the FDA really has statutory authority to regulate cloning, and when I called the FDA myself to find out what statute they were relying on, even they couldn't tell me.

So that's the state of the law. Human cloning is legal in 47 out of 50 states, and in about 175 of 200 countries, and the FDA may or may not be able to enforce safety and efficacy standards. The courts will have to decide that.

Constitutional Rights: Reproductive Freedom.

What I personally find most interesting about this topic is the profound questions raised by anti-cloning laws.

Can the state really ban cloning? I'm going to suggest that under current constitutional principles, it probably cannot.

Let's start with a few highlights of the legal arguments of infertile people for whom cloning technology, once it's reasonably safe, will be the only way possible to have biologically related children and families.

Reproductive freedom means a lot more than just the right to an abortion. The Supreme Court has said many times that every American has a constitutional right to have children, and to make all sorts of reproductive decisions without government interference. That right stems from the constitutional right to privacy, because reproductive decisions are some of the most private and personal and life-changing decisions an individual can make.

The statement that is quoted over and over again in cases discussing reproductive freedom comes originally from a Supreme Court case about the right to contraception, *Eisenstadt v. Baird*. There the Supreme Court said that "if the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

Now, some people argue, "that only applies to sex. People who need high-tech medical help to have children don't have the same right to reproductive freedom that healthy people do." Well there isn't a lot of case law on that yet, but what there is says just the opposite.

In 1990, for example, the state of Illinois tried to outlaw a variety of reproductive technologies and tests, some of which were related to IVF and could be used to treat infertility. In a decision that was later affirmed on appeal, a federal district court struck down that law, explaining that "[i]t take no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."

So it looks like you have a constitutional right to high-tech baby-making too, at least if you're infertile. And notice the progression. In 1978, 85 percent of the American people thought "test-tube babies" were terrible and ought to be outlawed. Just 12 years later, in 1990, courts were starting to rule that IVF was a constitutional right. But the right to privacy isn't the only constitutional principle that protects people from government interference with their reproductive decisions. There's also equal protection—the principle that you can't deny basic rights to some people and not to others without a very good reason.

In 1942, for example, the state of Oklahoma had a law requiring the sterilization of convicted criminals. It was a eugenics law, based on the idea that criminal tendencies could be passed down genetically to children.

The Supreme Court analyzed the case under the equal protection clause of the Fourteenth Amendment, and unanimously ruled that "procreation involves one of the fundamental rights of man" and that even a convicted criminal who is sterilized "is forever deprived of a basic liberty."

Because the Oklahoma law affected a fundamental constitutional right—which the Supreme Court described as the “right to have offspring”—the court applied what is known as “strict scrutiny.” That means that the Supreme Court placed the burden of proof on Oklahoma to justify its discriminatory law. And strict scrutiny is the highest and toughest burden of proof there is. The state couldn’t carry that burden, so the Supreme Court struck the law down. There are a number of other more recent cases that reaffirm that having children is a fundamental right and that laws that interfere with that right are subject to strict scrutiny.

This is my favorite reproductive freedom case because it means that sometime soon—certainly before the current anti-cloning law sunsets—lawyers for the state of California will have to explain to a court, under a strict scrutiny standard, why legally disabled citizens should have less of a right to have children and families than convicted rapists and child molesters do.

Now it’s time for a second historical footnote, a legal one this time.

The case I just told you about struck down a state “eugenics law.” Oklahoma was just one of 36 American states that passed eugenics laws in the early part of this century. Those laws required the sterilization of people who were thought likely to produce seriously defective children. People with leprosy and other dread diseases, mentally retarded people, mentally ill people, habitual criminals and others were sterilized, mostly because the best science of their day said that such people would probably produce children with the same defects.

Supporters of eugenics laws argued that they were necessary to protect the safety and welfare of children. It was said to be in the best interests of children who might be born with defects that they never be born at all. It wasn’t until the Vietnam war that our military came up with an accurate characterization of this brand of logic—it’s called “destroying the village in order to save it.”

The most successful—if you want to call it that—state eugenics law was California’s. During the early part of this century, our state government rendered more than 30,000 of its sick and disabled citizens unable to have children. So when the Nazis were drafting their own eugenics law, they modeled it in part on the eugenics law that came out of Sacramento.

But during World War II, Americans got a graphic demonstration of what politicians could do when given the power to decide who was and was not “perfect” enough to be born, and attitudes about eugenics began to change. By the 1960s almost all of our state eugenics laws had either been repealed, struck down as unconstitutional, or fallen into disuse, and states got out of the business of regulating their citizens’ reproduction.

Until now. Two years ago, California passed the first anti-cloning law in the nation. Once again, the state of California has singled out a class of disabled Californians and forbidden them by law to have children. Once again, the state has defined a class of children that it says are so likely to be born “imperfect” that the state won’t allow them to be born or to live at all. Once again, California has a reproductive police charged with stopping unauthorized breeding by California citizens. Once again, the politicians in Sacramento have a chance to play God. And once again California has a eugenics law.

What our legislature has done is radical all right, but it’s not unprecedented. We’ve been here before.

Scientific Freedom and the First Amendment.

Reproductive freedom isn’t the only constitutional value that anti-cloning laws infringe on.

For instance, there’s a lot of Supreme Court dictum to suggest that scientific freedom might have some constitutional protection, and some lower courts and about a million legal scholars have said that scientific freedom does or should have constitutional protection. That protection is based on the First Amendment right to free speech. In science, it’s not enough to argue for your theory, or to publish your theory. You and others—including those who disagree with you—have to be able to test your theory through experimentation. That’s how science works and how it finds the truth.

Now the Supreme Court hasn’t directly addressed that question yet. But cloning may not be such a bad case to try to determine the extent of constitutional protection for science. After all, as one member of the National Bioethics Advisory Commission observed, anti-cloning laws like California’s moratorium are the first time in American history that an entire field of medical research has been outlawed. That’s a very radical thing to do. And in Michigan today, a scientist who clones cells in a dish to try to find a cure for cancer can get up to 10 years in prison—that’s even more radical. In Michigan, the ACLU is considering challenging their anti-

cloning law on both scientific freedom and reproductive freedom grounds, and perhaps we will get some new case law on scientific freedom as well.

The REAL Question.

Now I want to conclude by telling you that I think there is only one question of lasting social significance that cloning presents to us. That question is this: Who Decides?

Who should decide whether and how a particular individual can have children—the individual, or the government?

Who should decide which classes of children are likely to be perfect enough, or happy enough, or socially desirable enough, or politically popular enough, to be born—the prospective parents or the politicians?

Who should decide which treatment is medically best for a particular patient, the physician acting with the informed consent of his patient, or the bureaucrat? Aren't doctors regulated enough already? Do they really need to have the reproductive police looking over their shoulder along with everyone else?

Who should decide how much risk is acceptable for a prospective mother and her unborn child, the mother, with the advice of her physician, or the legislature, making one risk-benefit calculation for all patients at all times, no matter what their personal medical condition is, no matter what their personal religious and moral beliefs may be, and no matter how the technology may have changed during the three or five years since the politicians last debated appropriate treatment protocols? You know, for 200 years American women have been free to make decisions that pose much greater risks to their unborn children than cloning possibly could.

And who should decide what subjects scientists can investigate, or what truths the general public is ready for them to uncover—the scientist or the platform committees at political conventions?

If the word "copy" is the scientific fallacy of the anti-cloning argument, the word "we" is the legal fallacy. The opponents of cloning are always wringing their hands and asking what should "we" do about cloning, and whether "we" should allow it. But "we" don't decide whether John and Mary Smith can have children, they do. That's a private decision, not a political one. And I don't think there is anything so horrible or horrifying about twins that would justify changing that.

This question—"who decides"—is the real heart of the cloning debate. And the Constitution, supported by over 200 years of American tradition and culture, permits only one answer.

Mr. GREENWOOD. Ms. Terry, you are recognized for 5 minutes.

STATEMENT OF SHARON F. TERRY

Ms. TERRY. Thank you, Mr. Chairman. I'm speaking on behalf of the Board of Directors of the Genetic Alliance and I've submitted written comment and I'll make a few comments here.

The Genetic Alliance is the largest coalition, internationally, of lay advocacy groups and professional and genetics organizations worldwide. We work together to promote healthy lives for millions of individuals affected by common and rare genetic disorders. We work to establish safeguards to ensure the benefits of genetic technologies and to encourage debate and informed public policies and we're committed to the highest standards in this regard.

I'll give you a little background about my involvement with the Genetic Alliance. My children with diagnosed with a genetic disorder about 5 years ago and my husband and I were devastated and went through all the things that parents typically do with such an incredible situation. They were diagnosed with something called pseudoxanthoma elasticum which is a disease which causes blindness and some gastrointestinal and cardiovascular difficulties. With no biological background at all, my husband and I were at a loss as what to do. I'm a former Roman Catholic nun and a teacher. We went to the Genetic Alliance to ask for help in setting up an advocacy organization and they helped mentor us to the point we are today.

As a result of my work with them, they connected me with networks, they gave me lots of resources. I decided to join the Genetic Alliance and am now on the Board of Directors as Vice President for Consumers.

The Genetic Alliance would like to request that all cloning of human beings be halted at this time and we have a couple of reasons for that. As we've eloquently today by scientists, medical, safety and efficacy issues are not resolved around human cloning and we really need to be sure of those issues before we look further at this issue.

Right now we think that those outweigh any current potential benefits. These things do not come close to meeting the rigors of minimum human protection, safety and efficacy standards.

In addition to just considering a ban, we would also recommend that we consider a large societal informed debate that would occur across many sectors of the population. We need to identify and understand these risks as a population and we have not had this debate as a society yet. We need to engage all stakeholders and as a society, we must discuss and debate the full range of the ethical, legal and social issues.

The issue of cloning a human being touches upon the essence of what it means to be human and so it deserves serious consideration. Families and communities must be involved in the debate within the context of culture and faith.

We must look at whether we are just propelled by justifiable societal needs or simply by new biomedical opportunities. Regardless of funding source, whether it's government or private, the spotlight should be on human subjects' protections.

Science and technologies are outpacing the development of appropriate policies for decisionmaking. Genetic testing, medical privacy, genetic discrimination and others are some of the issues we face without having the right policies in place. So we call for an immediate halt to all effort to clone human beings and we look forward to being an active partner and a resource in the broad societal debate that we hope will ensue.

Thank you.

[The prepared statement of Sharon F. Terry follows:]

PREPARED STATEMENT OF SHARON F. TERRY, VICE PRESIDENT FOR CONSUMERS,
GENETIC ALLIANCE

The Genetic Alliance, the largest coalition of genetics consumer and professional organizations worldwide, calls for an immediate halt to all efforts to clone human beings and recommends open and informed societal dialogue on this crucial issue.

The Genetic Alliance provides a unified voice for millions of people living with common genetic disorders such as diabetes and breast cancer, as well as rare conditions such as cystic fibrosis and sickle cell anemia. Our families and communities look forward to the tremendous potential of biomedical research and technologies to improve health and well being. We know that cellular, tissue and organ cloning holds significant promise for generating treatments and cures for common and rare diseases. We also underscore the fact that creating a living human being through cloning is very distinct to working with cells in culture to achieve new medical benefits. The Board of Directors of the Genetic Alliance maintains that efforts to clone human beings—in contrast to cellular, tissue and organ cloning—pose significant safety, medical, ethical, legal and social risks, far outweighing any current potential benefits.

The Genetic Alliance expresses grave concerns about recently announced plans by several individuals to attempt to clone human beings. Based on recent scientific reports about the current status of mammalian cloning, we know that there are tre-

mendous potential human safety risks for mother and child. The track record for mammalian cloning indicates that these medical risks are formidable and extreme, even dire. The fact is that current cloning techniques to produce a genetically identical human being do not come close to meeting the rigors of minimum human protection, safety, efficacy and medical standards.

Moreover, societal dialogue is urgently needed to identify and understand the social, legal and ethical risks posed by the application of this technology. Rapidly emerging scientific research and technologies—such as human cloning—force us to examine the very essence of what it means to be human. The immensity of these issues demands that we halt all current efforts to clone human beings and engage all stakeholders in open and informed debate about the implications and impact of this technology.

At every step in advancing technology, we must ask ourselves whether we are propelled by justifiable societal needs or simply by new biomedical opportunities. As a society, we must discuss and debate the full range of ethical, legal and social issues surrounding the cloning of human beings. It is critical that this broad-based dialogue engages families and communities within the context of culture and faith.

Central to this dialogue is consideration of the role and responsibility of society in preventing harm to individuals and families. Debate about the cloning of human beings highlights a fundamental necessity that all research and clinical projects, regardless of funding source, come under the spotlight of human subjects regulatory protections. This is the only way to ensure, in a landscape of escalating biomedical technologies, the well being and safety of families and communities. In addition, protections must extend beyond current levels to encompass all research and clinical projects, regardless of whether the funding comes from the government or private sector. The discovery of a new technology should not automatically translate into availability of that technology without regard for public safety and well being.

The Genetic Alliance recognizes that biomedical technologies are quickly outpacing the development of appropriate policies to inform the decision-making of researchers and the general public on many issues, including genetic testing, medical privacy, genetic discrimination and others. Grounded in the personal experiences of people already at the frontlines of technologies, the Genetic Alliance works to ensure the potential benefits of biomedical research, while promoting meaningful and informed public policies about the implications, impact and promise of these technologies. Our stance in calling for a halt to the cloning of human beings reflects the Genetic Alliance commitment to establishing the highest levels of medical, social, legal and ethical protections.

In summary, the Board of Directors of the Genetic Alliance recommends that Congress take immediate action to halt all cloning of human beings. However, we must take care not to obstruct current cellular, tissue and organ cloning that may result in significant health improvements for our families and communities. Moreover, the Genetic Alliance urges Congress to call for immediate and broad-based societal dialogue about the implications and impact of cloning human beings.

The Genetic Alliance looks forward to being an active partner and resource in the open, informed and broad-based debate that must guide public policy deliberations about the translation of biomedical technologies into mainstream medicine.

Mr. GREENWOOD. Thank you very much for that testimony.
Dr. Soules.

STATEMENT OF MICHAEL R. SOULES

Mr. SOULES. Mr. Chairman, thank you for the invitation to attend this committee hearing and to participate.

Before I start, I'd like to request that my written testimony that I've submitted already, plus our society had an ethics committee report in November 2000 to be made part of the record.

Mr. GREENWOOD. Without objection, they will be made part of the record.

Mr. SOULES. Thank you. My name is Dr. Michael Soules. I'm a physician. I think maybe among all the people testifying today, I'm the only practicing physician. I'm a Professor in the Department of Obstetrics and Gynecology at the University of Washington in Seattle and I'm also Reproductive Endocrinologist and Director of the Division of Reproductive Endocrinology in our Department.

I'm here today because I'm President of the American Society for Reproductive Medicine. Our society is somewhat unique among professional medical societies in that we have a diverse membership. It's not only physicians and a number of different physicians, but it's also biologists who do the laboratory work like with IVF, there's nurses, there's mental health professionals, there's clinic managers and so on, so we're quite a strong organization and all the members are dedicated toward improving the practice of reproductive medicine.

I have three basic points I wish to make in my testimony today. First, ASRM finds unacceptable any attempt at reproductive cloning of an existing or preexisting human being. At this time, we feel there is no clinical, scientific, therapeutic or moral justification for it. Put simply, this is a technology that's not ready for prime time.

Second, we are satisfied that the Food and Drug Administration already has the legal authority to stop any such attempts and the FDA has made that clear to the reproductive medicine community. I realize that was a point of discussion a little while ago, but about 18 months ago I got a letter at the University of Washington from the FDA making it clear that I would need an IND to proceed. So therefore, we don't think there's need for new legislation on this matter at this time.

My third point, I want to provide some information to help the committee understand the differences between reproductive cloning and sexual reproduction. I won't be redundant than what's been talked about, but where the differences seem at one level to be obvious, but the media reports and some of the testimony today, I suspect would confuse some people that were listening.

The American Society of Reproductive Medicine has been on record as opposing attempts at human reproductive cloning since the announcement of the successful cloning of a sheep in 1997. We reiterated this stance in 1998 by leading the effort for a moratorium on human cloning by scientific groups. That moratorium has now been joined by nearly every reputable and relevant scientific organization of which we are aware.

We have learned how to use cloning with microscopic organisms and any of us who do gardening or any work with plants would realize that not all cloning is bad, for instance, I come from Washington State and apple is the fruit of a cloned tree. But it appears that in larger more complicated animals, cloning can be made to work, but it is not yet reliable, efficient nor safe.

As we've heard, cows and sheep have been cloned, but there have been many problems that while that's unfortunate in animals, it would be a disaster in humans. Until there are better results in animals, we have no business even considering it in human beings.

Parenthetically, talking about different means to screen embryos and screen pregnancies, Dr. Zavos mentioned a number of methods that could be used to make it safe. Well, when I submit a grant to the NIH or a proposal to my IRB and I have a bunch of ideas like that, that's nice. But the first thing that a responsible committee at NIH would do would look at my preliminary data to see can I back it up, basically. And I would encourage Dr. Zavos, in fact, the ASRM of which Dr. Zavos is a member, we would encour-

age him to do this research and if he has background in animals, do the research in animals. There seemed to be a problem in the discussion sort of leaping from cows to humans. Well, there's an obvious animal model to use and that would be the nonhuman primate and so we would strongly encourage Dr. Zavos and we would be very disappointed at our society, our medical society would be very disappointed if Dr. Zavos would proceed with his work.

I realize there have been calls for additional or more explicit legislative prohibitions on human cloning. We feel these would be unnecessary and potentially harmful. We have seen in other countries and in some of the United States and even in Congress, proposed legislation which, if enacted, would endanger research, deny therapies and even hinder drug production in areas that have nothing whatsoever to do with cloning.

The very first tenet of medicine, that's what I take and physicians take, the Hippocratic Oath when we graduate is first, do no harm. The Hippocratic Oath appears to apply in this legislative context as well. Additional legislation will not deter a rogue scientist from making ill-advised attempts at cloning outside of the United States jurisdiction. Therefore, ASRM supports current FDA policy and sees no need for new legislation. But I would go on to say if the committee and Congress felt that they needed to or it was wise in your opinion to proceed with legislation, to keep it narrow. The biotechnology representative that was here earlier, we would totally agree with his statement that if cloning research was allowed to continue, and if the law basically said that no embryos would be implanted and you can't grow an embryo beyond 14 days basically even in the best labs and so if that embryo is not transferred, it's not going to become a life. And so I think that would be sort of a gatekeeper or an area to concentrate on it and our society would very—if Congress feels compelled to proceed with legislation, we would like to work with you in that regard.

Mr. GREENWOOD. Dr. Soules, excuse me. We're going to have recess. This will be the last recess of the day, the last vote of the day and we'll reconvene in 10 minutes.

[Brief recess.]

Mr. GREENWOOD. The hearing will come to order. Dr. Soules, your time had expired, but you seemed to be in mid-sentence, I think, when I interrupted you. Did you have a final thought that you wanted to make?

Mr. SOULES. One paragraph?

Mr. GREENWOOD. At most.

Mr. SOULES. I've got to find the best paragraph. I'd just like to make the point that, as I mentioned earlier, I take care of infertile patients every day. In fact, I have clinic tomorrow. But I employ a range of medical therapies, many of them quite complicated to help people to have children they desperately want. My colleagues and I are interested in helping our patients have children and start their families, but the main point infertile patients are desperate and they don't always make good decisions. That's what IRBs are for and that's what ethics committees are for. And I think anyone who justifies cloning based on they have a list of patients who want the procedure, have basically pandered to a vulnerable audience.

Thank you.

[The prepared statement of Michael R. Soules follows:]

PREPARED STATEMENT OF MICHAEL R. SOULES, PRESIDENT, AMERICAN SOCIETY FOR
REPRODUCTIVE MEDICINE

Good afternoon Mr. Chairman and members of the committee. Thank you for holding this important hearing and for inviting us to participate.

I am Dr. Michael R. Soules, Professor of Obstetrics and Gynecology, and Director of the Division of Reproductive Endocrinology and Infertility at the University of Washington in Seattle, Washington. Currently I am President of the American Society for Reproductive Medicine (ASRM). ASRM is a national professional organization whose nearly 9,000 members are dedicated to advancing knowledge and expertise in reproductive medicine and biology and treating infertility. Our membership is made up of physicians; (ob/gyns, reproductive endocrinologists, and urologists), reproductive biologists, laboratory directors, nurses and mental health professionals, all of who are dedicated to advancing the cause of reproductive medicine.

I have 3 simple points I wish to make in my testimony today:

First, that ASRM finds unacceptable any attempt at reproductive cloning of an existing human being. At this time, there is no clinical, scientific, therapeutic or moral justification for it. Put simply, this a technology that is not ready for prime time.

Second, that we are satisfied that the Food and Drug Administration already has the legal authority to stop any such attempts, the FDA has made that clear to the reproductive medicine community. Therefore we do not think there is a need for new legislation, or new activity at the FDA, on this matter.

Third, I want to provide some information to help the committee understand the differences between reproductive cloning and sexual reproduction. These differences are at one level obvious, but if one follows recent media reports, often misunderstood.

THE ASRM STANCE

ASRM has been on record as opposing attempts at human cloning since the announcement of the successful cloning of a sheep in 1997. We reiterated this stance in 1998 by leading the effort for a moratorium on human cloning by scientific groups. That moratorium has now been joined by nearly every reputable and relevant scientific organization of which we are aware. We have also assisted policy makers in determining the best way to protect the public on this issue. We have participated in earlier Congressional hearings and worked on cloning legislation. In November of last year our ethics committee released a very thoughtful report on somatic cell nuclear transfer (cloning), again concluding that because the safety and efficacy of the procedure had not been established, it would be unethical at this time to attempt human cloning. This year, in response to media reports and other non-scientific events, we again stated our view that attempts at cloning are unethical.

Please note we are not making a judgment on the ultimate ethical validity of human cloning. It is possible that some form of cloning might, under some circumstances, be warranted. We simply have not yet made that determination within our professional society nor has the general public. More information and indeed more discussion are needed. We welcome those discussions, but at present we need not come to any conclusion. Until more is understood about cloning in animals, there is no ethical justification for attempting it in humans.

We have learned how to use cloning with microscopic organisms and any of us who gardens know cloning works with many plants (e.g., apple). Some species of animals, such as frogs and mice can be cloned quite successfully. It appears that in larger, more complicated animals, cloning can be made to work, but it is not yet reliable. Cows and sheep have been cloned, but there have been many problems that, while unfortunate in animals, are completely unacceptable in human beings. Until there are better results in animals, we have no business even considering it in human beings.

FDA CONTROL

Fortunately, the very lack of scientific evidence that the procedure is safe or effective (that leads us to conclude it is unethical to attempt human cloning), would allow the FDA to stop any attempt at human cloning. The FDA has said quite clearly that any attempt at human cloning would require a New Drug Application (NDA), and I feel certain that such an application would not be approved given the current scientific realities.

I realize there have been calls for additional or more explicit legislative prohibitions on human cloning. We feel these would be unnecessary and potentially harmful.

We have seen in other countries, in some of the states, and even in Congress proposed legislation which, if enacted, would endanger research, deny therapies and even hinder drug production in areas that have nothing whatsoever to do with cloning.

The very first tenant of medicine in the Hippocratic oath is "First, do no harm." The Hippocratic oath appears to apply in this legislative context as well. Existing law gives FDA the authority to stop human cloning. Additional legislation will not deter rogue scientists from making an ill-advised attempt at cloning outside U.S. jurisdiction. Therefore ASRM supports current FDA policy and sees no need for new legislation.

ASSISTED REPRODUCTION IS NOT CLONING

I also want to provide the committee some assurance in regards to advanced therapies for infertility. Despite what you might see in the news media, human cloning is not easy, nor imminent. It presents many more scientific challenges than have been generally portrayed. People have said that anyone could take current technology used for assisted reproduction and apply it to human cloning. This is simply not true.

First, while we are constantly improving our ability to treat patients suffering from the disease of infertility, it is still far from easy. The education, training, and equipment required are extensive. Frankly, we resent the media reports that make it appear that anyone could set up an IVF clinic in their garage. The asexual replication in cloning is nothing like the Assisted Reproduction that has helped provide families with more than 100,000 new children in the U.S. alone.

More significant however, there are huge fundamental differences between Cloning and sexual reproduction, even if that reproduction occurs in a laboratory in both instances. In an IVF procedure we help a sperm and an egg "get together." Just as with natural conception, half the genetic material comes from the mother and half from the father. These gametes mix and mingle and align themselves in new ways to form a new and unique genetic combination. Cloning is the replication of an existing genome, and it's simply a copy. This is very, very different from the new being created through sexual reproduction.

For some primitive species, cloning is the main method of reproduction. However, it is sexual reproduction that has given us the magnificent diversity of species we have on our planet today. Many of the problems seen in recent attempts to clone animals stem from the fact that these clones are replications and not new combinations.

I take care of infertile patients every day. I employ a range of medical therapies, many of them quite complicated to help people have the children they so desperately want. My colleagues and I are interested in helping our patients have children and start families. Infertility is an emotional devastating disease. Infertile patients are desperate. Anyone who justifies cloning based on requests from infertile patients is pandering to a vulnerable audience.

However, we have seen first hand in the U.S., how fear and unwise policy decisions can make it extremely difficult for us to improve the treatments we have available to offer our patients. The decision to deny federal funds for research involving human IVF has harmed the millions of Americans suffering from infertility. I am fearful that a negative decision may be made on stem cell research that will cause needless suffering for patients with heart disease, diabetes or Parkinson's disease. Please do not make these situations worse by enacting new and unneeded prohibition on human cloning.

I thank you for your time and will be happy to answer any questions.

Mr. GREENWOOD. Thank you very much.

Mr. Wicker, thank you for your patience and you are recognized to testify for 5 minutes.

STATEMENT OF RANDOLFE H. WICKER

Mr. WICKER. Thank you. My name is Randolfe Wicker. I'm the Director of the Human Cloning Foundation and the founder of the Clone Rights United Front. I would request that my full testimony and the four attachments be included in the official record. I'm

going to read briefly from some highlighted sections of that testimony.

Mr. GREENWOOD. Mr. Wicker, could you pull your microphone in a little closer and make sure it's turned on. Is the light on?

Mr. WICKER. The light is on.

Mr. GREENWOOD. Okay, very well.

Mr. WICKER. Can I begin again, without losing time? Anyway, I would like to make quickly the points and summary that I made of rehighlighted points of my testimony. I ask that my full testimony and four attachments be included in the record.

Mr. GREENWOOD. It will.

Mr. WICKER. The points made are cloning is a part of every citizen's reproductive right. Stem cell research is based on human cloning technology. The FDA has no authority over the fertility industry. Cloning is a part of every American's right to religious liberty. The Raelian Movement is a legitimate, religious movement. The Raelian Movement and its Clonaid have behaved fraudulently. There is no need for new laws in this area. The dangers of animal cloning are not applicable to human cloning. And finally, the international consortium which includes Dr. Zavos is a cautious, professional, experienced team. The regulation of medicine should be left to physicians. Medicine and science are not areas in which unknowledgeable politicians should meddle.

Thank you for inviting me to testify today. This hearing is being held because everyone knows that human cloning is going to happen. As Dr. Zavos points out, the genie is out of the bottle. As a human cloning activist during the last 4 years, I've viewed with alarm the growing public hysteria surrounding this issue. The general public is both highly opinionated and totally misinformed regarding human cloning.

The first and most central issue raised by human cloning involves each individual citizen's reproductive rights, the decision by individual citizens about having children and their manner of conception has always been the decision made by a patient in consultation with her or his doctor. Politicians in Washington and politicians in State capitals have no business deciding for American citizens how and when they can have children.

The second critical issue raised by human cloning involves each individual citizen's right to religious belief and practice. I testified to the House of Representatives' Committee on Commerce in 1998. I'd like to quote a short part of that before tackling the difficult situation currently facing us. I would also like to note that on this issue, I'm speaking for myself and not as an official representative of the Human Cloning Foundation.

This is from my previous testimony, "Religious-based decisions have no place in the law. They violate religious freedom. Those who believe cloning offers a partial temporary immortality have the right to secure an extended life for their genotype. Human cloning does change, at least slightly, the traditional clear line between life and death. If even after death, a later born identical twin can be born carrying the originator's genotype into another life, doesn't that somehow deny death as traditional totality? An appropriate phrase might be right to life equals right to clone. As a Montreal-based group, the Raelians with which"—and this is from 1998—

“from which I have no association whatsoever, I might say, are virtually preaching an extended life through cloning. They offer to clone you for \$200,000 at their Bahamian facilities which we have found don’t really exist.” That was on page 11, February 12, 1998.

I’m submitting to this committee a copy of a press release and an invitation to me, sent on October 8, 2000 by Nadine Gerry on behalf of Clonaid entitled “The First Human Cloning Company” entitled “Human cloning will allow gay couples to have children that—enables gay couples to have children.” I ask that it be included in the official printed record. That’s Attachment 1.

Virtually all media, with the exception of Wired Magazine which had an excellent article, really factual, not opinionated. Exceptional cover story about Brian Alexander having ignored the outrageous hype and attempted fraud perpetuated by the Raelian Movement. Apparently, you can get away with almost anything in the United States if you just do it in the name of religion and call yourself a faith-based enterprise.

I would like to just quote the Raelians, they claim to have cloning facilities no one has ever seen. They prey on parents with dying children as if through cloning you can bring back a lost, loved one. This is morally reprehensible. In my opinion, the press release, Attachment 1 proves this group has attempted to defraud the gay community by creating, saying they can create children with the combined genes of two members of the same sex and that has at this time been scientifically impossible.

It is mind boggling that the most major media equate declarations by a group of space cadet wackos about their secret lab where they are claiming they are actually cloning human beings, that they compare that to the professional responsible cautious attempt to perfect cloning technology by two of the world’s most renown and experienced fertility doctors, Dr. Zavos and Dr. Antinori. During a personal meeting, less than a week ago, Dr. Zavos pointed out to me that he was not selling anything, compared to the Raelians who tell the media that he who pays the most, gets cloned first. Dr. Zavos’ services are not for sale. I believe he is as he appears to be, a dedicated, warm human being seeking to perfect a narrowly focused therapy for disabled, infertile couples so that they may have children genetically related to themselves. For instance, I would not qualify for Dr. Zavos’ and Dr. Antinori’s criteria. They have set narrow limits and strict guidelines.

The soundbyte for today is cloning is dangerous because animal experiments have shown it to be so. I would suggest that journalists read carefully the detailed screening procedures that will be undertaken before human cloning is even attempted by this professional international consortium. That is in his Exhibit 1, very excellent presentation. Please read that collaborative effort.

Now we face the great issue of animal deformities that resulted from animal experiments. This is the big issue this week. Well, to begin with, let us say 2 year old cloning technology and/or studies are equivalent to 10 year old computer technologies. I would ask any thinking person to consider the facts, the international consortium is working to perfect human cloning technology. Indeed, because it has taken a cautious, professional approach, it might well

be faced with the disastrous results from those crazies seeing money, fame and glory for their profit.

I respectfully submit this testimony to the committee and hope that the information contained in it helps it shape constructive, political and social policy for the new millennium.

I remain cloningly yours, Randolfe H. Wicker.

[The prepared statement of Randolfe H. Wicker follows:]

PREPARED STATEMENT OF RANDOLFE H. WICKER, FOUNDER, CLONE RIGHTS UNITED FRONT, DIRECTOR, HUMAN CLONING FOUNDATION

Thank you for inviting me to testify today. This hearing is being held because everyone knows that human cloning is going to happen. As Dr. Zavos points out: "The Genie is out of the bottle".

As a human cloning activist during the past four years, I have viewed with alarm the growing public hysteria surrounding this issue. The general public is both highly opinionated and totally misinformed regarding human cloning.

Cloning technology is a scientific achievement as significant as the conquering of smallpox, although less important than the discovery of the printing press. Cloning technology has achieved monumental importance due to its central role in stem cell research.

Despite all the hand-wringing and declarations against the cloning of human beings by biotech companies, stem cell research cannot be separated from human cloning. The same technology, inserting a cell into an enucleated egg, is central to both.

The only difference between the two is that, in stem cell research, a tiny embryo no larger than the dot at the end of this sentence is killed through transforming it into a stem cell culture. In human cloning, the same embryo would be implanted into a woman's womb and allowed to develop into a wanted and loved child.

The general public supports stem cell research because it promises to revolutionize medicine. The same public opposes human cloning, which itself is simply a medical cure for the human disability called infertility.

The FDA has issued invalid legally unenforceable politically popular feel-good regulations forbidding human cloning in American fertility clinics. Mark Eibert will elaborate on this later.

The Government that governs best governs least.

The first and most central issue raised by human cloning involves each individual citizen's reproductive rights.

The decision by individual citizens about having children and their manner of conception has always been a decision made by a patient in consultation with her or his doctor.

Politicians in Washington and politicians in state capitols have no business deciding for American citizens who can bear children and how they can have them.

The second critical issue raised by human cloning involves each individual citizen's right to religious belief and practice.

I testified to the U S House of Representatives Committee on Commerce, Subcommittee on Health and Environment, on Thursday, February 12, 1998. I would like to quote a short part of that testimony before tackling the difficult situation currently facing us.

I would also like to note that, on this issue, I am speaking for myself and not as an official representative of The Human Cloning Foundation.

"...Religiously based restrictions...have no place in the law. They violate religious freedom. Those who believe cloning offers a partial temporary immortality have the right to secure an extended life for their genotype...human cloning does change, at least slightly, the traditionally clear line between life and death. "If, even after death, a later born identical twin can be born carrying the originator's genotype into another life, doesn't that somehow deny death its traditional totality?"

[An appropriate phrase might be, "Right To Life equals Right to Clone."]

"Already, a Montreal-based group, the Raelians—with which I have no association whatsoever, I might say—are virtually preaching eternal or extended life through cloning. They offer to clone you for \$200,000 at their Bahamian facility, which we have found out doesn't really exist." (See page 111 of February 12, 1998, Testimony to the Subcommittee.)

I am submitting to this committee a copy of a press release and invitation sent to me on October 8, 2000 by Nadine Gary on behalf of CLONAIID, "The First Human Cloning Company," entitled "HUMAN CLONING WILL ALLOW GAY COUPLES

TO HAVE CHILDREN,” I ask that it be included in the official printed record. (See Attachment 1)

I am also submitting the opening few paragraphs of an article I wrote and which was published in *GayToday*, www.gaytoday.badpuppy.com that gives context and perspective to the CLONAIID press release with the same name. (See Attachment 2)

I am also submitting two other articles filled with valuable information. The first is an editorial from www.clonerights.com entitled “Religious Group Hijacks Human Cloning Movement,” January 8, 2001. (See attachment 3)

The second is one of many items sent to me to be shared with the press. It is titled “A Christian’s Letter to CLONAIID.” (See Attachment 4)

Virtually all media, with the exception of *Wired Magazine’s* exceptional cover story by Brian Alexander (February 2001), have ignored the outrageous hype and attempted fraud perpetuated by the Raelian Movement. Apparently, you can get away with almost anything in the United States if you just do it in the name of religion and called yourself a faith-based enterprise.

Freedom of speech does not give anyone the right to falsely scream “Fire!” in a crowded theater. Freedom of religion does not give anyone the right to commit fraud.

There is no need for new legislation or regulation on either reproductive freedom or religious belief. There is only a need to prosecute “fraud” whenever it occurs regardless of the person or group perpetrating it.

Finally, the last critical question raised by human cloning technology revolves around “who” should control and regulate it or whether control and regulation are even possible. It is nearly impossible to draft legislation to outlaw reproductive cloning without harming medical and scientific research in the process.

It is mind-boggling that most major media equate declarations by a group of space-cadet wackos about their “secret lab” where they are claiming that they are actually cloning a human being to the professional, responsible, cautious attempt to perfect cloning technology by two of the world’s most renowned and experienced fertility doctors.

This is like comparing “moon rocks” to polished Earthly diamonds. Drs. Zavos and Antinori speak in terms of “perfecting techniques,” which will make human cloning safe and viable.

During a personal meeting less than a week ago, Dr. Zavos pointed out to me that he was “not selling anything”—compared to the Raelians who tell the media that “he who pays the most gets cloned first.”

Dr. Zavos’ services are not for sale. I believe that he is as he appears to be—a dedicated warm human being seeking to perfect a narrowly-focused therapy for disabled infertile couples so that they might have children genetically related to themselves.

For instance, I would not qualify under Dr. Zavos’ and Dr. Antinori’s criteria. They have set “narrow limits” and “strict guidelines” regarding their goals. I would suggest that those interested read a leaflet about the 62-year-old woman who had a healthy child with Dr. Antinori’s help, which I will not submit as testimony unless requested by the Committee.

The “sound bite” for today is “Cloning is Dangerous Because Animal Experiments Have Shown It to be So.” I would suggest that journalists read carefully the detailed screening procedures that will be undertaken before human cloning is even attempted by this professional international consortium.

I see a line-up of witnesses ready to testify to this committee. We have Arthur Caplan, whose voice has so crowded out other voices within bioethics that he is recognized as an American secular Pope. In *Time Magazine*, he said, “The short answer to the cloning question is that anybody who clones somebody today should be arrested.”

Dr. Zavos and I have decided to “depose” this self-anointed secular Pope by refusing to debate him. See our leaflet “Let Other Bioethicists Be Heard,” which this Committee may include in its publication if it so chooses. How does one engage in civilized discourse with a man who begins the debate declaring that you should “be arrested”?

This “moral authority” who would have us arrested was the first ethicist sued because of his involvement in the unnecessary death of Tucson teenager Jesse Gelsinger. I would suggest that HE should be the one “arrested.” This is a man who has contributed to the death of a healthy young American citizen. I object to his being allowed to testify to this committee. His “morality” has been the subject of legal action.

I also see that you have another anti-cloning witness, Rudolf Jaenisch, from MIT. I listened carefully to this man’s arguments on “The Charlie Rose Show.” Basically,

he argued that Dolly, the sheep conceived through cloning, might be “mentally retarded and/or schizophrenic.”

I would appreciate Rudolf Jaenisch supplying me with an “intelligence test” or a psychological screening test to see if an apparently normal sheep is or is not schizophrenic.

You can’t win with these people. When I testified in 1998, the skeptics were asking if “we could be sure ‘Dolly’ wasn’t a fraud?” After that, the naysayers said “Dolly” was seven years old when she was born. Well, we now have five successive generations of cloned mice, and their telomeres seem to indicate that “cloning” actually increases life expectancy. Dolly, if she was six or seven years of age at birth, must be the oldest living sheep in memory to have had offspring just recently.

I am not an “expert” in sheep menopause. I refer you to Rudolf Jaenisch on that issue. And please, get me that “intelligence test” and that “personality evaluation” test for sheep so we can evaluate his allegations.

Now, we face the great issue of animal deformities that resulted from animal experiments. This is the “big issue” this week.

Well, to begin, let us say “two year old cloning technology and/or studies are equivalent to ten year old computer technology.” Adults come to this issue (and I might well be one of them) with emotionally-based biases around which they construct intellectual defenses.

I would ask any thinking person to consider the facts: the international consortium is working to “perfect” human cloning technology. Indeed, because it is taking a cautious professional approach, it might well be faced with disastrous results from those “crazies” seeking money, fame and glory for their “prophet.”

I would point to an extraordinary situation in Brazil (Economist, July 22, 2000) in which science funding is insulated from the whims of politicians and the general public’s hysteria. Shouldn’t this be the model for the United States of America?

I respectfully submit this testimony to this committee and hope that the information contained in it helps shape constructive political and social policy for the new Millennium.

[All attachments submitted are retained in subcommittee files.]

Mr. GREENWOOD. Thank you, Mr. Wicker, I’m sure your testimony will help us in just that way.

Mr. Hanson.

STATEMENT OF JAYDEE HANSON

Mr. HANSON. We have a flood a little smaller than Noah’s here, but I’m Jaydee Hanson speaking on behalf of the United Methodist General Board of Church and Society. The General Conference of the United Methodist Church is the only body empowered to speak for the entire church. The United Methodist has some 8.4 million members in the United States. This past May, the General Conference called for, and I quote, “a ban on all human cloning including the cloning of human embryos. This would include all projects, privately or governmentally funded, that are intended to advance human cloning.”

The General Conference based its position on the work of the United Methodist Genetic Science Task Force which began its work in 1989, some 8 years before the Scottish laboratory succeeded in cloning Dolly. The task force includes scientists, social scientists, theologians, ethicists, doctors and a lawyer.

Since the cloning of Dolly this issue of cloning has sparked enormous and sustained concern in the general public including the church. Many other denominations, other than the United Methodist Church have also issued statements opposing human cloning. The United Methodist Church’s opposition to cloning comes from our understanding of a theology of God’s creation and how humans are to be stewards of God’s creation.

The new biological technologies, including cloning, force us to examine as never before the meaning of life and our understanding

of ourselves as humans in our proper role in God's creation. Our "General Conference cautions that the prevalent principle in research that what can be done should be done is insufficient rationale and should not be the prevalent principle guiding the development of new technologies. Technologies need moral and ethical guidance.

As United Methodists, our reflections on these issues emerge from our faith. We remember that creation has its origin, value and destiny in God and that humans are stewards of creation, that technology has brought both great benefit and great harm to creation. As people of faith, we believe that our identity is more than our genetic inheritance, our social environment or the sum of the two. We are created by God and have been redeemed by Jesus Christ. In light of these theological questions, fears and expectations we recognize that our present human knowledge on this issue is incomplete and finite. We do not know all of the consequences of cloning, but it is important that the limits of human knowledge be considered as policy is made." That ends of the quote of the General Conference.

Rebekah Miles, a professor of ethics at Southern Methodist University is a member of our Genetic Science task force and I think has summarized well the questions we all should consider, at least those of us that are part of the church. "Will human cloning compromise our God-given uniqueness or distinctiveness? How might human cloning be misused by sinful humans to further their selfish ends and objectify other people? Is a desire to replicate one's genetic inheritance in a human clone an attempt to deny our inevitable finitude as human beings? Will human cloning further social justice? When does human alteration of creation so go far as to become a violation of God's creation? What is the difference between our human capacities for creation and God's?"

Our Genetic Science Task Force concluded that cloning would compromise human distinctiveness, that it would be used as a way to further social injustice, and that it was a violation of their understanding of God's creation.

The General Conference statement on cloning notes a number of ways that human cloning could have social and theological implications and they list the use and abuse of people, exploitation of women, tearing the fabric of the family, compromising human distinctiveness, lessening of genetic diversity, the direction of research and developing on cloning would like be controlled by profit. The General Conference further noted that given the profound theological and moral implications, the imperfection of human knowledge that there be a moratorium on cloning-related research.

One of the most basic Christian stories in the Bible concerns the temptations of Jesus in the wilderness. In none of these temptations was Jesus tempted to do bad things. Turn stones into bread, show the glory of God, become an earthly ruler, none of those were in and of themselves bad things. But Jesus resisted the temptation to do the wrong thing at the wrong time.

We face a similar temptation in our shared desire to have healthy children. But cloning is the wrong way to address infertility and other reproductive problems. Cloning proponents will argue that cloning will soon become a normal way of producing hu-

mans and that initial opposition will fade away when the safety concerns are addressed. The cloning of humans should never be allowed to become normal.

The U.S. Congress has the opportunity to join with many other countries and ban cloning. The rest of the world is looking to the United States for leadership on this issue. As the ethicist, Leon Kass notes, "This is not business as usual to be fretted about for a while but to finally be given our approval. We must rise to the occasion and make our judgments as if the future of our humanity hangs in the balance. For so it does."

Thank you for hearing me. I would request permission of the committee to expand my remarks for the record.

Mr. GREENWOOD. Any other material that you'd like to submit to the committee will be included in the record, sir.

Mr. HANSON. Thank you very much.

[The prepared statement of Jaydee Hanson follows:]

PREPARED STATEMENT OF JAYDEE HANSON, ASSISTANT GENERAL SECRETARY FOR PUBLIC WITNESS AND ADVOCACY, GENERAL BOARD OF CHURCH AND SOCIETY, THE UNITED METHODIST CHURCH

The General Conference of The United Methodist Church, is the only church body that speaks for the entire 8.4 million member United Methodist Church. This past May, the General Conference called "for a ban on all human cloning, including the cloning of human embryos. This would include all projects, privately or governmentally funded, that are intended to advance human cloning." (The Book of Resolutions of The United Methodist Church, 2000, p. 254)

The General Conference based its position on the work of the United Methodist Genetic Science Task Force which began its work in 1989, some 8 years before a Scottish laboratory succeeded in cloning "Dolly."

Since the cloning of Dolly, this issue of cloning has sparked enormous and sustained concern in the general public, including the church. Many other denominations other than the United Methodist Church have also issued statements opposing human cloning. The United Methodist Church opposition to cloning comes from our understanding of a theology of God's creation and how humans are to be stewards of God's creation. The new biological technologies, including cloning, force us to examine as never before, the meaning of life, our understanding of ourselves as humans, and our proper role in God's creation. The General Conference "caution(s) that the prevalent principle in research that what can be done should be done is insufficient rationale... and should not be the prevalent principle guiding the development of new technologies... technologies need moral and ethical guidance." (Book of Resolutions, p. 248)

As United Methodists, our reflections on these issues emerge from our faith. We remember that creation has its origin, value, and destiny in God, that humans are stewards of creation, and that technology has brought both great benefit and harm to creation. As people of faith, we believe that our identity as humans is more than our genetic inheritance, our social environment, or the sum of the two. We are created by God and have been redeemed by Jesus Christ. In light of these theological claims and other questions, fears and expectations, we recognize that our present human knowledge on this issue is incomplete and finite. We do not know all of the consequences of cloning... It is important that the limits of human knowledge be considered as policy is made. (Book of Resolutions, p.254)

Dr. Rebekah Miles, associate professor of ethics, at Perkins School of Theology, Southern Methodist University and a member of the United Methodist Task Force on Genetic Science summarized the questions asked by our taskforce.

Will human cloning compromise our God-given uniqueness or distinctiveness?

How might human cloning be misused by sinful humans to further their selfish ends and objectify other people?

Is a desire to replicate one's genetic inheritance in a human clone an attempt to deny our inevitable finitude as human beings?

Will human cloning further social injustice...?

When does human alteration of creation go so far as to become a violation of God's creation?

What is the difference between our human capacities for creation and God's?

Our Genetic Science Task Force concluded that cloning would compromise human distinctiveness, that it would be used as a way to further social injustice, and was a violation of their understanding of God's Creation and as such should be banned.

The General Conference statement on human cloning notes a number of ways that human cloning would have social and theological ramifications: *(the use and abuse of people, exploitation of women, (the) tearing of the fabric of the family, the compromising of human distinctiveness, the lessening of genetic diversity, the direction of research and development (on cloning would likely be) . . . controlled by corporate profit . . .* (Book of Resolutions, p. 254) The General Conference further noted that *Given the profound theological and moral implications, the imperfection of human knowledge that there be a moratorium on cloning-related research.*

Cloning proponents will argue that cloning will soon become a normal way of reproducing humans and that initial opposition will fade away when safety concerns are addressed. The cloning of human humans should never be allowed to become "normal". The US Congress has the opportunity to join with many other countries where the United Methodist Church has members and ban human cloning. The rest of the world is looking to the United States for leadership on this issue. As the ethicist, Leon Kass notes, *This is not business as usual to be fretted about for a while but to finally be given our approval. We must rise to the occasion and make our judgements as if the future of our humanity hangs in the balance. For so it does.* (Leon Kass, "The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans.")

Mr. GREENWOOD. Rael, you are recognized to testify for 5 minutes.

STATEMENT OF RAEI

Mr. RAEI. Thank you, Mr. Chairman, for inviting me. I have a request to include to my text, manifesto signed by 36 scientists and philosophers of the world from New Humanist Association including Frances Crick, co-discoverer of DNA and numerous Nobel prize laureates who support the freedom for human cloning as part of freedom of science be attached to my testimony.

Mr. GREENWOOD. Without objection, it will be included in the record.

Mr. RAEI. Thank you, Mr. Chairman. I wish to dedicate my testimony to Giordano Bruno who was burned alive four centuries ago, sentenced to death penalty by the Catholic Church for saying that there was life on other planets.

Why did I ask Brigitte Boisselier to create the first human company in America? Because as the country of freedom you have a Constitution which would be a model for the world and the most wonderful jewel of your system, the Supreme Court, which guarantees a respect of your Constitution and the freedom of your citizens, events against your own government and law makers.

I am quite confident that even if human cloning was done, Supreme Court of America would consider this law as unconstitutional as they did for IVF. Two hundred thousand children alive today thanks to IVF in the world. If the laws against IVF had been kept, the 200,000 children will not exist. The life being denied under the pressure of the religious power. Before IVF was legalized, proponents were also predicting that this procedure would give birth to monsters and disformity. If 100 years ago religious powers could have passed law against the freedom of science we today would have no antibiotic, no surgery, no blood transfusion, no organ transplant, no vaccine, no cars, no electricity, no computers and no airplane. Stopping science is a crime against humanity. If these discoveries were forbidden 100 years ago, 2 billion people would never have enjoyed life, dying at very early stage of their

existence and they may have included your own parents and yourself.

We can see that at least 90 percent of the people in this room are still alive today thanks to science. Three billion people, this is more than any other criminal against humanity ever killed, including Hitler or Napoleon. Today, you have in your hands alive of billions of people, alive now or future generations. You have the choice to be remembered as heroes for saving billion of life or as criminal against humanity for denying them a possible cure, a new life or even eternal life by retarding scientific progress, retarding because it will be done anyway, somewhere, some day as thankfully nothing can stop science.

But law can slow down research and it is the people who will suffer from it and you will be responsible for the delay and the death and the suffering it will create. The deaths and suffering can be yours as well as lawmakers are not immune to sudden disease or your own beloved children or beloved grandchildren. Religious people were against human cloning should be free to refuse it for themselves or their own children as they are free today to refuse abortion, blood transfusion or surgery.

Human cloning will make it possible for us to reach eternal life. It is the right of the people who want to enjoy the fruit of scientific progress, including human cloning and eternal life, to benefit from it. If religion and superstition which are the same have power over science, we would still be living in the Dark Age. Your great Constitution includes the freedom of religion and that means also the freedom to be atheist, freedom to believe there is no god and benefit from science without any moral restriction.

We at Raelian believe that science should be our religion. Science saves lives, while religion and superstition kill. Science destroys superstition and supernatural belief. That's why religion was always an enemy of science and progress and is again trying to stop science at its best.

It should be the freedom of the people to decide if they want to benefit or not from human cloning. Legalizing human cloning is protecting the right of the unrebored as cloning makes it possible a second chance to live for infant, like the one Clonaid planned to clone now, a 10 month old baby killed by medical malpractice. It could be your own beloved child or grandchild, think about them personally. Lawmakers should not be accomplice of Dark Age power and superstition as they will be judged by history.

Human cloning is the first step to what is a great discovery, the creation of totally artificial form of life, like that was done by our creator, Zealohim, when he created us on earth. Not is human cloning is not against the wish of what people called God, but it is our creator's plan to discover and use it as many other religious leaders claim becoming as it is written in the Bible, equal to our work creator's.

[The prepared statement of Rael follows:]

PREPARED STATEMENT OF RAEL

The conservative, orthodox, fanatic traditional religions have always tried to keep humanity in a primitive stage of darkness. It is easy to see that in countries like Afghanistan which are back to the middle ages due to a fanatic Moslem government.

But this was also true in occidental powers. The first medical doctors who tried to study the human by opening cadavers were excommunicated by the Catholic Church. It was considered a sin to try to unveil the mystery of the creation of god... So were the first antibiotics, blood transfusions, vaccines, surgeries, contraception, organ transplants... religious fanatics were always saying that "it's a sin to go against the will of god... If somebody is sick, let him die, his life is in god's hands."

If our civilization would have respected these primitive ideas from dark ages, we would all die around 35, and 9 out of 10 babies born would die in their first 2 years.

Traditional religions have always been against scientific progress. They were against the steam engine, electricity, airplanes, cars, radio, television, etc...

If we had listened to them we would still have horses and carts and candles...

Twenty-two years ago they were against IVF, talking about monsters, Frankenstein and playing god, and now IVF is well accepted, performed every day by thousands and helping happy families with fertility problems to have babies.

Today human cloning will help other families to have children, and again they are against it. It will also help to cure numerous diseases, will help us live a lot longer, and finally will help us reach, in the future, eternal life.

Nothing should stop science, which should be 100% free.

Ethical committees are unnecessary and dangerous as they give power to conservative, obscurantist forces, which are guided only by traditional religious powers.

As well as there should be a complete separation of state and religion, there should also be a complete separation of science and state, or science and religion.

If there was an ethical committee when antibiotics, blood transfusions and vaccines were discovered it would have certainly been possible that these technologies would have been forbidden. You can imagine the poor health the world would be in today...

Ethical committees should be necessary when a deadly technology is making the production of weapons of mass destruction possible... And to my knowledge there are no ethical committees concerning nuclear, chemical or biological weapons. These things are created to kill millions of people and possibly destroy all life on earth. Cloning is a pro-life technology, a technology made to give birth to babies!

The first benefit of human cloning is to make it possible for couples who cannot have children using other existing techniques to have babies inheriting genetic traits from one of their parents. They can be infertile heterosexual couples or gay couples.

The second benefit is for families who lose a child due to crime, accident or disease to have the same child brought back to life.

All conservative "pro life" groups always talk about "the right of the unborn", but in this case we must talk about protecting the rights of the "unborn". As cloning technology makes this possible, why should we accept the accidental death of a beloved child, when we can bring this very child back to life?

People who are opposed to it are always influenced by a terrible Judeo-Christian education... the same as those who could have made antibiotics, vaccines, transfusions, surgery and organ transplants forbidden. Their main objections are:

1. "It is an unsafe technology, which is not advanced enough: the best way to develop this technology like all other technologies is by doing it. The first surgeries, organ transplants, and IVF were unsuccessful. But by doing it, scientists were able to develop their expertise.
2. "It will create monsters": a percentage of "normally" (sexually) conceived babies are born "monsters" or with genetic faults... Would you make a law against making babies sexually through the "natural" way because of these problems? Of course not and the percentage amongst cloned babies will be lower as they will be more precisely scrutinized from the first days after conception.
3. "The children made by cloning will have a terrible life being looked at as abnormal people": not more than IVF conceived children, or twins, or physically handicapped children or gay or colored people. It is not the problem of the children themselves, but the responsibility of the society to educate the public to respect the differences, all the differences, between human beings.
4. "It is against biodiversity to create cloned children, creating identical people": we have already on earth millions of twins and this is not a problem. The conception through cloning will always be used by a limited number of people and that will not affect biodiversity. But even if you imagine 6 billion human beings being cloned, the biodiversity is still the same as we still would be 6 billion different people!
5. "Cloned children will not be exactly the same": so what is the problem? As long as the families are informed about this, (and they are) there is absolutely no problem with that. People against cloning keep saying "it is terrible they will

- be the same” and then suddenly they argue “they will not be exactly the same”...So what is the problem?
6. “Cloned children will have terrible psychological problems being created to replace dead babies, but they will never be exactly the same”: loving families who lose a child and want to have him back through cloning have so much love for this child, a child they hope so much to have back, that I cannot imagine a child being loved more. More than other families, those who lose a child due to disease or accident or crime have learned so much about how life is fragile, that they will protect and care for these children much more than “normal” families. And a good education is to accept that your children are not exactly what you would want them to be. “Normal” families experience that every day when a father who is a medical doctor sees his child only interested by music or painting, as the father was dreaming to have his son become a doctor like he is... Real love is accepting the differences, and that includes the differences between the image you have of your child and who he really is.
 7. “Human cloning is unnatural”: we already answered to this objection. Nor are blood transfusions, antibiotics, organ transplants, vaccinations, surgery, etc... If we let “mother nature” work we would be all dead around 45 and 9 out of ten babies would die as infants...
 8. “Only God can create life”: this is pure belief, and religious people who are against human cloning have the right and the freedom not to do it, as they can refuse blood transfusion, organ transplant, surgeries, antibiotics, contraception, abortion, etc., but those who decide to do it should be respected as well.

These are the most frequent objections to human cloning, but we should also consider the advantages in the middle and long term aspects of human cloning for a non-fanatically religious society.

Human cloning will help cure numerous if not all diseases. It will also make possible to create a genetic bank where you will be able, if you need an organ transplant, to have it. Not by creating babies to take replacement organs from them...but by preserving stem cells of your body in very early stage embryos of yourself and develop in vitro only the organs you need in case of disease or accident.

One more time those opposed for religious reasons to this just should be free not to use it.

Finally, in the more long term, human cloning will make possible—when Accelerated Growth Process will be discovered to clone an adult copy of ourself directly just before we die and when Brain Data Transfer will be discovered, to transfer, or download (or upload) our memory and personality in this new young body for a new long life. The progress of humanity will be exponential at this level. Presently, when a scientist is at the top of his art, he starts to age and dies. We can imagine Einstein, Newton and Leonardo Da Vinci still alive and working together... the discoveries they could do would be unlimited. And the same for artists like Mozart, Beethoven and Bach being still alive.

Not only should human cloning be allowed for the good of today’s people, but even more for future generations who will remember your historical decision forever.

That’s why I chose America to create the first Human Cloning company, because it is the country of individual freedom and science on earth. Thanks to the U.S. system, which should be a model for the whole world, and special thanks to the Supreme Court, I am confident that the right to clone yourself as an individual, freedom, guaranteed by the great U.S. constitution, will be protected.

Mr. GREENWOOD. Thank you, sir, for your testimony.

The Chair recognizes himself for 5 minutes and I’m going to indulge myself with an editorial comment or two before I ask questions.

First, Mr. Rael, what strikes me is that what I’ve experienced today in this hearing is not religious voices overcoming scientific voices, but in fact, the respected scientists perhaps in opposition to your religious group. With regard to the law and science, our responsibility is to make sure that we use the best science in order to set policy.

I recall when I was a young boy, some very good scientists developed a medicine called thalidomide and that medicine was used to prevent morning sickness. And it was the scientists who ultimately we relied upon, the country relied upon to understand, to teach us, that this thalidomide was causing terrible deformities in children.

So we utilized good science to direct the scientists that were involved in thalidomide so as not to harm children.

Which causes me to turn my attention to the comments of Mr. Wicker and Mr. Eibert about what the responsibility of the law is and the politicians is with regard to having children. Before I was a politician, I was a social worker and I worked with abused and neglected children. Part of my responsibility was to see who it was and when it was that parents could safely rear children and to remove and deny the rights of parents who could not safely rear their children. So I think the real question for us here is not to assume that there's some ultimate and absolute right of anyone to have children. There's a lot of reasons why that's not the case, but as Mr. Pence suggested, to find out whether that we quote, "we must ask whether it was wrong for some other associated reason, mainly whether a child created by cloning would be harmed psychologically or physically." And that's the question we have to determine: whether cloning is such a threat to the physical well-being or the psychological well-being of a child so that we would pre-empt the right of someone to pursue their desire to be a parent when we think that the interest of the child or the prospective child come foremost and would be affected by that.

So let me address my question then to you, Dr. Pence, because what seemed to be circular about your testimony to me was that what you said I think is that we should permit cloning if we can determine that it can be done safely.

Mr. PENCE. Yes.

Mr. GREENWOOD. The question is how can we determine that cloning is safe for children if we don't clone children as an experiment and take the risk that it will be harmful? It seems to me the very difficult question here is that I don't know how to permit cloning experiments to go on when we could have deformed children born who would have to live their lives with those deformities, if they're fortunate enough to live their lives, who might have apparently been born physically well, and as others, some of the scientists have testified, could be walking, ticking biological time bombs because we don't know what the long-term effects of cloning might be. So they may have conditions that don't materialize for years and then materialize into something that is completely unpredictable and completely horrible. Certainly there is no way, it seems to me, to know what the psychological consequences are of being not a unique individual produced by the merging of the cells of a mother and father, but rather to be the replica of a pre-existing person. I don't know how we could ever determine beforehand that that was safe.

So my question is how could we possibly determine that it is safe enough to do this, without having taken the risk of doing it in the first place?

Mr. PENCE. I'm not so worried myself about the psychological harm, although I could speak to that, but I think the physical harm is really the devastating objection right now. I think if the science changed and we did get a handle on the reprogramming, especially in animal studies, primates would be the appropriate place to study that and to actually study them over the term of their life. At some point, if that—if we thought we understood that,

the primate studies, we probably would have to take a risk for the first child. I should point out that we did this with ICSI, intercytoplasmic sperm injection, a technique where we just use one sperm to impregnate the egg and create an embryo. This was really not tested before it was tried and 3 days after it was used, announced in Holland, it was being used across the country. But there was pretty good evidence that it would work. So I think primate studies would be the way to go.

Mr. GREENWOOD. And since I heard you say that we would need to do primate studies, plural, and since I heard you say that we probably need to study those primates over the course of their lifetime—

Mr. PENCE. What Dr. Jaenisch says is that the defects may not show up.

Mr. GREENWOOD. I do know that the closest primate genetically to the human is the chimpanzee and I know that chimpanzees live for a very long time.

Mr. PENCE. Yes.

Mr. GREENWOOD. So I would assume that we're probably talking decades under that theory, decades before you could actually clone enough chimpanzees or other relatively close genetic relatives to humans and observe them over their lifetimes, looking for the unknown before one would dare perform such an experiment on humans. Do you concur with that?

Mr. PENCE. Right, in this country. I mean what other people do in other countries, we can't control and we may get some bad data from that, but in this country, yes.

Mr. GREENWOOD. Thank you. The Chair recognizes the gentle lady from Colorado for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. I've been thinking about something here and you know, maybe Mr. Wicker you can tell me. Is cloning something you yourself would be interested for yourself? Would you be interested in being cloned?

Mr. WICKER. Yes, I would.

Ms. DEGETTE. You can answer with the mike.

Mr. WICKER. Yes, I would because I believe it's my reproductive right and my—

Ms. DEGETTE. Yeah, I got you.

Mr. WICKER. [continuing] to live on to another lifetime.

Ms. DEGETTE. Mr. Rael, would you personally be interested in being cloned?

Mr. RAEL. Not actually, because I have already two children, but—

Ms. DEGETTE. No, no, my question is would you yourself be interested in being cloned?

Mr. RAEL. Not at the actual level because I have already two children. The problem is for people who have no children.

Ms. DEGETTE. Thank you. So you only want this for people with no children, so as a reproductive issue.

But here's the question I have and Dr. Pence, you're Dr. Pence, right? I'm sorry, I wasn't here for the beginning of the testimony.

Maybe some of you can answer this, because with cloning technology, see, you're not talking about traditional infertility treatments in that you have two people who want to donate sperm and

egg and so on. What you're talking about is taking cells from really one person and it seems to me there are some yet unresolved ethical issues about say issues like Mr. Wicker who would like to be cloned or maybe for someone who had a baby who tragically died at 10 months and they might want to clone that, versus someone who did not want to be cloned, like let's say I tragically died and my family decided they wanted to clone me. Doesn't that present a fairly serious bioethical issue that we're going to need to deal with in this debate? What about cloning of people who don't want to be cloned and how do we deal with that?

Mr. PENCE. I take it that's for me?

Ms. DEGETTE. Yes. You seem to be our remaining ethicist.

Mr. PENCE. I don't know what happened to the other one. I'm sorry, I can't read your name, what is your name?

Ms. DEGETTE. DeGette.

Mr. PENCE. DeGette. You seem to be asking the right questions today. I think if it became safe that you would have a right to control what happens to your genotype, an absolute right. I mean I don't think we want people going around stealing Brad Pitt's hair.

Ms. DEGETTE. How do we control that? I mean that's exactly right.

Mr. PENCE. I suppose legally. You can't—we have a decision in the Moore case where a man's cell line was used to create a very valuable product and he sued to try to have a piece of that. There are some existing precedents for people having control.

Ms. DEGETTE. Dr. Cameron, did you want to comment?

Mr. CAMERON. Indeed, I mean I think this whole question of the accessibility of genetic material is a very serious practical problem.

Ms. DEGETTE. That's right.

Mr. CAMERON. And even if we were to take the view that cloning were some kind of human right, as some of our colleagues have suggested, this practical issue really is a roadblock here because unless you go around with a plastic bag over your head all the time, I mean you are shedding genetic material and the notion that this can somehow be kept private, this is a practical issue, aside all together from the other ethical issues involved here.

Ms. DEGETTE. And I would assume an issue that we really are going to need to investigate in depth before cloning becomes widespread at all.

In other words, as everyone is saying, the genie is out of the bottle, before it gets much farther out of the bottle, I think we really need to look at these ethical issues, wouldn't you agree?

Mr. CAMERON. I certainly agree and it does seem to me that we are just being so slow, this discussion, of course, is—this particular discussion is now 3 and 4 years old, in addressing issues when the curve is going up so sharply, that if we are going to be able to cope with this genie climbing out of the bottle, cloning is one of the simpler issues involved here.

Ms. DEGETTE. Yes. Dr. Soules, you can speak to that and then I have another question for you.

Mr. SOULES. I have an analogy for you. We have a reproductive technology ethics committee at the University of Washington and the analogy is this posthumous use of sperm.

Ms. DEGETTE. Right, exactly.

Mr. SOULES. If a man dies, within 24 hours or so the sperm is still viable and we can create an embryo and we went through some requests on that and our local university ethics committee decided without the man's written explicit, written consent, in other words, he had cancer and knew he was going to die, but these accidental deaths, they did not allow us to do posthumous—

Ms. DEGETTE. And what if someone picks up one of my hairs and tries to clone me.

Mr. SOULES. In other words, it's an analogy. Cloning is the bigger issue, I think, but the analogy was a conservative stance in terms of if the person did not explicitly state they wanted to have reproduction occur after their death, that it was not allowed.

Ms. DEGETTE. And just one final question for you, why haven't we done primate studies? People have been referring in this panel to primate studies. Why haven't they been conducted yet?

Mr. SOULES. I think people have tried. They're more expensive and complex, but NIH does have a series of regional primate centers and the studies—if you look at progression of studies, it's usually from mouse to higher animals and so on, and it's just getting to monkeys now and to jump to humans now would be premature.

Ms. DEGETTE. Dr. Pence, did you want to comment on that?

Mr. PENCE. I think people, especially in Oregon have tried, but they haven't gotten good results, so we aren't hearing anything.

Ms. DEGETTE. So you would agree also that it's far too premature to start cloning?

Mr. PENCE. Absolutely.

Ms. DEGETTE. Thank you. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair recognizes the gentleman from Florida, Mr. Deutsch for 5 minutes.

Mr. DEUTSCH. Thank you, Mr. Chairman. At some level I think most of you who have sat here all day, as most of us have sat here all day as well, and I almost feel at least initially to give you the opportunity to ask each other questions in which I will do. Does anyone feel compelled while you are sitting there as a panel who would like to ask any of the other panel members a question? You can ask us questions too, if you want.

Mr. WICKER. I found it somewhat stumpuous for the woman representative to say cloning me would be one cell, one parent. My native born twin would have two parents. They were my parents. I think when the chairman talked about how do we have to have it perfectly sure that this is going to be the perfect child, you're almost talking about perfect human beings and we'd have to watch them forever. My mother is 85 years old and has Alzheimer's. She's been in perfect health until that time. So I mean I think there comes a time where there's no such thing as surety. No such thing as a perfect person. And finally these questions about psychological consequences of being a second somebody else is utter nonsense because every human being, including identical twins are their own unique first self. And I don't understand why you gentlemen seem to sit and rather than deal with reality, think up problems, it's almost like what issues can we raise to delay cloning 3 years, 30 years or 300 years? The bottom line is I get the impression that many of you would like to ban cloning for all time regardless of how safe and how promising it would be.

Mr. DEUTSCH. I think that's accurate.

Mr. WICKER. Thank you for an honest answer.

Mr. DEUTSCH. And again, I will tell you, we have a role more than just I think pure science as elected Members of the U.S. Congress. I think what I've gained from today and also from reading before this hearing is I don't think there's really a debate that at this point in time human cloning is medically totally unsafe. The last answer to the question on primates, I mean we're not even able, willing to do this on primates as much sort of—when we had testimony that you can't rely upon cows and mice for people, well, maybe primates are better, but we have no primate data. So there's no question. I mean so that's one level and I guess we had testimony from ethicists earlier about the health-related issues.

I do think though that there are very legitimate other issues that Congress legislates, we legislate morality in a sense and we have the ability to and I think as a society, we have the obligation to. Not all science is good science. I mean the worse example I'm aware of in human history goes to Nazi scientists who all felt they were doing good things. They all felt they were doing good work, who could document and articulate very rational, significant reasons for things that they were doing which I think all of us would have—or I would hope, all of us would have a consensus were despicable, immoral acts. I guess to some level the concept—and again, maybe I'm limited in terms of putting that on the table at this point in time, but I think there is positive research, there's positive things that we can get out of research related to this, but the concept of what we're talking about, I have a real problem with and I guess, Rael, I take it seriously everything you said. If you could respond to that, I mean just in terms of saying science by definition is positive, then how do you respond to uses of science which I think by any definition would be evil.

Mr. RAEL. I am surprised that everybody is in a hurry to create ethical committees and ruling for cloning because it's giving birth, it's not killing. And there is no ethical committees against nuclear weapons who killed hundreds of thousands of people in Hiroshima and Nagasaki and chemical warfare and biological warfare. There should be ethical committee for this science who are now under government manipulation in the world and who are mass killing. But giving birth to a child I do not see any reason.

Mr. DEUTSCH. I just want you to have at least the opportunity to respond as well. Would you question what I said earlier in terms of just the medical science status today? Would you question that assessment of where science is today in terms of cloning?

Maybe putting the question another way, how, in your assessment as a lay person, not as a scientist, but obviously someone very involved in this, if the Federal Government doesn't get involved, when will the first human clone be born?

Mr. RAEL. It will happen anyway as nothing can stop science.

Mr. DEUTSCH. I guess I don't want to pin you down too much, but two things, one is is it safe to do it now, now, and No. 2 is, when will it happen?

Mr. RAEL. As one of the scientists explained earlier, when IVF started there was only 2 percent of success. How did they improve to reach almost 100 percent today? By doing it. If they stopped

doing it, science has to do it to progress. The first heart transplants were deadly. The first airplanes were deadly. But we didn't stop it because of that. Because by doing it, scientists can improve the technology and finally be successful.

Mr. DEUTSCH. I don't feel you answered it, but that's okay. Let me just respond because I think it's worthy of response, specifically, with in vitro fertilization. When it wasn't successful, you didn't create a live birth or a miscarriage that is tragic consequences. I think that the problem that we have here is the lack of success in each in vitro situation, the downside risk was minimal. The downside risk of the unsuccessful cloning process based on everything that we've seen at this point is dramatic. I mean very, very serious, for the person involved, for the mother involved, for the child involved, for society as a whole. So I think the comparison is a totally unfair comparison.

Mr. RAEL. May I answer?

Mr. DEUTSCH. It's up to the chairman at this point.

Mr. GREENWOOD. We've broken all the rules today, so you go right ahead, Rael and respond.

Dr. Soules, did you wish to respond as well?

We will allow both of you to respond.

Mr. SOULES. We've been hearing that it's relatively easy if you have an IVF clinic to do cloning and that's simply not true. If somebody gave the University of Washington about \$5 million and we recruited a couple hundred donors, donor eggs that is, and I had about 20 Ph.D.s working on it, we could pull it off, probably in a couple of years. So I think there's 55 IVF clinics in New York City so they could do at any time. I'm in an IVF lab almost every day talking to our basic scientists and it's just not that easy. I'm not saying it can't be done. Our society, ASRM, says it shouldn't be done, but yet on the other hand it's not easy and it's not efficient.

Mr. GREENWOOD. Rael, did you wish to make a comment?

Mr. RAEL. Yes, I just wanted to say that every day thousands of children in the world are born with problems as what some people call monsters, retarded people, handicapped people, made, conceived by sexual intercourse. Because of that should we make sexual reproduction forbidden? Of course not, nothing is perfect as has already been said, but we cannot have double standard, I mean.

Mr. GREENWOOD. We've already addressed the issue and we decided not to make sexual intercourse illegal.

Let me quickly respond. First off, it is not the case that this committee is rushing to judgment on cloning per se. I think, speaking for myself, that there are a myriad of extraordinarily good uses for cloning, therapeutic uses to cure diseases, to create organs for transplant and so forth. And I should also tell you that there's a lot of work that gets done in this town to try to ban weapons of mass destruction, be they nuclear, biological and chemical and so forth, so there is a lot of work on that.

I would just like to make one comment to Mr. Wicker in response to his, some of his comments. The issue, it seems to me isn't just about your right to pass your genetic material on into the future. To me, there's a question which is some day a little boy, were you to succeed at that, some day a little boy would say to his mother and father, whoever was raising him. Where did I come from, mom

and dad? We all did that when we were little boys and girls. And most of us heard a response well, mommy and daddy got married and then, you know. In this case somebody would say well, there was this fellow Mr. Wicker and Mr. Wicker wanted to pass his genetic material on to the future and so he made a genetic copy of himself and that's who you are. That's the philosophical question that we're wrestling with.

Mr. WICKER. No, no. This boy would know that he was so wanted and loved that I dedicated all my money to see that he received the gift of life and I want to make one other point, you set standards of safety and a good example was recently on the Charlie Rose show. Dolly, when I was here in 1998, they said how do we know Dolly isn't a fraud. Then Dolly was supposed to be 6 or 7 years old at birth and about ready to drop dead. Well, now she's 5 or 6 years and she's still having lambs. I think she's past sheep menopause, but Dr. Rudolf Jaenisch said on the Charlie Rose Show, she seems normal, but how do we know that Dolly is not mentally retarded or schizophrenic. You can't win an argument. If Dr. Jaenisch would just give me a test so I can test the intelligence of sheet or test their personality adjustment, I mean the point I'm making is that even if you seem absolutely perfectly normal and whatever, people that are opposed to it will demand unreasonable and reasonable perfection.

Mr. GREENWOOD. The Chair recognizes from gentleman from Illinois, Mr. Rush, for 5 minutes to inquire.

Mr. RUSH. Thank you, Mr. Chairman. First of all, I want to tell all the witnesses that I really respect and appreciate the fact that you've spent most of your day here and you've done quite well and I certainly apologize for the length of time that you've been here, but it's been very, very interesting, your testimony and this hearing has been very, very interesting.

I'd like to ask Mr. Hanson, Mr. Hanson, there's clearly issues of separation of church and State that abounds in this particular issue. However, what do you feel faith has to bring to this discussion, to this issue of cloning? Where should we—we've heard the scientists and the ethicists and others, but enlighten us a little bit in terms of what role faith has in this, your perspective.

Mr. HANSON. First off, let me say that our denomination would be among those that would be first in supporting the rights of other religious bodies to hold their beliefs, so nothing that I say really should be interpreted as infringing on other religious bodies to hold beliefs. I think one of the uniqueness of this U.S. system is that the government is not to legislate a required religion. That being said, I think that one of the things about this country is we are one of the most religious countries in the world, that our citizenry does take seriously their religious practices, all of them. The faith community is very often the first place someone dealing with these difficult issues of reproduction turn to. People go to their priests and rabbis and ministers, seeking help to decide difficult questions. We have, because of that, a wealth of very practical experience as well as our theological reflections.

The United Methodist Church has not entered this discussion quickly. We have—some of the issues taken here, we do not have a policy against IVF. We are a denomination that supports the

legal right that a woman has to an abortion. We have lots of caveats about how that should happen.

I think what's interesting about this issue is that you have the United Methodist Church, the U.S. Conference of Catholic Bishops, the Southern Baptists, the United Church of Christ, all saying very similar things. When you have such a broad spectrum of religious voices, I would suggest that it is something that the faith community has something to say about.

Mr. RUSH. Okay.

Mr. GREENWOOD. Ms. Terry, did you wish to respond?

Ms. TERRY. Yes. I would just add, in our testimony from the Genetic Alliance we called for faith communities dialoguing about this issue because we believe that many people form decisionmaking and their values based in a faith community in America and so that should be part of the dialog. And in addition, I think technologies like this and other genetic technologies can create great disparities between disenfranchised communities and marginalized communities and faith communities are often a way for them to access the dialog and they should be included in the dialog.

Mr. RUSH. Thank you. Mr. Eibert, earlier in my questioning I quoted a question from you and I want to get back to that, give you a chance to respond to it. Your testimony says today, the FDA claims to have statutory authority to regulate reproductive cloning. A pretty radical claim since America has never had a Federal reproductive police. However, virtually every lawyer on both sides of the debate agrees that the FDA has no such authority under current law. And you say you will be happy to tell us why during the question period. Why don't you take a shot at that?

Mr. EIBERT. Thank you, I would have loved to tell you during my time, but I only had 5 minutes. I'm not sure I can expand too much on what Chairman Tauzin has said because I agree with him completely. There is nothing in the Food Drug and Cosmetics Act or the Public Health Service Act or any relevant piece of legislation that gives the FDA authority over cloning or anything that even arguably could be defined as cloning. Nor does the FDA have the authority to regulate the practice of medicine, that's typically done by the states or to regulate the reproduction of American citizens.

What it does have authority to do is to regulate certain statutorily identified and listed things. And as even Congressman Ellers who, as you know, is one of the main leaders of anti-cloning sentiment in Congress has said, "it's hard to argue that a cloning procedure is a drug." Given the complete absence of any support in legislative history, case law, statutory language or in the legislative, the regulatory history of the FDA itself, it's even harder to argue that human embryos are a drug or that human embryos are biological products such as a toxin which is my understanding of what their current position is.

I don't believe that the Congress that passed the Food, Drug and Cosmetics Act in 1902, had any intention of making the FDA the reproductive police or giving them control over human embryos.

As Chairman Tauzin said, 1 year ago the Supreme Court struck down the FDA's unilateral effort to seize control or gain control over tobacco, citing the fact that like cloning, tobacco was not listed among the enumerated items that the FDA can regulate in the

Food, Drug and Cosmetics Act or the Public Health Service Act and they also pointed out that as with reproductive medicine, the FDA had a history of ignoring that area including things which are extremely similar to cloning, both in technique, ICSI, cytoplasm transfer, things like that.

I would anticipate that the FDA's authority will be challenged. I think it's more likely to be challenged by patients than by doctors and I think it's going to come out the same way as the tobacco thing happened.

My last point is that what I heard the FDA representative saying was well, okay, maybe it's true it's not in there, but we recently, as of January 2001 have finalized regulations where we say we have authority over not embryos, exactly, but something else. Well, I would say number that's a bootstrapping argument as the Supreme Court pointed out. Just because they say they have authority over something doesn't mean that they and second, that's a pretty new regulation and I think we should wait to see what the courts have to say about that before we assume that you can regulate one thing, you can then regulate whole human beings which is what we're talking about here.

Mr. RUSH. Dr. Cameron, you wanted to chime in here?

Mr. CAMERON. Thank you, if I might briefly. Of course, much of our effort this afternoon has been focused on the safety question and this FDA context is exclusive of a safety question as has been pointed out and on the assumption that safety issues were removed, then it would be hard for the FDA to contain the cloning situation. And I simply want to make sure we don't leave our discussion underlining the fundamental moral question here is not the safety question. That is a fundamental moral question of itself, but back of that lies the question of cloning in itself. And I made some reference to the European Convention on Biomedicine and Human Rights which wants an international treaty on bioethics which has been as a protocol to ban cloning and I just want to read the two lines in the convention which specifically give the fundamental ground for this ban on cloning. There's a reference to psychological, social, medical problems which may be expected. But the basic phrase is this one, because of the instrumentalization of human beings, through the deliberate creation of genetic and identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine, that to have this discussion is not about the safety issues. That is one reason why some of us think the FDA is inadequate. By the same token, it's why the moratorium approach is not adequate. The question at the heart is whether ever human beings, even if it's perfectly safe should be created as photocopies of other human beings. And whereas we've had various people say that they would quite to be cloned, I think we've yet to have somebody say they wish that they had been born a clone. And the bottom line for me in this issue is that every child has a right not to have been born a clone because the instrumentalization of the child which is a central moral question at stake.

Thank you.

Mr. RUSH. Yes, Dr. Soules?

Mr. SOULES. I could just comment a little bit on the FDA. In terms of their ability to stop a clinic from cloning I can't comment, but we've been working with the FDA for the last 2 years in the sense of this cell and tissue based products and it has more to do with the efficiency and safety of the embryology laboratories that do IVF today. And so it's been a good relationship with the FDA and we're in agreement on how to make these laboratories function better, so in that sense it is working with the FDA, but in terms of stopping a cloning clinic, I'm not sure how that would work.

Mr. RUSH. Thank you, Mr. Chairman. I yield back.

Mr. GREENWOOD. I thank the gentleman. I thank the witnesses. You have done yeoman service today, both in your forbearance and in your testimony. As a matter of record keeping, I'd like to enter into the record my letter of March 15 to Ruth Kirschstein, M.D., Acting Director of National Institutes of Health and her response to me of March 26.

This issue is probably the most complex and profound issue that this Congress will wrestle with in this new millennium. These are unchartered waters and the question for us, I think, is difficult because we don't know what lies beneath these waters. What makes it even more agonizing is that we're asked not to place ourselves or our witnesses on these waters, but little babies to float out on these very unchartered waters. It is my view that risk is so grave and it appears to be that grave for the foreseeable future, for decades, that we will have to act and I suspect that, in fact, I am certain that in the near future Chairman Tauzin, the chairman of this committee, myself and Mr. Deutsch, the ranking member, will introduce legislation to ban the cloning of a human being in this country and perhaps we'll have you back to testify about that legislation at some point in the future.

Thank you again. This hearing is adjourned.

[Whereupon, at 6:20 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF ROBERT A. BEST, PRESIDENT, THE CULTURE OF LIFE
INSTITUTE

Mister Chairman, Representative Deutsch, members of the Subcommittee, I applaud your determination to keep abreast of the facts about human cloning and I appreciate the opportunity to submit testimony. As our elected representatives, you have an essential role to play in framing laws regarding human cloning. There are many reasons why human cloning in all forms should be prohibited, but one that relates closely to your Constitutional role is that human cloning attacks the understanding of equality, which is the organizing principle of our Republic. The equality clause of the Declaration of Independence and the concept of "one person, one vote" lose their meaning when human persons become manufactured products. In other words, a democracy that permits human cloning will not remain one for very long.

I know the subcommittee will look carefully at the question of cloning for therapeutic purposes, in other words the creation by cloning of human embryos which are used for research in the embryonic stage (resulting in their destruction) or are developed into a fetal stage, used for research, and then killed prior to birth. Even if such a practice were not lethal to the embryo or fetus, it would still be objectionable in terms of the moral and ethical tradition of this country. Research on cloned embryos and fetuses, like research on any other human embryos and fetuses, would constitute medical experimentation on human persons without their individual voluntary consent, and would violate the Nuremberg Code. This Code, enunciated following the trials of Nazi leaders at the close of World War II, is not a law or a treaty obligation. But the Code is a fair summary of the civilized ethical standard of experimentation on living human beings.

Mister Chairman, the embryo may not look it, but it is a human being. Whether by cloning or by the fertilization of an egg by sperm, the resulting embryo is a new and unique human being with its complete genetic code in place and the capability, properly protected and nurtured, to become as apparently independent as you or I. Some say the need for protection and nurturing invalidates the embryo's claim to humanity, but which of us, at any stage of life, does not require protection and nurturing? The only difference is of degree, and if we accord human rights only to those who are substantially free of the need for protection and nurturing by others, than many people in hospitals and nursing homes and supersonic airliners and space stations and at this moment in the Metro tunnel under the Potomac between Foggy Bottom and Roslyn are not human beings, either.

Mr. Chairman, there is nothing "therapeutic" about killing a human being, even in the earliest stages of life. "Therapeutic", according to my Webster, means "to serve, take care of, treat medically . . . of or pertaining to healing". The proponents of human cloning have masked their mission of killing one human being or group of human embryos to "create" another human being. Whatever their motives, there is no moral justification for killing an innocent human being. Once we go down that road, life becomes cheap, culture become coarse, killing becomes thrilling or "therapeutic".

Mr. Chairman, we as a nation dare not go down that road. The precedents for using human beings as fodder for creating the "perfect" human being resulted in disaster for more than one nation in the twentieth century. German scientists and the medical profession of that nation created a climate in which they determined which life was "worth living", the ultimate arrogance. By the time Hitler came to power, the medical profession in Germany had already engaged in massive killing of innocents for the sake of a "pure race". The culture of death started in German long before Hitler came to power; he turned a culture of death against the Jews and others who he deemed unworthy of living.

At the dawn of a new millennium, we must see in every human being someone precious and worthy of our love. The Pope, who lived under both the Nazi's and the Communists, has called out for a culture of life. To foster a culture that loves life is not a partisan or even a "religious" cause; it is a human cause that Democrats, Republicans, Independents and all people of good will should aspire to and champion.

Those who want to conduct experiments that involve the killing of human embryos understand the issue, and therefore seek to call embryos by some other name, at least for the duration of the experiment. Thus some maintain that no human embryos should be termed as such during their first two weeks of existence. Terms like "totipotent cell", "clump of embryonic cells", and "unfertilised oocyte" are used to evade the issue. However, the scientific data are clear: a successful somatic cell nucleus transfer to a de-nucleated egg creates an embryo.

Experimentation on embryos and fetuses turns human beings into spare parts sources and test beds for other human beings. Such experimentation not only kills individuals, and is therefore cruel, but it also denigrates the dignity of being human by bringing a person into existence and then manipulating him or her for one's own purpose. The advocates of such use of human embryos and fetuses describe the suffering caused by defects and diseases which might be cured by their experiments, but adult stem cells, which are freely available without killing or manipulating anyone, have shown more promise thus far than have either embryonic stem cells or fetal tissue.

Let me be clear: good cannot come from a bad action. Even the most dire human suffering would not justify the involuntary death of another human being, embryonic, fetal, or ambulatory. But the promise of adult stem cells may obviate even this insufficient but emotionally strong argument for lethal experimentation on human embryos and fetuses.

There are many other reasons why all human cloning should be banned, and I stress that these reasons are practical, not theoretical, and are based on universal truths. First, cloning changes the nature and meaning of human sexuality. If a new person can be produced by taking the nucleus of a somatic cell from a man and injecting it into the de-nucleated oocyte of a woman, then human sexuality becomes superfluous. From its age-old purpose of transforming human love into new life, sexuality in an age of cloning would become, even more than it has unfortunately already become, simply an itch to scratch. We have seen in the past half-century, as the connection between sexuality and reproduction has weakened in the "sexual revolution", a rise in negative social indicators such as a divorces, abortions, an explosion of sexually transmitted diseases including one that is 100% fatal, and greatly increased exploitation of women in prostitution and pornography. By further weak-

ening sexuality's reproductive purpose, cloning would therefore further weaken families and communities.

Second, human cloning would weaken or even pervert basic human relationships such as family, fatherhood and motherhood, consanguinity, and kinship. For example, if a clone resulted from the nucleus of a somatic cell taken from his "father", his biological tie to his "mother" would be vastly different than that of a natural child. Apart from mitochondria DNA, which is outside the nucleus and is always passed on the maternal side, the clone would inherit no characteristics, no other DNA, no genetic material, from his mother. This very different biological tie could contribute to a different emotional mother-son tie as well. Further, as the clone would likely be "the spitten image" of his father, the mother's already different relationship with her child would become truly bizarre. Human cloning therefore perverts the relationships that are fundamental to our mental health and to the health of society.

Third, human cloning would compromise the dignity of the cloned person because she would forever know she was biologically identical to another person. Richard Seed, a scientist who wants to set up a cloning clinic in the U.S., has reportedly said that he wished he could have obtained a blood sample from Mother Teresa from which to clone a saint. Of course, the resulting little girl would only be *biologically* identical to Mother Teresa. Her own environment and experiences would make her a unique person. But the expectations that others would put on that child, and the expectations she would place on herself, would make for a miserable life. She would have lost the essential human freedom to be oneself. The children of the famous and notorious sometimes carry a heavy burden, but at least they retain the freedom of their own individuality. The cloned person would have lost that basic freedom because of the decision of another person.

The threat of power over others is a fourth reason to oppose human cloning. Most parents consciously choose to have children, and some try to influence the development of their child *in utero*. All responsible parents exercise authority over the children after birth and use their authority to educate and develop their children. This use of parental authority is natural. But human cloning gives a person absolute dominion over the existence of another. Whether the person comes into existence at all, when the person comes into existence, what the person's genetic material will be, what the person's intelligence and appearance and special skills will be—all this would be determined by another person. As I noted earlier, if people can have this kind of power over others, than the equality clause is just empty words from a quaint past. Those who would clone people seek a dominion over others which can only be termed "Godlike". Like the bypassing of human sexuality to achieve reproduction, the calling into existence of a precisely specified new person is an exercise in apparent human omnipotence.

A fifth reason to oppose human cloning is that it will increase a trend which we need to reverse, if we want to retain our freedom: the trend toward evaluating other people on the basis of their qualities instead of on their existence. Human cloning will always be the outcome of a choice about the specific traits and qualities of a child. As we have seen, cloning turns human reproduction into a manufacturing process. In time, given our national genius at capitalism, particular qualities and the raw material needed to obtain them will be available in exchange for money. Health insurers, for example, have a financial incentive to favor healthier children. Wealthy parents will use cloning to get ever-higher "quality" children ("quality" meaning whatever the fashion of the time dictates) while poor people, reproducing in the traditional way, would lag ever farther behind. Again, the strain imposed on our concept of equality will be too much, and self-government will end.

I said earlier that human cloning would be an exercise in apparent human omnipotence. I say "apparent" because, unlike the natural reproductive system which has brought us to this point, cloning is fraught with physical risks. Many of those risks have already been displayed in the cloning of mammals. For example, Dolly the cloned sheep was the one live birth derived from 277 sheep embryos which were created in the experiment. Cloned embryos appear to develop into larger-than-normal fetuses, resulting in a high incidence of stillbirths and Caesarean section deliveries. Developmental problems associated with abnormal size of human clones would include a high incidence of death in the first few weeks from heart and circulatory problems, diabetes, underdeveloped lungs, or immune system problems. The January death from a common infection of a cloned wild gaur (an endangered South Asian species) at Trans-Ova Genetics in Sioux Center, Iowa, may indicate that cloned animals have a lower resistance to disease. Another problem is the potential for clones to have aging DNA and thus an accelerated aging process. Lord Robert Winston, one of the developers of *in vitro* fertilization, has stated that because of the faster aging process, he would not want a child of his to be cloned.

The current low rate of cloning success with mammals (two clones born per 100 implantations, according to one source, up to 17 per 100 according to another) suggests a similarly low success rate for human cloning. And even if a seemingly normal and healthy animal is born, a defect that was not apparent can suddenly cause death, as was the case with a cloned sheep born last December at the same centre which produced Dolly. The March 25, 2001 *New York Times*, reporting on the cloning of animals, described a high rate of spontaneous abortion and post-natal developmental delays, heart defects, lung problems, and malfunctioning immune systems among cloned animals who had initially seemed normal. But let us stipulate that human ingenuity will gradually increase the success rate: who could live with having caused the pain of the many human clones who suffered and died along the way?

Mister Chairman, for these many reasons the Culture of Life Institute urges you to protect the lives of an untold number of individuals and to protect the principle of equality which is the basis of our legal and governmental system by drafting and passing a bill which would prohibit the cloning of human beings, at any stage of development, for any purpose. Thank you.

PREPARED STATEMENT OF C. BEN MITCHELL, PH.D.¹

"I was convinced that there was still plenty of time."² With those haunting words, Aldous Huxley looked back to the 1931 publication of his prescient book, *Brave New World*. Huxley's vision of an oppressive culture of authoritarian control and social engineering was among the more shocking literary events of the twentieth century. But a mere 27 years after the publication of his novel, Huxley was already aware that he had underestimated the threat of modern technocratic society.

EXPLAINING OUR DIS-EASE WITH CLONING

When Wilmut, et. al, announced the first successful cloning of an adult mammal, there was a public gasp, as it were. That which could only be imaged as science fiction had become science fact. If one mammalian species could be cloned, surely the cloning of *Homo sapiens* could not be far off. As we now know, the cloning of a human being is a present reality. Not have maverick scientists Severino Antinori and Panos Zavos begun their quest to clone a human being, but Australian researchers have disclosed that they have already clone human embryos. The clone age is here.

Nevertheless, the public is decidedly against cloning human beings. In nearly every poll, the overwhelming majority of those surveyed find the idea of cloning a human being repugnant. In a poll released by ABC's NIGHTLINE program the day after the Dolly announcement, 87 percent of those polled said the cloning of a human being should be banned. Eighty-two percent said cloning human beings would be morally wrong, and 93 percent said they personally would not choose to be cloned.

In an often cited article in *The New Republic*, Leon Kass of the University of Chicago argued compellingly that cloning is not "to be fretted about for a while, but finally to be given our seal of approval... the future of our humanity hangs in the balance."³ Human cloning, he maintained, ought to be prohibited immediately. We were forewarned.

Some scientists and a few ethicists have asked us to lower our defenses and give human cloning a shot. In an editorial in the same issue of *Nature* which premiered Dolly the cloned sheep, we were told that "Ethical constraints aside, there are even some rare genetic and medical disorders for which [cloning] would be a desirable way for a couple to produce offspring."⁴ President Clinton's temporary moratorium on human cloning was castigated in the same article: "At a time when the science policy world is replete with technology foresight exercises, for a US president and

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The Ethics & Religious Liberty Commission is the moral concerns, public policy, and religious liberty agency of the Southern Baptist Convention, the nation's largest non-Catholic religious denomination with over 15.8 million members in over 40,000 congregations nationwide. The ERLC has offices in Nashville, Tennessee and Washington, DC.

²Aldous Huxley, *Brave New World Revisited* (New York: Harper and Row, 1958), p. 3.

³Leon R. Kass, "The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans," *The New Republic* (2 June 1997), p. 18.

⁴Editorial, "Caught Napping By Clones," *Nature* 385 (27 February 1997).

other politicians only now to be requesting guidance about what appears in today's *Nature* is shaming."⁵ At the same time, the International Academy of Humanism, a group which includes such luminaries as Francis Crick, Richard Dawkins, Anthony Flew, W. V. Quince, Kurt Conneaut, and E. O. Wilson, "call[ed] for continued, responsible development of cloning technologies, and for a broad-based commitment to ensure that traditionalist and obscurantist views do not irrelevantly obstruct beneficial scientific developments," which include human cloning.⁶

We anticipated such reactions. Boston University professor of health law George Annas pointed out a long time ago that "ethics is generally taken seriously by physicians and scientists only when it either fosters their agenda or does not interfere with it. If it cautions a slower pace or a more deliberate consideration of science's darker side, it is dismissed as 'fearful of the future,' anti-intellectual, or simply uninformed."⁷ Taking a strong stance against cloning a human being is hardly being a fear-monger.

WHY HUMAN CLONING IS WRONG

In my view, it will take something much stronger than moral intuition to prevent the cloning of a human being. The technological imperative ("if we can do it, we should do it")⁸ and the commodification inherent in contemporary biotechnology are powerful forces. The technopologists are many.⁹

Probably the first question most persons find challenging with respect to cloning is: "Is a cloned human being a human person?" For sake of space, I will have to make short work of this question. Not only do I think we have to agree that a human clone is a human person, but I think it would be dangerous not to think this would be the case. Joseph Fletcher, the father of so-called Situation Ethics, teased us with this question back in the 1960s. He invited us to imagine cloning chimeras or sub-humans who could do the menial and repetitive tasks which were either too dangerous or too demeaning to full human existence.

There is no good reason to assume that a human clone would be any less human than a person conceived through normal reproduction. A cloned human being would have the full complement of genomic information in her DNA. If Dolly is the prototypical clone, a cloned human being would possess all the qualities and faculties of any other human being.

From a Christian perspective, a cloned human being would be as much a person as any other human being. She would be an embodied soul and would be an imager of God (Cf. Genesis 1:27; 9:6ff). Humans are, according to both Jewish and Christian theology, the only beings made in the image of God (*imago Dei*). As an imager of God, human clones would possess the same dignity and divinely-bestowed moral worth as any other member of our species.

The dignity of individual human lives both prescribes and proscribes how human beings are to be treated. Human beings may not be used as means to our own ends. They may not be the subjects of experiments without their knowledge and permission. We may not demean human beings by imposing upon them conditions they might not have consented to, if allowed to make the decision for themselves.

These principles would make immoral most of the reasons that have been suggested as reasons to clone human beings. Thus, human clones would not be suitable "organ farms" for those needing transplantable organs. Human clones would not be acceptable "substitutes" for children who died leaving their parents grief-stricken. Human clones likewise, would be ethically unacceptable candidates as "icons" in some kind of narcissistic cult of self-worship.

Furthermore, research on human embryos for cloning is wrong on the face of it. Note that it took some 277 attempts to clone one little lamb. That means that 276 little lamb embryos were sacrificed on the altar of biotechnology. While this might be an acceptable practice when cloning sheep (providing the sheep were not abused in the lab), such experimentation would be unconscionable when applied to human embryos.

⁵Ibid.

⁶Press Release, International Academy of Humanism, "Statement in Defense of Cloning" (16 May 1997).

⁷George J. Annas, "Whose Afraid of the Human Genome?" Hastings Center Report (1989), p. 21.

⁸Neil Postman reminds us that "technology is not a neutral element in the practice of medicine: doctors do not merely use technologies but are used by them." Neil Postman, *Technopoly: The Surrender of Culture to Technology* (New York: Alfred A. Knopf, 1992), p. 105.

⁹For a very engaging discussion of the commercial interests at stake in the burgeoning biotechnology industry, see Lori Andrews and Dorothy Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (New York: Crown Publishers, 2001).

TIME magazine's pictorial, "How to Clone a Human,"¹⁰ is absolutely chilling. The authors estimate that it might take 400 human ova which would be coaxed into dividing through somatic cell nuclear transfer. "According to experts," the caption says, "producing a single viable clone will require scores of volunteers to donate eggs and carry embryos—most of which will have major abnormalities and never come to term. The clones that do survive could suffer more subtle problems that might show up well after birth."¹¹ Toward the end of the chart there is an image of a "baby clone." Next to that image are images of two human babies surrounded by dotted lines (similar to the lines used to mark homicide victims on pavement) with the caption: "some babies do not survive." Even if the end were justifiable (and it is not), the means would not justify the end.

More recently, research on animal clones has demonstrated that cloning humans would result in untold loss of life and grotesque consequences in the lives of those who survived. University of Hawaii researcher Ryuzo Yanagimachi has observed that "Cloned embryos have serious developmental and genetic problems."¹² Dr. Brigid Hogan, professor of cell biology at Vanderbilt University calls human cloning "morally indefensible"¹³ and Dr. Rudolph Jaenisch of Massachusetts Institute of Technology calls human cloning "reckless and irresponsible."¹⁴ Jaenisch points out that if cloned embryos are created "most of those will die in utero. Those are the lucky ones. Many of those that survive will have... abnormalities."¹⁵ Cloning a human embryo is morally unconscionable and scientifically repugnant.

I am troubled, therefore, by the decision of the National Bioethics Advisory Commission (NBAC) to support the cloning of human embryos, as long as those embryos are not allowed to develop into babies.¹⁶ According to the Executive Summary of the NBAC report on human cloning, "The commission concludes that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning."¹⁷ Yet, the commission nowhere condemned experimentation on preborn children. In fact, the commission's recommendations would permit the cloning of human embryos.¹⁸ It is too early, of course, to know the precise language of forthcoming legislation, but at this point it seems clear that NBAC and President Clinton left the gate wide open for privately-funded embryo research, including embryo cloning.¹⁹ We are now paying for their moral negligence.

There is no relevant moral distinction between an embryo and a postnatal baby. Because both are imagers of God, both possess the same dignity and deserve the same protection. Philosopher-ethicist and former bench scientist Dianne Irving has argued convincingly that the terms "preembryo" and "preimplantation human embryo" reflect a politicization of science rather than biological facts.²⁰ "Embryo," "baby," and "adult" are merely three terms we use to discriminate between stages of biological development. They are not terms that ought to carry moral baggage. With respect to the ontological status of *Homo sapiens*, these terms represent a distinction without a moral difference.

In 1997, my own denomination, the Southern Baptist Convention, passed a resolution on genetic technology and cloning which made just this point. Messengers at the convention affirmed, "WHEREAS, Southern Baptists are on record for their con-

¹⁰ TIME, 19 February 2001, pp. 52-53.

¹¹ Ibid.

¹² Reuters News Service, "Report Says Scientists See Cloning Problems," 24 March 2001.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ Jeremy Manier, "Potential Perils Born in Cloning," *Chicago Tribune*, 4 March 2001.

¹⁶ Rick Weiss, "Panel Backs Some Human Clone Work," *The Washington Post* (4 June 1997), A1, 29.

¹⁷ Executive Summary, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* (June 1997), p. iii. Emphasis added.

¹⁸ Patricia Wilson, "U.S. Ethics Panel Urges Ban on Human Cloning," Reuter's News Service (8 June 1997). President Clinton announced in 1994 a ban on tax-funded research which involves producing human embryos solely for research which would result in their destruction. This leaves open, however, the private-funding of human embryo research.

¹⁹ George Annas, Art Caplan, and Sherman Elias have opined, "To create human embryos solely for research—or to sell them, or to use them in toxicity testing—seems morally wrong because it seems to cheapen the act of procreation and turn embryos into commodities. Creating embryos specifically for research also puts women at risk as sources of ova for projects that provide them no benefit. The moral problem with making embryos for research is that as a society we do not want to see embryos treated as products or mere objects, for fear that we will cheapen the value of parenting, risk commercializing procreation, and trivialize the act of procreation." George Annas, Arthur Caplan, and Sherman Elias, Sounding Board, *New England Journal of Medicine* (16 May 1996).

²⁰ Dianne N. Irving, in Diane M. Gianelli, "Embryo Research Division Set to Spark Controversy," *American Medical News* (20 June 1994).

sistent and vigorous opposition to the devaluation of human life and the encroachment of the culture of death... BE IT FURTHER RESOLVED, That we call on Congress to enact federal legislation against producing human embryos for the purpose of experimentation, whether by tax-funded or privately-funded researchers.”²¹

Interestingly, the United Methodist Church’s General Board of Church and Society concurs with this view. Their Genetic Science Task Force issued a statement on May 9, 1997, stating:

1. At this time, we call for a ban on human cloning. This would include all intended projects, privately or governmentally funded, to advance human cloning. (For purposes of this document, human cloning means the intentional production of genetically identical humans and human embryos.)
2. We call for a ban on therapeutic, medical, and research procedures that generate waste embryos.
3. As Christians, we affirm that all human beings, regardless of the method of reproduction are children of God and bear the Image of God. If humans were ever cloned, they along with all other human beings, would have inherent value, dignity, and moral status and should have the same civil rights...²²

Since neither I nor, presumably, the United Methodists, wish to be viewed as reductionists, it must be said that human cells, genes, tissues, etc., are not human beings. We are more than the sum of our or genetic parts. That is to say, even though I think cloning human embryos is wrong, that does not mean cloning human genes for research purposes or cloning individual human organs for transplant or cloning human nerve cells to treat spinal cord injuries would be wrong. In fact, I would support such uses of cloning, as long as the means of getting there does not treat humans sub-humanly.

THE NEWEST REPRODUCTIVE TECHNOLOGY AND THE FAMILY

Another of the major foci in the cloning debate is the way human cloning would impact the family. Family is, obviously, a very important institution in Jewish and Christian theology. It is clear to observers that human cloning would upset traditional family patterns.

Mark Sauer, M.D., an infertility specialist at Columbia Presbyterian Medical Center in New York sees cloning as offering a potentially powerful new reproductive technology for helping infertile couples.²³ At the same time, Randolfe Wicker, one of the founders of the Mattachine Society, an early homosexual rights advocacy group, sees cloning as a desirable means of asexual reproduction. Jack Nichols, author of *The Gay Agenda: Talking Back to the Fundamentalists*, says, “Let’s not rush to judgment and forget the way in which the technology might help gay people create their own families, free from the coercion of the state.”²⁴

Quite apart from the debate over homosexuality, cloning raises the important question, “Why have children? Why reproduce?” In his article, “Why Have Children?” Marshall Missner suggests that persons choose to have children for either social or personal goals. He includes:

Social goals

1. The survival of humanity.
2. The survival of one’s culture or community.
3. Biological drive.

Personal goals

1. A simple desire to have children.
2. Viewed as part of a “full” human life and young adulthood.
3. Financial benefit and/or improved social status.
4. Religious conviction.
5. As a kind of personal immortality.
6. Enhancement of personal happiness.
7. Altruism.²⁵

²¹ “Resolution on Genetic Technology and Cloning,” adopted by messengers to the 140th annual Southern Baptist Convention, meeting in Dallas, Texas, June 17-19, 1997.

²² Statement from the United Methodist Genetic Science Task Force, General Board of Church and Society of the United Methodist Church, Washington, DC (9 May 1997).

²³ Gina Kolata, “For Some Infertility Experts, Human Cloning Is a Dream,” *The New York Times* (7 June 1997), A6.

²⁴ Chris Bull, “Send in the Clones,” *The Advocate* (15 April 1997), p. 37.

²⁵ Marshall Missner, “Why Have Children?” *The International Journal of Applied Philosophy* 3 (Fall 1987). Of course all of these questions were thrust into the American conversation in the Ayala case, where a California woman chose to give birth to a child for the purpose of pro-

Continued

John A. Robertson, University of Texas law professor (and one who testified at the NBAC hearings on cloning), has argued that “in almost all instances an individual or couple’s choice to use technology to achieve reproductive goals should be respected as a central aspect of people’s freedom to *define themselves* through reproduction.”²⁶ Is that what is going on in reproduction? Are we having children in order to “define ourselves”?

Before I proceed, I suppose I should confess that I am half of an infertile couple. My wife and I have been married for 26 years and have been unable to have children. I mention this to explain that I understand something of the psychology of infertility. I also have written on the ethics of the new reproductive technologies. If anyone has a personal stake in cloning, I do.

Nevertheless, I find that moral and theological reasons against cloning as a reproductive (or should I say, replicative?) assistance technology always trump the psychosocial reasons for the technology.

From a biblical perspective, then, sexual differentiation (male and female) and the place of childbearing within the matrix of a monogamous heterosexual marriage is normative. From the beginning God said, “. . . in the image of God he created them: male and female he created them” (Genesis 1:27) and “Therefore shall a man leave his father and mother, and shall cleave unto his wife: and they shall be one flesh” (Genesis 2:24). From this one-flesh relationship children proceed. They are “a heritage from the Lord,” as the psalmist says. They are a gift from God. Procreation should not be viewed as a form of self-definition. Rather, bearing children is a covenant responsibility granted sovereignly by the God who made us.

Now, assuredly, in the biblical witness there is a presumption in favor of procreation. We are told to “Be fruitful, and multiply, and replenish the earth . . .” (Genesis 1:28). As Anglican theologian Oliver O’Donovan points out, “Some understanding like this is needed if the sexual relation of a man and woman is to be more than simply a profound form of play.”²⁷

Nevertheless, children are to be viewed as a divine gift, not a narcissistic means of self-definition. The gift of children comes with an enormous bundle of moral and spiritual obligations. They are to be reared “in the training and instruction of the Lord” (Ephesians 6:4 NIV). Parents, fathers in particular, are not to provoke to wrath or exasperate their offspring (Ibid).

My point is that the time is long overdue for us to re-examine and recommit ourselves as a culture to fulfill our obligations to our children as treasured members of the familial covenant—not commodities to be used for our desired ends. If Barbara Defoe Whitehead’s volume, *The Divorce Culture*, teaches us anything, it teaches us that, removed from the context of a nurturing, two-parent family, children are tragically sacrificed on the altar of modernity’s selfishness.

Contrary to what some feminists believe, “the conjugal bond is not a biological trap from which we should seek escape. The marital relationship is the only divinely sanctioned locus of human sexuality, and the bearing of children. The blessing of children is the intended result of the marital bond and the conjugal act.”²⁸

Some forms of reproductive technology have separated fertility and child bearing from the conjugal act, and in many cases from the marital relationship. This separation is of great moral consequence. As Gilbert Meilaender has said, “In our world there are countless ways to ‘have’ a child, but the fact that the end ‘product’ is the same does not mean that we have done the same thing.”²⁹

In a post-Enlightenment culture which celebrates atomistic individualism as its crowning achievement, the use of cloning as a reproductive technology would be like sending divers down to repair the screws as the Titanic slowly sinks into the darkness.

There are many additional concerns raised by human cloning, such as,

1. To what extent children have a right to expect to have a mother and father?
2. How do we combat the inherent eugenics motivations behind human cloning?
3. Would persons with disease genes be cloned? Would the near-sighted, far-sighted, or deaf be cloned? Would the obese or frail be cloned?

ducing a bone marrow donor for her 16 year-old daughter. See “Conceiving a Child for ‘Ulterior Motive’ Creates Ethics Furor,” *Medical Ethics Advisor* (April 1990), p. 41-43.

²⁶ John A. Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* (Princeton: Princeton University Press, 1994), p. 18.

²⁷ Cited by Gilbert Meilaender in his testimony before the National Bioethics Advisory Commission, 13 March 1997.

²⁸ R. Albert Mohler, Jr., “The Brave New World of Cloning: A Christian Worldview Perspective,” forthcoming in Ronald Cole-Turner (ed), *Religious Perspectives on Cloning* (Louisville: Westminster/John Knox Press, 1997).

²⁹ Gilbert Meilaender, *Bioethics*, pg. 15.

In fact, Leon Kass may not be far off when he says of the cloning debate: "We must rise to the occasion and make our judgments as if the future of humanity hangs in the balance. For so it does."³⁰

CONCLUSION

Human cloning, including the cloning of human embryos, ought to be banned immediately. The January decision of the British House of Lords to allow human embryonic cloning coincided nicely with the publication of WIRED magazine's lead article predicting that someone will clone a human in the next twelve months.³¹ The decision by the House of Lords is troublesome in many ways. First, the Peers had the opportunity to postpone their decision in favor of establishing a select committee to assist in doing the ethical analysis warranted by such a momentous step. After all, some of the most respected voices in England, including Lady Warnock's, called for such a commission. Instead, the Lords rushed in where angels fear to tread. Even worse, the policy proposed by the House of Lords requires that any cloned human embryo would have to be destroyed within 14 days after the procedure. Mandatory destruction hardly seems a fitting end for a human being who entered this world at the will of human somatic cell nuclear manipulators.

The temptation to manipulate another human life is almost irresistible to some. University of Kentucky reproductive physiologist, Panos Zavos, and an his Italian colleague, Severino Antinori, doubtless believe they are more like Lewis and Clark than Butch Cassidy and the Sundance Kid. They are nevertheless scientific mavericks with egos the size of the Grand Canyon.

It hardly takes prognosticatory gifts to know that someone has already successfully cloned a human being or that a human will be cloned soon. The near inevitability of cloning does not, however, make its imminence more welcome. We are exquisitely ill-equipped morally to deal with the reality of a human clone in our midst.

He or she would first have to suffer the notoriety of being born through human somatic cell nuclear transfer. Next, his or her future would be shaped by someone else's past. That is to say, those who reared the clone would, no doubt, want to duplicate the environment of the donor as much as possible. Otherwise the experiment would be less likely to produce an identical replica of the original, since environment is as important as inheritance. So much for that celebrated quality called human freedom. Furthermore, proprietary interests would be at stake. Who owns a clone—the cloned, the clone, or the cloner? In the commodified world of biotechnology, the one with the most investment money is likely to win. So, obviously, the cloner would own the clone. Prospective parents might be able to purchase a clone, but the market would determine the selling price. Will the price be set in pounds, dollars, Euros, or yen?

If there were ever an appropriate time to clone a human being (and there is not), this is not that time. At the beginning of the 21st century, we are experiencing a period of unequalled technological prowess combined with unparalleled moral vacuity, especially when it comes to judging who counts in the moral equation. Do clones count as persons? On what moral ground could one deny the personhood of a cloned human? When does protectable personhood obtain? How does one avoid being arbitrary in determining personhood? Until these questions are answered thoroughly and satisfactorily, cloning a human being ought to be forthrightly banned or effectively postponed in order to engage in a global debate about the morality of human cloning. Critics of such a proposal say that the debate would prove intractable. Perhaps that fact alone is a necessary and sufficient reason to prohibit cloning a human being in the next twelve months, twenty-four months, or forever.

³⁰ Leon R. Kass, "The Wisdom of Repugnance."

³¹ Brian Alexander, "(You)²," WIRED 9.02, February 2001, pp. 120-135.