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Federal Stem Cell Research: What Taxpayers Should Know

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ROBERT E. MOFFIT: We are in the midst of a major national debate on stem cell research. There are a variety of ethical, moral, and religious views on this issue, and these perspectives are vitally important. But there are also practical and scientific issues, as well as prudential questions about the expenditure of taxpayers' dollars. We have three outstanding speakers today who are going to enlighten us about the ethical, the scientific, and the policy questions involved in the ongoing debate on federal funding of stem cell research.

Our first speaker is Dr. Kelly Hollowell, who is a molecular and cellular pharmacologist and a patent attorney. She is the senior strategist at the Center for Reclaiming America and a founder of Science Ministries, Inc. Dr. Hollowell got her Ph.D. in molecular and cellular pharmacology at the University of Miami, her Juris Doctor from Regent University, and her Bachelor of Arts from New College in Sarasota, Florida. She has published in *Regent University Law Review*, and the *Journal of Neurobiology*. Dr. Hollowell will talk about both the state of the science and the ethical aspects of stem cell research.

Philip Coelho is the chief executive officer and chairman of the board of ThermoGenesis Corp., which provides cord blood stem cell processing and cryopreservation systems used by major cord blood stem cell banks. He previously served as president, vice president, and director of research and development at the firm. He also serves on the board of directors of Kourion Therapeutics and Mediware Information Systems.

Talking Points

- The derivation of stem cells from human embryos raises a wide range of difficult ethical and moral questions. These include the status of the embryo as human life or merely property, and the potential exploitation of women in the production of embryos for the harvesting of cells.
- In contrast to embryonic stem cell research, adult stem cells and neo-natal cord blood stem cells have a strong track record in the treatment and cure of disease. Over 6,000 patients with 70 different diseases have been treated with neo-natal cord blood.
- The current national debate on stem cell research focuses on the expanded use of federal tax dollars. Both private sector and state government funding is currently available for embryonic stem cell research. Beyond grave ethical objections, critics of this research oppose the use of taxpayers' dollars to fund what many private venture capitalists refuse to finance.

This paper, in its entirety, can be found at:
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Before coming to ThermoGenesis, Mr. Coelho was president of Castleton, Inc. Phil has his Bachelor of Science degree from the University of California at Davis, and he will focus on the state of stem cell research, including the progress of using cord blood stem cells.

Representative David Weldon is our third speaker. Dr. Weldon is a physician and an Army veteran who represents the 15th Congressional District of Florida. He is the first medical doctor to serve from the state of Florida and the second physician ever to serve on the House Appropriations Committee. He is also a founder and chairman of the Congressional Aerospace Caucus.

Dr. Weldon is a native of New York. He received his Bachelor of Science degree from the State University of New York in Stony Brook and his doctorate in medicine from New York's Buffalo School of Medicine. Completing his residency in internal medicine at Letterman Army Medical Center and military training in San Francisco, he did a three-year tour of duty at Army Community Hospital in Fort Stewart, Georgia. After completing his military service as a major in 1987, he entered private practice at Melbourne, Florida. In Congress, Dr. Weldon is known among his colleagues as an expert in health policy and biomedical ethics. He has appeared on *ABC, CBS, CNC, MSNBC, and the Fox News Network.*

—Robert E. Moffit, Ph.D., is Director of the Center for Health Policy Studies at The Heritage Foundation.

DR. KELLY HOLLOWELL: I'm going to address three questions: What are embryonic stem cells, how is stem cell research related to cloning, and is embryonic stem cell research a prudent investment?

Embryonic stem cells, as most of you know, are the unspecialized cells that form the basic building blocks for all of the 220 specialized cell types in your body. By harvesting and manipulating these master cells, researchers hope to treat diseases. Currently the primary sources for embryonic stem cells are aborted fetuses and donated and unused embryos housed in IVF (in vitro fertilization) facilities.

To obtain embryonic stem cells, an embryo is formed and allowed to mature for five to seven days. The inner mass of the stem cells is then removed, plated, and treated with chemicals to become specialized cell types. The problem is that in this process the embryo itself is destroyed.

How Is Embryonic Stem Cell Research Related to Cloning? The distinction between "reproductive cloning" and "therapeutic cloning" is misleading because the technology involved is essentially the same. The most common practice for obtaining a clone is simply to enucleate an egg (that is, remove its DNA), take the DNA from the animal that you want to clone and inject that DNA into the enucleated egg, and *voila!* A clone is born.

We can already do this with just about every animal. "Therapeutic cloning" was specifically developed as an answer to the problem of tissue rejection. It entails the same process I just described—somatic cell nuclear transfer—using donor DNA from a cell of the patient to create a genetically identical embryo.

After a number of days the stem cells are extracted, destroying the embryo, and the stem cells are used to treat the patient's disease or replace dying tissue. Both reproductive and therapeutic cloning begin by creating a human life. The distinction in the procedures is merely the intended purpose. In *reproductive cloning* the purpose is to actually give birth to the clone, or the genetic twin—"Dolly" the sheep in Scotland was the groundbreaker for this effort. In *therapeutic cloning*, the intended purpose is to create an embryo to be sacrificed for the donor/patient using its genetically identical stem cells.

A major source for standard embryonic stem cell research is the donated embryos that are created with sperm and egg in IVF facilities. Currently, it is predicted that the number of these leftover embryos housed in frozen storage in IVF facilities is somewhere between 300,000 and 500,000. Another source of embryonic stem cells is the product of therapeutic cloning, in which you create a clone of yourself. The embryo you create is not created through an egg and sperm; it is created through somatic cell nuclear transfer.

Is Embryonic Stem Cell Research a Prudent Investment? Beyond the financial issues, there are a number of ethical issues, but I will address only two.

The primary ethical question embryonic stem cell research raises is this: Are human embryos people or property when they are destroyed for the purpose of obtaining their stem cells? This is not a new question, and, more importantly, the answer is not new.

The United States Congress received the answer that life begins at conception most definitively in 1981. At the April 1981 hearings on the Human Life Bill (S. 158), held by the Senate Judiciary Committee's Separation of Powers Subcommittee, internationally renowned scientists Dr. Micheline Mathews-Roth (Harvard Medical School), Dr. Jerome Lejeune (the father of modern genetics), Dr. Hymie Gordon (chairman of the Mayo Clinic), and Dr. Landrum Shettles (the father of IVF) all testified that life begins at conception. This, as far as the medical and scientific community is concerned, is not an issue. The debate is in the legal and political realms.

Today's medical technology enables us to affirm what we have known for decades: that life does begin at conception. From conception, we are biologically alive. We are genetically human, we are genetically distinct, we are sexually distinct, and we have the ability to direct our own growth. Twenty-four hours after conception, the new life splits into two cells, and eight days later, pregnancy officially begins.

My point in sharing the technology and biology with you is to illustrate the continuum that science affirms and has affirmed for many years. But technology is additionally allowing wonderful new insights. With advances in ultrasound technology and neonatal medicine, we know that after four to six weeks, the heart has begun to beat, and by six weeks, brain waves can be detected. By 21 weeks, children have become patients in utero. At 24 weeks, children have reached viability and at 40 weeks are born. So, long before the child is born, it's clear life remains on a continuum from the beginning. Again, I must emphasize that this is not a medical debate; the status of the unborn is really just a legal debate.

A second ethical issue lies in the extreme inefficiency of harvesting embryonic stem cells. Specifically, the process requires women's eggs. To treat, for example, only the 17 million diabetes patients in the United States would require a minimum of 850 million to 1.7 billion human eggs. You can literally envision women becoming egg factories. Collecting 10 eggs per donor will require a minimum of 85 million to 170 million women, and the total cost would be astronomical, at $100,000–$200,000 for 50 to 100 human eggs per each patient.

Even more important than the dollars and the difficulty associated with therapeutic cloning is that the process of harvesting a woman's eggs for stem cells places a woman at risk. Specifically, superovulation regimens for fertility treatments would be used to obtain women's eggs. The risks associated with high-dose hormone therapy are debated, but there is a growing body of evidence that these practices, when used for standard IVF, can cause various problems. These problems include memory loss, seizure, bone loss, lupus, joint pain, baldness, stroke, brain damage, infertility, cancer, and death. And this is under the conditions of IVF, not under the conditions for which we would need to produce eggs in large quantities for research purposes. Clearly, this points to yet another ethical issue: the future commercial exploitation of women, particularly poor women, to collect their eggs.

As for obstacles in standard embryonic stem cell research—research where you would not create a clone of yourself but would perhaps go after the embryos created through sperm and egg and currently frozen in IVF facilities across the nation to the tune of 400,000 or so—no currently approved treatments have been obtained using embryonic stem cells. There are no human trials despite all the hype and all the media. After 20 years of research, embryonic stem cells haven't been used to treat people because the cells are unproven and unsafe. When they are used in animal models they tend to produce tumors, cause transplant rejection, and form the wrong kinds of cells. It will be a minimum of 10 years before treatments *might* be available, and that is a very optimistic prediction. The successes in animal models are modest and rare. What are those successes? They have had the success of teasing the master stem cells down into specific cell types, specifically neural cells, blood cells, heart

cells, and pancreatic islet cells. One big problem that they have faced in the animal models is rejection. This is almost predictable since it would be like you transplanting your organ into me without any efforts at a match taking place. So therapeutic cloning is introduced as an alternative to avoid this tissue rejection.

Successful Alternatives. The alternative research is adult stem cell research, which is an ethical alternative. For more than two decades, we have been treating more than 58 different types of diseases using adult stem cell research. Some of the most startling advancements using adult stem cells have come in treating Parkinson's disease, juvenile diabetes, and spinal cord injuries. And the sources for this adult stem cell research clearly do not present any ethical problems because you use blood, placenta, fat cells, and, most notably, the cord blood, which Mr. Coelho will talk about in a few minutes.

To review: Standard embryonic stem cell research creates embryos with the sperm and the egg, and therapeutic cloning creates embryos of one's self. Both procedures are fraught with obstacles. That means if you pursue therapeutic cloning for the purpose of extracting stem cells from the genetic clone, you are combining all of the risks and problems associated with embryonic stem cell research with all of the problems associated with cloning. Obtaining the high number of eggs required in cloning puts women at great risk. Embryonic stem cell research requires human sacrifice, and there are currently no cures in sight. Adult stem cell research does not involve the same ethical obstacles. Nor does it cause rejection; nor does it cause tumors; nor does it cause genetic instability. In fact, it has been, for more than two decades, treating thousands of people.

The Use of Tax Dollars. So should our tax dollars be spent on embryonic stem cell research? The answer is: No. The scientific data on embryonic stem cell research simply do not support the continued investment in research. Many researchers have failed. Even private investors are not backing this, and that is a strong indication of the lack of success. Even if it was successful, it is clear that embryonic stem cell research is morally bankrupt and endangers women, while adult stem cell research doesn't present any of these problems.

I want to tell you something very personal as I close. A lot of people retort to me that perhaps I'm not interested enough in cures, but I'm very interested in cures—and not just for people I don't know. My own grandmother died of Parkinson's disease; my father died of cancer; and my baby was diagnosed in utero at 15 weeks with a genetic disease. That affects me tremendously.

Even if I did not have all of the ethical objections that I do to embryonic stem cell research, I assure you there is absolutely no hope being offered by embryonic stem cell research to cure my baby, to have cured my father or my grandmother. The cures are in adult stem cell research, and we need to turn the focus and attention to that and not to the exploitation of our unborn children and our women as egg factories for this research.

PHILIP H. COELHO: Let's take a look at three sources of stem cells: embryonic stem cells, adult bone marrow stem cells, and neo-natal cord blood stem cells. Embryonic stem cells have theoretical advantages: they unquestionably can become all the different tissues of the body and they have long telomeres, which mean they have a whole life's worth of cell divisions available to them. But harnessing their possible clinical benefit presents daunting technical challenges. Embryonic stem cell lines are notoriously hard to obtain and maintain and it has been reported that they have triggered malignant carcinomas in animals. Knowledgeable researchers are cautious about expecting any clinical trials using embryonic stem cells in the near term.

Adult stem cells are typically drawn from the bone marrow of patients, and they also have advantages. They have been used clinically about 30,000 times. However, they do have some disadvantages: There are risks to the donor during extraction, there is significant risk of transmission of infectious disease from donor to recipient; and the cells have the potential for fewer divisions.

My company, ThermoGenesis, has focused our activity over the last 12 years on neonatal cord blood stem cells because, although they have simi-

larities with embryonic and adult stem cells, they have some dramatic advantages. Like embryonic stem cells, they can become several—and perhaps all—the different tissue types; unlike both embryonic and adult stem cells, their harvest results in no donor risk; they have the capacity for many cell divisions; and, in contrast to adult bone marrow stem cells, they cause less graft versus host disease (GVHD), a medical condition in which the donor cells attack the tissues of the patient's body.

The production of units of cord blood stem cells for clinical use must be done with great care if the cells are to be viable upon transplant—which may be years or decades later. Cord blood stem cells are harvested following the birth of a baby. Blood from the leftover placenta is collected and sent to the cord blood stem cell bank. Through some complicated processes, substantially all the stem cells are concentrated into a specialized freezing container, the red blood cells into a second, and the plasma into a third. Each container has bar code labels which tie it back to the original collection. The stem cell container is then inserted into a special Teflon over-wrap bag and placed into a stainless steel canister in preparation for cryopreservation of the stem cells. Next, the canister is placed into a controlled-rate freezer module which is then inserted into the robotic freezing and storage system. Each unit of stem cells receives a very precise freezing rate and then the robotic arm transfers the frozen unit directly into –196 degrees centigrade liquid nitrogen. At this temperature—colder than the surface of the moon—these cells will remain viable for many years.

Cord blood stem cells are clinically used right now to fill in behind the National Marrow Donor Program (NMDP) that maintains a registry of 6 million potential donors of adult bone marrow stem cells to treat leukemia, lymphomas, and a number of genetic diseases. A General Accounting Office (GAO) study in 2002 reported that, despite $50 million a year from the federal government, less than 10 percent of patients needing stem cell transplants actually received them from the NMDP. That is an astonishingly sobering statistic. Nine out of ten people were unable to be matched at all or were unable to be matched in time. When you are diagnosed with these lethal diseases and told you need a stem cell transplant, you don't have much time.

Luckily, a new, more readily available source of stem cells was becoming available. The first patient to be treated with cord blood stem cells in 1988 today shows no evidence of the Fanconi Anemia that he suffered from as a child. When he was diagnosed, there was no bone marrow match, which is not unusual. Luckily, in his case, there was a match using the cord blood stem cells from his mother's later pregnancy. On the basis of that success, Dr. Pablo Rubinstein, director of the National Cord Blood Program at the New York Blood Center, and Dr. Joanne Kurtzberg, director of the Pediatric Bone Marrow and Stem Cell Transplant Program at Duke University Medical Center, launched cord blood transplant medicine.

The very first transplant was in 1988. Four years later, the National Institutes of Health (NIH) provided money to set up the first public cord blood bank, because the greatest use for these stem cells would be to treat the patients who were unable to obtain appropriately matched bone marrow stem cells from the NMDP. In 1994, ThermoGenesis was asked by Dr. Rubinstein to develop a robotic cryogenic freezing and storage system to provide the precision cryopreservation and archiving required to assure these cells would be viable when thawed and transplanted. Essentially, Dr. Rubinstein wanted to elevate this process to pharmaceutical grade quality (GMP) standards. In 1996, Dr. Rubinstein obtained the first FDA IND approval to perform a large-scale clinical trial with cord blood stem cells. We delivered our BioArchive Robotic System to Dr. Rubinstein in 1999 and, as of December 31, 2004, there were 104 of these robotic systems in the major cord blood stem cell banks in 25 countries. Over 6,000 patients have now been treated, the FDA license of cord blood stem cells is under review, and there is legislation in Congress to establish a national cord blood stem cell bank network.

Cord Blood Success. So far, more than 6,000 patients and 66 diseases have been successfully treated with neonatal cord blood stem cells, including hematological malignancies such as leukemia and lymphoma; the immunodeficiency diseases SCID, CID, CVID, and WAS; bone marrow failure

syndromes; hemoglobinopathies such as sickle cell anemia and thalassemia major; and inborn errors of metabolism such as ADL, MLD, GLD, Tay-Sachs disease, and MPS I, II, III, and IV. Because stem cells from cord blood don't cause nearly as much graft versus host disease, they do not need a perfect match the way bone marrow does; as a result, a national inventory of only 150,000 ethnically diverse cord blood stem cell units will provide 80 percent of U.S. citizens with a suitable match.

In 1998 there was a first look at the comparative rate of survival of cord blood and bone marrow patients at three years post-transplant. Many patients died in both cases because these patients all suffer from terrifying lethal diseases. At this time, cord blood was at a great disadvantage to bone marrow because the probability of obtaining an optimally matched cord blood unit was very low, as there was only an inventory of a few thousand cord blood stem cell units and, in contrast, the NMDP had a registry of more than 6 million potential bone marrow donors.

Nevertheless the results were very encouraging for cord blood stem cells. Survival of patients receiving a perfectly matched cord blood stem cell unit was 68 percent, compared to only 46 percent for those patients receiving a perfectly matched bone marrow. Equally as remarkable, patients receiving cord blood stem cells with two to three mismatches had a 30 percent survival. This degree of mismatch with bone marrow would have resulted in no survivals. Most remarkable of all was that these results were achieved with cord blood stem cells with a patient population that was much more advanced in their disease than the patients receiving bone marrow. Since bone marrow was the "standard of care" and cord blood was "experimental," the patients who received cord blood had been waiting and waiting and waiting for a bone marrow match until their condition was so dire—out of remission and in relapse—that they finally proceeded with the "experimental" cord blood stem cell transplant. However, even in these cases, the data indicate that cord blood, even in its earliest stages, was very successful.

The clinical advantages of cord blood are promising. A recent study from the University of Tokyo Medical Center reported a survival rate of around 70 percent among high-risk adults treated with cord blood. Results are even more promising with children. The same cell population is a proportionately larger cell population, and Dr. Kurtzberg has reported an 80 percent survival rate for children with immunodeficiency diseases. An article by Dr. Kurtzberg and Dr. Rubinstein in the *New England Journal of Medicine* last year showed a 90 percent success rate in treating a disease called Hurler syndrome that affects the brain. For the first time, Dr. Kurtzberg noted that cord blood was not only arresting the disease, but it was beginning to reverse the symptoms.

The main nervous system diseases—Alzheimer's disease, Parkinson's disease, Huntington's disease, and amyotropic lateral sclerosis (Lou Gehrig's disease)—all involve neural cells and the loss of neural cells. Basically, the neural cells in the brain, the neurons, are supported by the function of the astrocytes and oligodendrocytes, or glial cells, which provide comprehensive support for the neural cells. Dr. Kurtzberg has recently reported evidence that glial cells derived from the donor cord blood stem cells are growing in the brains of her patients who were treated for enzyme insufficiency genetic diseases.

CBS recently reported on a case in South Korea in which a woman who had been paralyzed for 20 years was able to take a few steps after being treated with stem cells from an umbilical cord injected directly into her spine. Now, that's only one patient, and when there are 10, we can be a little more comfortable with the accuracy of this initial report. There are other phenomena that might account for what she has been able to do, but it certainly falls within the pattern of other things we know about the ability to generate neural cells with cord blood stem cells.

There is an intensive focus on creating cord blood banks in Asia, because it is their belief that this is the area in which they're going to pass the United States.

Expanding Access To Treatment. How will cord blood banking work in the United States? There will be cord blood banks in a national net-

work. To get a match for a patient, you wouldn't need to track down the person with the match and find out, for example, that he moved or that someone showed him the informed consent and then someone else showed him the needle to get his bone marrow. Instead, you would simply call up on a computer screen a search request form and fill it in for your patient; then, with a mouse click, the entire inventory is sourced and shipped. On the following day, it can be at the transplant center.

There are two bills in Congress that I would like to direct your attention to, H.R. 596 in the House and S. 681 in the Senate. In the House, Representative Chris Smith (R–NJ) is the lead sponsor, and leads a bi-partisan group of co-sponsors including many of the Black Caucus. In the Senate, Senators Orrin Hatch (R–UT), Arlen Specter (R–PA), Sam Brownback (R–KS), and also Senators Tom Harkin (D-IA), Charles Schumer (D–NY), and Christopher Dodd (D–CT) lead the bipartisan legislation.

This legislation would provide funding for 150,000 units of HLA typed, cryopreserved units of cord blood stem cells, which, if collected with the planned ethnic diversity, should provide at least 80 percent of all U.S. citizens of any ethnic group. You may be aware that if you're African–American, you have half the probability of a Caucasian to get a bone marrow match. The 150,000-unit national inventory of cord blood stem cells should provide 80 percent of Americans with an acceptable match—a very substantial improvement over the 9 percent reported by the GAO for the Marrow Donor Program.

There are also Homeland Security ramifications in the building of this National inventory of cryopreserved, instantly available, stem cell units. When the Chernobyl disaster happened, of the 200 people in the building, only 13 were alive by the time the first bone marrow transplant showed up—two and one-half months later. Please note, I am not representing that these stem cells are a defense against death in a radiation incident. Clearly if you're in the blast radius, you're without help. But there is a subset of patients who will have lost their blood forming stem cells but may be able to survive if these replacement stem cell units are available quickly.

Finally, the legislation requires that up to 10 percent of the collected units go free of charge to peer-review stem cell research.

REPRESENTATIVE DAVID WELDON: This is a tough issue, and part of the reason is that it's complex biology, so you're trying to explain to people things that they have a challenge understanding. To make matters worse, one of the groups of people that have a real challenge in following and understanding all this is journalists. They majored in journalism and not in molecular biology, but they are nonetheless given the responsibility of explaining to the American people what is going on here.

Adult stem cells and, in particular, cord blood stem cells are going to be the sources for the regenerative, miraculous medicine in the future. Embryonic stem cells are just a pipe dream. I have been challenging my opponents in this debate for years: Show me your data. But embryonic stem cell research is just not getting good research results. In a few years, the researchers working with embryonic stem cells are probably going to give up because they're just not getting good results, whereas the adult stem cell work and, in particular, the cord blood work is just phenomenal. I think we're up to 10 kids that have been cured, maybe more, of sickle cell anemia, and as a clinician who used to take care of kids with sickle cell anemia, to be able to cure people with sickle cell anemia is just huge. That's the reason why the whole Black Caucus is on this Cord Blood Bill; they realize what's going on here.

The Federal Policy Debate. From a policy perspective, the Congress spoke to this issue several years ago when Congressman Roger Wicker (R–MS) and then-Congressman Jay Dickey (R–AR) authored language that said that no NIH funds can be used for any research involving the destruction of a human embryo. President Bill Clinton signed that bill and then shortly after that came up with a clever way to get around the so-called Dickey-Wicker language simply by allowing outside researchers to destroy embryos and move the stem cells over to NIH.

That was essentially what George Bush inherited. His solution, I thought, was rather eloquent: he

allowed ongoing funding for research on the stem cell lines that had been accumulated because the embryos were destroyed, but no more additional federal funding would be provided for the destruction of embryos.

And that is basically the debate we are moving into this year. Congressman Mike Castle (R–DE) and Congresswoman Diana DeGette (D–CO) have introduced a bill in the House, and there's a companion bill in the Senate, to partially override the President's position and allow NIH dollars to be used on the "excess embryos" from fertility clinics. The Juvenile Diabetes Foundation, among others, says that there are 400,000 excess embryos in the fertility clinics. According to a RAND study, the vast majority of those 400,000 embryos are wanted embryos. The parents are holding on to them because they want to do another cycle and possibly have another baby. Many of the parents are not comfortable at all with donating their embryos for destructive research, and many of them want to adopt them out. The other thing that is very interesting is that when you thaw these embryos, there's a very high mortality rate. They have been in the freezer for a long time, and a lot of them die. It's estimated that you would really only get about 250–300 cell lines if the Castle bill were to become law.

You might ask: Why are all these researchers pounding on the doors of all these Senators and Congressmen, saying that embryonic cells are the best way to go and we really need to fund this research, when all the scientific data show that the cord blood and the adult stem cells are much, much better? Why are these researchers doing this?

Number one, some of them just do not want to be told they can't get funding for this. They look through a microscope, and it looks just like a cow embryo, so what is the big deal? In other words, they have no belief in the sanctity of human life. They have absolutely no qualms in exploiting it, throwing it in the trash. They have some sort of secular humanist worldview that takes them to that place.

The other important thing you need to remember is that if you develop a highly successful intervention for treating, say, sickle cell anemia with cord blood, that is not really a money-making intervention under our current patent system. But if you can develop the embryonic stem cell line that could cure Parkinson's disease, you'll be hanging out with the wealthiest people in the world, because the embryonic stem cell line itself will be patentable and worth a lot of money. And that is why a lot of these folks want to go down this path and want to do this.

I feel very, very strongly that this debate will go away. I think the President's position is right. There are millions of Americans who do not want to fund destructive embryonic research for the same reason they don't want to fund abortions. They believe in the sanctity of human life, and they feel that their tax dollars should not be used to destroy it.

I think our prohibition on federal funding in this area is the proper way for us to go, since we have a divergence of opinion in the population. There is no prohibition on private funding. There is also state funding. The state of California has moved forward. They're going to be able to fund millions of dollars of embryonic stem cell research. I think their taxpayers, in time, will regret that decision when they see absolutely no good cures coming out of it.

But the President's policy is the right policy. The Dickey–Wicker language is the right thing for us to have in law.

QUESTION FROM THE AUDIENCE: I believe that the intellectual property rights issue is really the crux of why we are having this debate at all, because the science so strongly supports adult and cord blood stem cell research. Do we just have to wait for the science to prevail, or is there some legislation that might be wise to deal with the intellectual property rights issue?

REPRESENTATIVE WELDON: The history behind the intellectual property rights problem, and why so many biomolecular researchers want to pursue the embryonic stem cells because of the patentability issue, got started about eight years ago when the Congress was confronted with physicians who were trying to patent various procedures. There was a very serious concern that if that were

allowed to move forward, it could stifle the free flow of ideas and information and dramatically increase the cost of health care.

After some considerable debate, we modified our patent laws in the 1990s, saying that if you develop a new way to take somebody's gall bladder out, you can patent the instrument, but you cannot enforce the patent when that specific method is used by other physicians. That basically meant that you cannot effectively patent adult stem cell and cord blood stem cell interventions, but if you could have some sort of uniquely, genetically engineered embryonic stem cell, that is a patentable product.

I'm not convinced that that is the total reason why many members of the biomolecular community want to pursue the embryonic stem cell preferably to the adult stem cell research. One of the other reasons, and the reason why a lot of these white-lab-coat researchers really like these cells, is that they proliferate greatly. The adult stem cells are hard to work with. The cord blood stem cells, however, are much better. They're much more like embryonic stem cells.

The other thing is that embryonic stem cells differentiate very easily, but that tendency to grow and differentiate easily tends to cause them to form tumors and be genetically unstable when you do a clinical application of it. So these bench researchers want to play with them.

But we're not in the business of funding this just because they want to do it. What Congress needs to be looking at is the likelihood of this leading to treatments of disease. In my opinion, it's unlikely. It's highly speculative. More important, other interventions seem to be moving along much more quickly that show a tremendous amount of promise, and those are, specifically, adult and cord blood stem cells.

QUESTION FROM THE AUDIENCE: If, as you say, embryonic stem cell research isn't effective and there are no data, wouldn't the normal screening process through NIH get rid of this?

Also, why are we dealing specifically with one type of research through policy and not other types of research that may not be showing promise that are being funded through NIH?

REPRESENTATIVE WELDON: The Congress does not intervene in basically peer review decisions that NIH officials are engaged in with a whole host of diseases because we don't have the expertise to be doing that. We intervened in this case, in the original Dickey–Wicker language, because there is a very serious ethical and moral dimension to this, and I think it's very appropriate for us to do this.

Regarding the specifics of your question, I had an interesting conversation with NIH Director Dr. Elias Zerhouni that relates to your question. They are funding adult stem cell research and embryonic stem cell research, and one of the complaints from the left is, "Why aren't you funding more embryonic stem cell research?" What he told me is they have not had an adequate number of really good applications that would withstand their peer review process. The quality was not there to justify a vast increase or the demand for new cell lines.

He did say to me that, over time, these cell lines may be depleted and there could be a scenario where there is potentially interesting research that people may want to pursue and there may not be enough embryonic stem cell lines; but the principal problem is an adequate number of applications of quality research projects. So the process, I think, is working, and the Bush policy is a very good approach to the problem.

DR. HOLLOWELL: As Dr. Weldon points out, there are not a lot of strong applicants using up all of the money that is available, so new researchers, in particular, are going to write grants for money that is currently untapped. There is money there to be obtained for research projects.

Second, the fox is guarding the hen house when it comes to peer review of these very grants. When it comes to pushing the envelope and finding new possibilities, new cures using embryonic stem cells, you often have people who are like-minded with regard to the sanctity of human life reviewing these grant applications, and they don't necessarily, in

most cases, see the ethical issues that you and I might see if we were reviewing them.

These applications are often reviewed by other scientists who want to "push the envelope" in the scientific community, and if they can get rich and famous in the process, and if society benefits, that's a wonderful thing too. When it comes to review of these grant applications, and if there's even the remote possibility that money can be had and that a cure might be found, they're going to use up the funds that are available and that are not currently being exhausted.

MR. COELHO: Large money tends to flow when you're doing human clinical trials, and to get there, you need to undergo animal trials. So far, embryonic stem cells have performed intermittently in animal trials of any sort. In one trial, I read that 80 percent of the animals got malignant carcinomas that were triggered by these stem cells.

Remind yourselves that one case of leukemia in a gene therapy trial shut down that industry for 10 years. Another one just happened when they started up again. So, if you have that kind of data in the animal trials, you have a lot of work to do that's actually lower cost in trying to figure out what is going on with these cells. The large funds cannot flow until you at least overcome that in animals and get on to humans.

QUESTION FROM THE AUDIENCE: Could I ask Dr. Weldon to comment on the global dimension of this discussion? In the upcoming debates on the Hill, shouldn't this be given appropriate attention? Ron Reagan, Jr. and others, have labeled this a "religious right" issue. In fact, however, it is impossible to get funding for this research in the whole of Old Europe.

Germany wrote the President's ban into German Federal Law, and France has almost no funding for anything of this kind. The European Commission came very close to deciding two years ago formally to adopt exactly the same policy President Bush adopted. My understanding is that it didn't work because some of the conservatives wouldn't compromise there.

But globally, this debate is a very cautious debate, and I would like to know whether that perspective is going to help free the discussion from the kind of ideological labeling which has been used here in the U.S.

REPRESENTATIVE WELDON: That's a really interesting aspect to this whole debate, and it drags in the issue of cloning because that is another example where the United States appears to be out of step with the rest of the civilized world. Indeed, the U.N. just recently issued a decision to oppose cloning, not just reproductive cloning, but embryonic cloning as well.

I just want to amplify what Dr. Hollowell was saying. The reason cloning always comes up in these conversations about embryonic stem cells is that, theoretically, if embryonic stem cells proved to be useful, you could not, if you had Parkinson's disease or Alzheimer's disease, get an embryonic transplant because you would be getting foreign tissue and would enter into these tissue rejection issues.

That's where you come up with the cloning nexus. What they want to do is to make a clone of you and then get the embryonic stem cells from your clone. They call that therapeutic cloning. It's real science fiction. It's never been done. There's no animal model for it. There's not even an animal model of successfully treating an animal disease with embryonic stem cells. They've got a couple of papers; there's a suggestion that it may work; but there's really not a good study.

Meanwhile, adult stem cell research is percolating along fabulously: over 50 diseases treated—in humans, not animals. So the question is: Will the pressure from the outside world ultimately cause the United States to get off dead center? I should hope so. We're going to be having some interesting debates this year, and one of the issues that will come up is that the United States is to the left of the rest of the world. This is a human life issue, and we claim to be the great champions of human rights and the sanctity of human life, but in reality, we're way to the left.

I want to read to you a fascinating quote from William Haseltine, the CEO of Human Genome

Sciences, Inc., of Rockville, Maryland and a leading advocate for embryonic stem cells: "The routine utilization of human embryonic stem cells for medicine is 20 to 30 years hence. The time line to commercialization is so long that I simply would not invest. You may notice that our company has not made such investments."

What's going on in California, with the taxpayers funding embryonic stem cell research, is that the taxpayers are funding what the venture capitalists will not fund. They know what is going on, and they won't fund it. That is exactly what is going to happen in Washington: People are going to be trying to get the federal taxpayers to fund what the venture capitalists will not fund.