

The PRESIDING OFFICER. Without objection, it is so ordered.

#### STEM CELL RESEARCH

Mr. FRIST. Mr. President, I rise to speak to a topic that is very much on the minds of the American people as well as policymakers in Washington, DC; that is, the issue of embryonic stem cell research. The issue of embryonic stem cell research is one that has captured the imagination of people all over the world in the last 2 to 3 years. It wasn't that long ago that the idea of taking cells very early in life and having their potential captured and set in different directions to help treat disease—to help make diagnoses—was really just a pipedream. Literally, it was 2 or 3 years ago.

Now, because of the advances in science, the advances in technology and the tremendous research that is being conducted in this country and, indeed, around the world, a whole new frontier has opened—the frontier of what is called stem cell research. I will mention a little bit about what that is, but what captures people's minds so much is the promising aspect of this research. What has inspired such interest in this is the fact that people with numerous diseases, for really the first time in their lives, can look ahead and say there is the potential for a cell at its earliest level to be channeled in certain directions to make the care of that disease easier, and possibly even cured.

The same hope—I hear it daily—is expressed by people with diabetes, Alzheimer's disease, or Parkinson's disease, and for spinal cord injuries. Indeed, this stem cell research—both adult stem cells and embryonic stem cells—has opened up a new frontier that is full of potential, full of hope, and full of promises.

The issue is being addressed by the leaders of our country. It is being addressed in amendments on the floor of the Senate. It is being addressed by groups considering the ethics among the think tanks. It is being considered by the administration as we speak.

I would like to make four points.

No. 1, in any of these arenas where we are talking about life—and indeed I believe upon fertilization—there is a continuum from a sperm and an egg, to a blastocyst, to a fetus, to a child, to an adolescent, to an adult. That continuum is indeed life.

As policymakers, we will be injecting our own feelings and our own beliefs into this debate as we go forward. Therefore, I wish to make it clear to my colleagues that from my perspective I do value life and give moral significance to the embryo and to the blastocyst and to that full continuum.

I, indeed, am pro-life. I oppose abortion. My voting record on the floor of this body is consistent with that. Those beliefs are based on the very strongly held spiritual beliefs that I have. They are based on my medical

understanding, having spent 20 years in the field of medicine, and in science—that medical understanding of this process of life and of living tissues. I do give moral significance to the embryo, as I mentioned earlier.

Second, I am a transplant surgeon. I had the opportunity to serve on committees that looked at the ethical considerations surrounding the use of tissues and the transplantation of those tissues. I have served on committees sponsored by the United Network For Organ Sharing—the registry that oversees transplantation in this country. I have served on the board of local organizations and tissue procurement agencies. I have served on the ethics committees within hospitals. I have had the real privilege of writing scores of peer-reviewed papers in the field of transplantation and scientific papers in the field of transplantation—both basic science and clinical transplantation of living tissues. I wrestle on a daily basis with these decisions surrounding life and death and health and healing. I have had the opportunity to routinely deal with many of these end-of-life tissues.

I have also been blessed with having had the opportunity and the training to transplant tissues myself—to take a beating heart out of an individual who has healthy lungs, a healthy heart, healthy kidneys, and to take that beating heart from that individual that, yes, does terminate the living function of the lungs and the kidneys and the other organs, but to take that heart and give it to another on really a weekly basis before coming to the Senate, and allowing that individual to live in a new life, a better quality of life; an individual who without that transfer of tissue otherwise had no hope.

I mention that, because the ethical construct and ethical and moral decisionmaking that we are having to face today in a much earlier point on this continuum of life is very similar to what we debated and talked about—what our scientists debated and talked about—what our ethicists did—what our medical scientists did about 30 years ago in transplantation. To whom do you give scarce resources? To whom do you not give a heart or a lung because we have this shortage? Which organ tissues are suitable for transplantation?

I have had the privilege—really the blessing—to be able to see the rigorous consent process we have now established in a very solid fashion surrounding the use of tissue taken from one source and given to another source. Again, it is not an exact parallel, but it is similar from the large ethical construct in transplantation 30 years ago to what happens after birth, to the moving of tissues, or cells in this particular case, in a period much earlier along the time line, at a time 5 to 6 days after a sperm and egg come together.

I am convinced, based on this personal experience, based on professional

experience, that we can address this use of living tissue, living tissue that otherwise would not be used. It is critically important that we understand, and in our moral and ethical framework ensure, that this tissue otherwise would not be used. It is similar to the fact that when I do a heart transplant, that heart otherwise would not be used for anything useful. That individual would likely be buried 6 days later or 10 days later.

To use that tissue that has no other use—and that is where this informed consent process is important when we are talking about stem cell research, to benefit other people, people with diabetes and Parkinson's disease and Alzheimer's and spinal cord injuries, who may potentially benefit from this new research.

It was not easy in transplantation 30 years ago, but we did it. And through organizations such as the United Network for Organ Sharing, a national registry, strong Government oversight, full transparency, full public accountability, discourse among not just the scientists—because they are going to push for it hard—but discourse on the public square, where you get the input of the theologians and the ethicists and the philosophers and the medical doctors and the clinicians, and the parents, as well as the scientists themselves—the consent process; I will come back to it very briefly—but the consent process must be comprehensive.

That is the only way we can avoid the potential abuse, the potential for overcommercialization of this process. We have to make sure the consent process protects against coercion. We can look back to that transplant arena because we addressed it 30 years ago. Again, this is much later in the continuum of life, when we are doing heart transplants and lung transplants, but we must come back and superimpose a comprehensive consent process much earlier in time.

The third issue is research. As I mentioned, this is new research. It is exciting. It gives hope to millions and millions of people. But let's not oversell the potential. This research is new. It is uncharted. It is evolving. It is untried and untested. Therefore, we cannot predict exactly what is going to come from this research. So let's not oversell the research in order to build public support for whatever position we take.

We should not let the potential of this research drive the moral considerations themselves. Thus, we must set up a very important, strong, transparent, ethical construct in which this decisionmaking can be made, and needs to be made, on an ongoing basis. We do not know what the next great discovery is going to be 6 months from now. We cannot lock into place either the moral considerations or the way we consider whether or not it is appropriate to look in a new field of science.

So the oversight process has to be responsive, has to be ongoing. It has to

recognize that science moves very quickly. The lack of predictability means there is the potential for abuse of the science itself. Again, that is why we must consider this issue in this body, why politics or policy must be engaged to prevent the potential for abuse. Anytime we are talking about the manipulation of life or living tissues at this early point, there is the potential for abuse. Thus, I conclude that embryonic stem cell research and adult stem cell research should be federally funded within a carefully regulated, fully transparent, fully accountable framework that ensures the highest level of respect for the moral significance of the human embryo, the moral significance of the human blastocyst.

There is this unique interplay of this potentially powerful research—uncharted research—this new evolving science with those moral considerations of life, of health, of healing. That interplay demands this comprehensive, publicly accountable oversight structure I propose.

I very quickly have addressed this issue in a comprehensive way. The reason I am in this Chamber and take this opportunity to speak is for people to actually see that the issue is a complicated issue but one that has to be addressed in a larger framework than just to say: Funding, yes or no.

There are basically 10 points I think we must consider, and I have proposed an answer. Again, I don't know the answer, and I struggle, like every person, on this particular issue to make sure we have the appropriate moral considerations. But I will outline what my 10 points are.

No. 1, we should ban embryo creation for research. The creation of human embryos solely for research purposes should be strictly prohibited.

No. 2, we should continue the funding ban on the derivation of embryonic stem cells. We need to accomplish this by strengthening and codifying the current ban on Federal funding for the derivation of embryonic stem cells.

No. 3, we should ban human cloning. We need to prohibit all human cloning to prevent the creation and the exploitation of life for research purposes.

No. 4, we should increase adult stem cell research funding. These adult stem cells, stem cells that are removed from an adult, that you can back out in such a way that you can capture the potential for using them for treatments for various diseases—we should increase this funding for research on adult stem cells to ensure the pursuit of all promising areas of stem cell research, on both adult stem cells which occur much later in life and the embryonic stem cells which are derived at the 5- or 6-day-old blastocysts.

No. 5, provide funding for embryonic stem cell research only from blastocysts that would otherwise be discarded. We need to allow Federal funding for research using only those embryonic stem cells derived from blastocysts that are left over after in

vitro fertilization and would otherwise be discarded.

No. 6, require a rigorous informed consent process to ensure that the blastocysts used for stem cell research are only those that would otherwise be discarded. We must require a comprehensive informed consent process establishing a clear separation between a potential donor's primary decision to donate blastocysts for adoption or to discard blastocysts and their subsequent option to donate blastocysts for research purposes. Such a process is modeled on this well established and broadly accepted organ and tissue donation process in which I have been so intimately involved over the last 20 years.

No. 7, limit the number of stem cell lines. I believe we should restrict federally funded research using embryonic stem cells derived from blastocysts to a limited number of cell lines. This does not mean limiting it to research using stem cells that have already been derived to date, most of which would reportedly not be eligible even under the current NIH guidelines that need much strengthening. In transplantation, when I remove a heart from an individual and I give it to another individual, that one individual benefits. With stem cells, it is very different. From a stem cell line, you derive the cells, and that stem cell line can be used for multiple experiments, thousands of investigations as we go forward.

No. 8, establish a strong public research oversight system. I believe we should establish an appropriate public oversight mechanism, including a national research registry, to ensure the transparent, in-depth monitoring of federally funded and federally regulated stem cell research and to promote high ethical, moral, and quality research standards.

No. 9, require ongoing, independent scientific and ethical review. We need to establish an ongoing scientific review of stem cell research by the Institute of Medicine and create an independent Presidential advisory panel to monitor evolving bioethical issues in the area of stem cell research. In addition, we need to require the Secretary of Health and Human Services to report to Congress annually on the status of Federal grants for stem cell research, the number of stem cell lines created, the results of stem cell research, the number of grant applications received and awarded, and the amount of Federal funding provided.

Lastly, No. 10, strengthen and harmonize fetal tissue research restrictions. Because stem cell research would be subject to new, stringent Federal requirements, I believe we must ensure that informed consent and oversight regulations applicable to federally funded fetal tissue research be made consistent with these new rules.

During the past several months, rarely has a week passed without a newspaper story or scientific publication

about possible research breakthroughs involving adult or embryonic stem cells—and the ethical issues raised by this research. Today, Americans' thoughts on stem cell research are debated on Sunday talk shows; photographs of microscopic blastocysts grace the cover of our nation's news magazines; and—twice in the last week alone—we have been reminded by those on the unregulated medical research frontier that human cloning and the creation of embryos for research is no longer relegated only to the realm of science fiction.

Across the country, families are discussing the difficult moral issues that are raised by stem cell research around their kitchen tables. At their offices, co-workers are weighing the potential benefits of stem cell research against its morality. And many of my colleagues are personally grappling with the difficult decision of how best to approach these issues.

An explosion of medical and scientific innovations are producing new treatments and hope for patients suffering from a wide range of disease. This has been accompanied by a newfound awareness among policymakers, and the public, of the potential of biomedical research—an awareness that has spawned an insatiable appetite for more and faster advances. As a physician and a researcher, I am honored to have played my part in this movement—helping to foster broad, bipartisan support for increasing funding for biomedical research and, specifically, for the National Institutes of Health (NIH).

However, we must always remember that science should not be practiced in a vacuum. And, with the ever-increasing pace of progress has come new challenges—posed by a variety of ethical dilemmas—that have, at times, outraced the ability of public policy and we, as legislators, to respond. Yet, I deeply believe that we have an obligation to do just that.

There are those, I believe, who would tell us that “politics” should not impinge on the scientific process. As a legislator and a medical researcher, I can tell you that is not the case. Rather than leaving the progress and the ethics of science only to be determined by researchers and bioethicists, “politics” should, and does have, an important role in deciding what research is not only scientifically promising but also societally acceptable. This role is to determine, as the Washington Post noted several years ago and as I have referred to since, “is there a line that should not be crossed, even for scientific or other gain, and if so, where is it?”

Moreover, politics and policy plays a crucial role in guiding and ensuring the ethical pursuit of science, as well as restraining the inclination of science, left unchecked, to move beyond ethically acceptable boundaries. That, then, is our challenge.

Today we are faced with the issue of embryonic stem cell (ES) research—research that carries both great promise and great peril. Most of us have been made aware, by now, of the tremendous potential of embryonic stem cells for therapeutic advances for a variety of conditions—diabetes, Alzheimer's disease, Parkinson's disease, leukemia, spinal cord injuries, to name a few.

Embryonic stem cells are derived from a five to six day old embryo, also called a blastocyst. By this stage, the embryo has formed two layers: the inner cell mass which will form the embryo proper and the extra embryonic tissues that form the placenta and supportive cells. Although these inner cells, roughly 20–30 cells, have lost the ability to form supporting tissues, they retain the ability to develop into any cell type found in the body and are considered “pluripotent.” Over time and if allowed, they continue to multiply and differentiate further, becoming committed to specific lineages. It is from these inner cells found in the blastocyst stage that embryonic stem cells are derived. Such pluripotent embryonic stem cells, when properly isolated and cultured, appear to contribute to all cell types found in the adult and to be capable of indefinite self-renewal.

These embryonic stem cells being discussed here are obtained from embryos left over following the conclusion of in vitro fertilization (IVF). Many of us have known couples who, because of their inability to have children through natural reproduction, have turned to IVF as an alternative. Since its introduction to the United States in 1981, more than 45,000 babies have been born using IVF procedures.

However, because of the significant implantation failure rate involved in infertility treatment, current IVF techniques require couples to create more embryos than initially needed as a sort of insurance policy. Typically, physicians will obtain roughly 10 eggs. Of these eggs, only six to eight will become fertilized—producing an embryo. Then, in order to avoid producing multiple-fetus pregnancies, physicians will only transfer 2–3 embryos to the uterus. Those not used may be frozen for later use or donated for adoption. In fact, many couples decide to leave embryos frozen, in case they decide to have additional children, rather than beginning the entire process again.

Adult stem cells, by contrast, are relatively undifferentiated and self-renewing cells that help repair tissues harmed by injury, disease, or natural cell death. The most widely known and understood example of such a cell is the hematopoietic stem cell, found in bone marrow and responsible for the production of blood cells. Other promising cell types include neural stem cells and mesenchymal stem cells. There have also been publications touting the potential of stem cells found in human fat tissue as well as umbilical cord blood. Until recently, adult stem cells were considered to be very rare, if

they even existed, and inflexible—only able to form the cell types for the tissue in which they were found. However, recent news suggests adult stem cells may have more plastic properties than previously believed.

Both embryonic and adult stem cell research hold tremendous potential for a wide range of uses, including clinical applications of cell-based therapies for a number of diseases and injuries. This research may be useful in providing scientists a better understanding of the human cellular growth and differentiation process—allowing researchers to seek out and attempt to treat or prevent the causes of birth defects and genetic abnormalities and diseases. It may also be useful in pharmaceutical development, allowing researchers to grow large numbers of various cell types in order to test drug effectiveness and toxicity.

However, it is important that advocates not over-sell the potential of either embryonic or adult stem cell research for medical treatments. This evolving science is relatively new, and much basic research remains before we can reasonably expect to see clinical trials and possible treatments. In fact, to date, with the exception of hematopoietic stem cells that have been used in bone marrow transplantation for many years, none of these sources has yet demonstrated proven therapeutic applications.

Some of the challenges that remain for both adult and embryonic stem cell research include: learning the signals that control the differentiation of stem cells into a desired type; overcoming the challenge of immune rejection in cell transplantation; and establishing consistent, effective methods to culture, isolate, and grow the cells in a timely manner that is consistent with good manufacturing processes. Yet the hope that they will someday yield therapies for those suffering from chronic and debilitating and life-threatening diseases is powerful.

In my work as a physician and heart and lung transplant surgeon, I have for years wrestled with decisions involving life, death, health, and healing. Having taken part in hundreds of organ and tissue transplants, I've experienced the ethical dilemmas involved in end-of-life care on numerous occasions. I have seen families faced with the most difficult decision of saying farewell to a loved one. Yet I have also seen their selfless acts in the midst of this sadness to consent to donate living organs and tissues of their loved ones to benefit the lives of others.

Moreover, having performed surgery in the early days of heart and lung transplantation, I know the powerful impact that medical progress has had on each of my patients, many of whom are alive today because of the life-saving treatments developed through medical research.

Because of my professional experiences, I have, during my nearly seven years in the United States Senate, de-

voted a significant portion of my time to address health policy issues as a way to impact patients on a broader scale than the one-on-one interaction which I knew previously. However, this effort has remained guided by the same basic principles that informed my career as a practicing physician and scientist—to improve the lives and health of patients and deeply respect the dignity of life.

During the past few months, I have read much of the medical, scientific, and ethical literature relevant to this debate. I have queried my colleagues in the scientific and medical community who have first-hand experience with stem cell research, reproductive treatments, and the ethical issues enmeshed in each. I have talked with bioethicists. I have reviewed my own professional medical experience for guidance. I have examined federal public policy precedents involving medical research. And I have spent a great amount of time in prayer and reflection on this issue.

As the Senate's only physician, and its only medical researcher, I feel compelled to explain to my colleagues and the American people my views on the proper public policy approach with respect to stem cell research. This is a critically important decision—one that cannot be left, as some have suggested, only to scientists—and it is vitally important that each of us is fully aware of the depth of the scientific, ethical, and moral issues involved.

I mention that this issue should not be driven totally by the research community. Nor should it be determined solely by National Bioethics Advisory Commission (NBAC) commissioners or by patient advocates. Each of these stakeholders certainly has its role to play. The NIH has advocated on behalf of what they see as the direction in which science is heading. The NBAC has debated the issue and determined it worthy of Federal support. And patient advocacy groups have rightly worked to advance science that could benefit their particular illnesses.

However, as a researcher, as someone who has participated in scores of clinical investigations on the transplantation of human tissues to benefit others, I know that this decision cannot be left to the sole jurisdiction of the scientific community. It is our responsibility as legislators to determine the proper role of our Federal government in this evolving, new research and to build in appropriate ethical safeguards.

After grappling with the issue—scientifically, ethically, and morally—I believe that both embryonic and adult stem cell research should be federally funded within a carefully regulated, fully transparent framework that ensures the highest level of respect for the moral significance of the human embryo. Because the unique interaction between this promising but uncharted new science with the ethical and moral considerations of life is continually evolving and presenting new

challenges, we must ensure a strong, comprehensive, publicly accountable oversight structure that is responsive on an ongoing basis to moral, ethical and scientific considerations.

As a legislator, I have been consistent in my work to ensure that human life is treated with the utmost respect and dignity. I am pro-life. My voting record in the Senate has consistently reflected my pro-life philosophy. In my 6-plus years in the Senate, I have voted time and time again to preserve human life. For instance, I am proud to have been a leader in the fight to ban the partial-birth abortion procedure. As a physician, my sole purpose has been to preserve and improve the quality of life.

Throughout my career on the forefront of heart and lung transplantation, I have had to face the ethics of life and death with my patients and their families. As a surgeon, I have frequently removed a heart from one individual whose brain has died and placed that heart into another patient who would otherwise die. But this requires determining when brain death has occurred a process that was very controversial when it was first developed just 33 years ago.

A similar dilemma now confronts us in the field of embryonic stem cell research, and I have turned to my own experience as a transplant surgeon for wisdom. The question is much like that faced in the early days of organ transplantation—do we remove organs and tissue for transplantation and research from an individual who is brain dead, but whose other organs continue to live and function normally? Do we allow research using stem cells derived from blastocysts that could, if implanted, become a fetus, but which the parents clearly have determined to discard? I believe this is the proper course, but only under the strictest of regulations to ensure a clear separation between the decision of whether to discard excess embryos or donate them for adoption and the option to donate such embryos for research.

Scientifically, I consider human embryonic stem cell research to be a promising and important line of inquiry. I am fully aware and supportive of the advances being made each day using adult stem cells. However, it seems clear that research using the more versatile embryonic stem cells does have greater potential than research using adult stem cells and may, under carefully considered and appropriate conditions, be conducted ethically. The scientifically prudent course for us as policymakers seems to provide for the pursuit of both embryonic and adult stem cell—research allowing researchers in each field to build on the progress of the other.

Let me make this clear, however. To say that the research may ethically be conducted is not to say that the guidelines promulgated by the National Institutes of Health (NIH) are sufficient, as some of my colleagues have as-

serted. To the contrary, they are severely lacking in appropriate safeguards. Nor do any of the present versions of legislation pending in Congress to authorize ES research include sufficient protections.

Therefore, federal funding for stem cell research should be contingent on the implementation of a comprehensive, strict new set of safeguards and public accountability governing this new, evolving research—to ensure the progress of this science in a manner respectful of the moral significance of human embryos and the potential of stem cell research to improve health.

I transplant hearts and lungs. I spent 20 years in both medical training and engaged in surgery. I am board certified in two surgical specialties. I have spent countless hours research and publishing this research in peer-reviewed medical journals. I was active in clinical transplantation. In each case, families of the donor individual has completed a comprehensive informed consent process giving consent to organ donation. I would weekly get calls in the middle of the night summoning me to the operating room, where I would come face-to-face with individuals near death and their grieving families. Through these experiences, I have seen firsthand the impact that medical progress and technological have had in reshaping legal and ethical criteria, and, in turn, I have seen how ethics has shaped the practice of medicine.

Historically, death was not particularly difficult to determine or define. Generally, all vital systems of the body—respiratory, neurological, and circulatory—would fail at the same time and none of these functions could be prolonged without the maintenance of the others. With major technological advances in life support, particularly the development of ventilators, it is possible to keep some bodily systems functioning long after others have ceased.

Over time, most state laws adopted a neurological standard for determining when death occurs. Thus, it has become common, accepted practice that requires that both the cerebral cortex and the brain stem irreversibly cease to function—this is the so-called “whole brain death” standard. There is now broad public support for organ donation upon this basis. But the interplay of science, ethics, and policy did not come easily.

As we came to no longer face the inevitable simultaneity of systemic failures, it became necessary to define with greater precision which physiological systems are indicators of life and which are not. In 1968, a Harvard Medical School special committee report first urged that brain death be used rather than the older definition of irreversible circulatory-respiratory failure. This was later embraced by a Presidential Commission in 1981 as a recommendation for state legislatures and courts.

In this context of life and death decision-making, physicians remove organs from individuals for the purpose of organ donation based upon the informed consent of families after determination of “brain death,” at which time the individual is considered to be dead. However, this decision-making process is carefully protected to ensure that the decision to withdraw life support or declare brain death is made entirely independent of any consideration of obtaining the individual’s organs for donation. Even though the body and other organs and tissues are technically alive with the assistance of ventilators and other medical devices, the brain has ceased to function. When I removed a heart—or a heart and lungs—other organs were living and still functioning. Their organs would be used to save the lives of others. If the family consents following a comprehensive and broadly accepted consent process, we permit surgeons to remove living organs from the body of the individual.

The decision to donate the organs of brain dead individuals is, as it should be, a decision separate from all other medical decision-making. It is made by informed consent of family to carry out the intent of the individual. It meets both ethical and practical requirements. First, it ensures that families are not faced with this difficult decision at a time when they are already struggling with saying good-bye to a loved one. It ensures that the treating physician is not the individual approaching the family for consent. On a very practical, public policy level, it strengthens the organ donation procedure by reassuring the public that decisions of best medical treatment are clearly divorced from the considerations of organ donation.

The example of organ and tissue donation holds one framework to review in fashioning an approach that both respects the human embryo and promotes this new, evolving research. I believe that the human embryo is inherently valuable and has moral significance regardless of whether it will be implanted in a woman’s uterus or is left-over in the colder, artificial setting of an infertility clinic. Because an embryo holds a high measure regardless of status, that embryo should be afforded a high level of respect.

Because embryonic stem cells appear capable of indefinite self-renewal and differentiating into all adult cell types, this research has tremendous potential to provide new, important cell-based therapies.

Research using adult stem cells also holds tremendous promise for treating disease, and recent studies have altered long-held conceptions about the abilities and usefulness of adult stem cells. However, there appear to be characteristics—in particular, that they appear to have more limited life spans, are presently more difficult to isolate in useful quantities, and may not be able to form all cell types—that may limit

the potential of adult stem cell research. However, it does appear that adult stem cells may be able to be manipulated on a scale previously thought impossible. Moreover, the apparent differentiation limitations placed on adult stem cells may indeed pose an advantage over embryonic stem cells.

Nonetheless, it appears clear that research using adult stem cells does not hold the same potential for medical advances as does the use of the more versatile embryonic stem cells. But, as in all research endeavors, what we are considering is the potential for advancements. Scientifically, we will see the best advances in both adult and embryonic research by allowing the two to proceed along parallel tracks, fostering valuable collaboration and interplay between researchers on each side.

Some of my colleagues have advocated that the guidelines promulgated by the National Institutes of Health provide a sufficient framework to ensure that embryonic stem cell research can be conducted ethically. I strongly disagree. On the contrary, I find the NIH guidelines lacking in appropriate safeguards.

Therefore, Federal funding for stem cell research should be contingent on the implementation of a strict new set of safeguards and public accountability governing this new, evolving research. The following 10 points are essential components of a comprehensive framework that allows stem cell research to progress in a manner respectful of the moral significance of human embryos and the potential of stem cell research to improve health.

One, require a rigorous informed consent process: To ensure that blastocysts used for stem cell research are only those that would otherwise be discarded, require a comprehensive informed consent process establishing a clear separation between potential donors' primary decision to donate blastocysts for adoption or to discard blastocysts and their subsequent option to donate blastocysts for research purposes. Such a process, modeled in part on well-established and broadly accepted organ and tissue donation practices, will ensure that donors are fully informed of all of their options.

As with organ and tissue donation, we must first ensure that health care providers make no mention of the option to donate excess embryos until completion of infertility treatment and the decision has been made independently by both members of a couple to discard embryos remaining in frozen storage at the clinic. Once that decision has been made, the destiny of the embryos is certain. When couples make this decision and authorize a clinic to discard the embryos, it is clear that the embryos will be dead within a short time frame. Only after both members of a couple have made a firm decision to discard these additional embryos should health care providers or researchers be allowed to approach them

about the opportunity to donate these embryos for use in research.

Moreover, the NIH regulations should strengthen the informed consent process by requiring stronger informed consent. And regulations should ensure greater oversight and accountability in the derivation process by requiring site visits of labs where cell lines are derived and prospective approval of line derivations.

Two, ban embryo creation for research: The creation of human embryos solely for research purposes should be strictly prohibited.

Last week, researchers announced the creation of three ES cell lines derived from embryos created for the express purpose of research. Limiting federal funding to research using embryos left over after being created for reproductive purposes will not prevent the creation of embryos only for research purposes by unethical researchers. Such an action has been nearly universally decried from all quarters. Therefore, we should include a comprehensive ban on the creation of embryos through IVF for the sole intent of performing research.

Three, continue funding ban on derivation: Strengthen and codify the current ban on federal funding for the derivation of embryonic stem cells.

While we find it important to scientific research and ethically acceptable that limited and strictly regulated ES research proceed, this does not mean that federal funds should be used in the derivation of ES cells. Rather, a continued ban on federal funding for the derivation of ES cells is a right and proper indication and acknowledgment that the American people are conflicted on the ethical and moral propriety of this issue and do not feel that the proper use of federal funds is in the derivation process.

Four, ban human cloning: Prohibit all human cloning to prevent the creation and exploitation of life for research purposes.

Ban all uses of human cloning. Most are agreed in their opposition to reproductive cloning. It is important, however, to also ban non-reproductive or research cloning both for the practical, implementation reason of making it more likely that such a ban on reproductive cloning will be successful as well as for the broader moral reasons shared by the majority of the American people that human embryos should not be created for the purpose of research and exploitation.

Five, increase adult stem cell research funding: Increase federal funding for research on adult stem cells to ensure the pursuit of all promising areas of stem cell research.

Although not presently as scientifically promising as ES research, AS research has seen many advancements in recent years and holds important potential for treating disease and injury. Many scientists have noted that not enough science has been completed to determine which of the two lines of in-

quiry will produce therapeutic applications and that it is therefore scientifically premature to limit research to one type of research only. Accordingly, in funding ES research, it is important to see that this is done in a manner complementing ongoing AS research so that both lines of inquiry are pursued aggressively and that neither is pursued to the scientific detriment of the other.

Six, provide funding for embryonic stem cell research only from blastocysts that would otherwise be discarded: Allow Federal funding for research using only those embryonic stem cells derived from blastocysts that are left over after in vitro fertilization (IVF) and would otherwise be discarded.

Specifically, the regulations should allow the use only of embryos that were created but unused for infertility treatment. These may only be donated from IVF clinics following completion of infertility treatment. Regulations should also include safeguards to prevent unethical creation of embryos in excess of clinical need.

Seven, limit number of stem cell lines: Restrict federally funded research using embryonic stem cells derived from blastocysts to a limited number of cell lines. In addition, authorize Federal funding for stem cell research for five years to assure ongoing Congressional oversight.

Limiting the number of cell lines would allow Federal funding to jumpstart the research into the basic properties of ES cells for more in-depth discovery of the capabilities, shortfalls, and properties of these cells, while respecting the ethical sensitivity of the research to the American people. Moreover, numerous researchers have expressed concern that, because existing embryonic stem cell lines would not be in accord with the present guidelines and regulations laid down by NIH, additional cell lines will have to be created. By limiting the creation of cell lines, the research will go forward, but under strong restrictions.

Eight, establish a strong public research oversight system: Establish appropriate public oversight mechanisms, including a national research registry, to ensure the transparent, in-depth monitoring of federally funded and federally regulated stem cell research and to promote ethical, high quality research standards.

A national research registry would serve as a holding and distribution facility that would provide another level of Federal oversight and control in the process. The registry would also be able to serve an important role of tracking the progress of this research as well as providing a strong oversight mechanism to track the research and its attention to public regulations.

Nine, require ongoing, independent scientific and ethical review: Establish an ongoing scientific review of stem cell research by the Institute of Medicine (IOM) and create an independent

Presidential advisory panel to monitor evolving bioethical issues in the area of stem cell research. In addition, require the Secretary of Health and Human Services to report to Congress annually on the status of Federal grants for stem cell research, the number of stem cell lines created, the results of stem cell research, the number of grant applications received and awarded, and the amount of Federal funding provided.

Stem cell research is so significant both ethically and scientifically, that continued Congressional oversight is important. All of this research should be the subject of ongoing scientific and ethical review.

Ten, harmonize restrictions on fetal tissue research: Because stem cell research would be subject to new, stringent Federal requirements, ensure that informed consent and oversight regulations applicable to federally funded fetal tissue research are consistent with these new rules.

These principles provide for an appropriate amount of research using human embryonic stem cells but ensure that such research is not conducted to the detriment of research utilizing adult stem cells. They balance the desire to move this research forward on a greater scale with the imperative to maintain the highest level of oversight to prevent abuses and the importance of continuing Federal oversight as this research advances.

These 10 principles help answer the question I posed earlier: "Is there a line that should not be crossed even for scientific or other gain?" The clear response is "Yes." It is clear to me that the creation of human embryos for research purposes should not be undertaken, regardless of the potential for scientific gain. It is clear to me that the use of human cloning should be strictly prohibited to prevent the commoditization and exploitation of human life. It is clear that the present restriction on the use of Federal funds for the derivation should be maintained and strengthened to reflect the concerns of the American people.

I know that many people with deeply held views on this issue will disagree with some portion of the position I have outlined today. Others may attempt to divorce certain of these issues from consideration of the others.

This should not be done. The fact is that these issues—of stem cell research, the creation of embryos, human cloning, public restrictions on the scope of research broadly are all pieces of a larger whole.

By pursuing the policy framework I have laid out today, we can help set the stage for groundbreaking research with the potential to help untold millions of Americans and individuals worldwide. We will have laid a firm foundation for that research to succeed—a foundation without which the goal of seeing treatments through embryonic stem cell research will falter on the fears and uncertainties of Amer-

icans. This framework provides that firm ethical foundation instilling confidence in comprehensive and transparent oversight ensuring that such research is conducted with close attention to the difficult ethical and moral issues involved.

We must define the role of the Federal Government in harnessing this technology for good. Our task as citizens is to exercise responsible stewardship of the precious gift of life. This effort represents a first step in this process.

Mr. President, I look forward to continued participation in this dialog on embryonic and adult stem cell research.

The PRESIDING OFFICER. The Senator from Texas.

Mrs. HUTCHISON. Mr. President, I ask the Senator from Tennessee if he needs further time to finish his statement. His statement was very thoughtful, and this is a crucial issue facing our country. If he would require added time, I would be happy to yield.

Mr. FRIST. Mr. President, I appreciate the offer of the Senator from Texas. I believe my statement will complete my thoughts. I do look forward to continued participation of all of us. She and I were both in a hearing a few minutes ago talking about this very issue.

Mrs. HUTCHISON. Mr. President, I appreciate very much what Senator FRIST, who is the only physician in the Senate, is contributing to the issue of stem cell use for research purposes. We have just spent several hours in a hearing learning from scientists and many others about the differing viewpoints on the need for the use of stem cells for research into many diseases where it is hoped we can find an answer through the use of these embryonic stem cells. The debate is valid.

Senator FRIST has pointed out some of the legitimate ethical questions. I hope we can move forward in a way that does increase the ability to use these types of stem cells and cord blood for looking into the causes and, more importantly, even the treatment of some of the cancers and diseases, such as Alzheimer's, Parkinson's disease, multiple myeloma, many forms of cancer where there is great hope that we might have treatment that would allow people to live healthy lives, normal lives, with this kind of treatment, even though they have these diseases.

I thank the Senator from Tennessee for his thoughtful contribution to this debate.

#### ENERGY AND WATER DEVELOPMENT APPROPRIATIONS ACT, 2002—Continued

Mrs. HUTCHISON. Mr. President, I rise to talk about the Nation's lack of an energy policy. Many have spoken earlier today about the fact that we have not taken up an energy policy for our country. It doesn't seem to be a priority for the Senate.

I disagree with that. I think it is the highest priority for the Senate, and I urge the majority to let us debate an energy policy. It is time that we have a long-term strategy. We know from what is happening in California right now, where the energy shortage has hit very hard the people of California and the economy of California, that we can't wait and try to do something quickly because quickly doesn't work when you are dealing with something that is so long range.

For instance, one of California's big problems is they don't have a distribution system. They have a shortage. Even if they could get the energy into their State, they don't have an adequate distribution system.

President Bush has put forward an energy policy that would address long term some of these issues. As our economy is growing, they are going to become even more acute.

The Congress also has put forward a plan. Senator MURKOWSKI has been a leader in this effort, as past chairman of the Energy Committee. We need to be able to debate these issues and see where our country is going.

The interesting thing is, our country is going to increase its oil consumption by 33 percent in the next 10 years. It is expected that our foreign oil imports will go from 55 percent to 67 percent by the year 2020.

Natural gas consumption will increase by 50 percent. Demand for electricity will rise 45 percent in the next 20 years. We cannot sit on antiquated, unreliable, and inadequate distribution systems if we are going to be able to keep our economy strong, to keep the businesses going, to keep the jobs in America, and so consumers have good and adequate sources of energy. We must address this policy.

I call on the majority to make this a priority. Yes, appropriations bills are important, but that does not address the long-term needs of our country.

What would a good energy policy entail? It would entail modernization and expansion of our energy infrastructure. That is the distribution system. We need more pipelines. We need more powerplants. We need to be able to get the electricity into the homes and businesses of our country.

We must have diversification of our energy supplies. I have been trying for 3 years, with support across the aisle, very bipartisan, for tax credits for small drillers, people who drill 15-barrel-a-day wells. When prices go below \$18 a barrel, those people cannot stay in business. Yet all of those little bitty producers together can produce 500,000 barrels of oil a day, the same amount we import from Saudi Arabia. But they can't stay in business when prices fall to \$18, \$17, \$16 a barrel. We had \$9-a-barrel oil just 2 and 3 years ago, and those people went out of business. They kept their wells, and they will never be able to reopen their wells because they are too small. The margins are too thin.