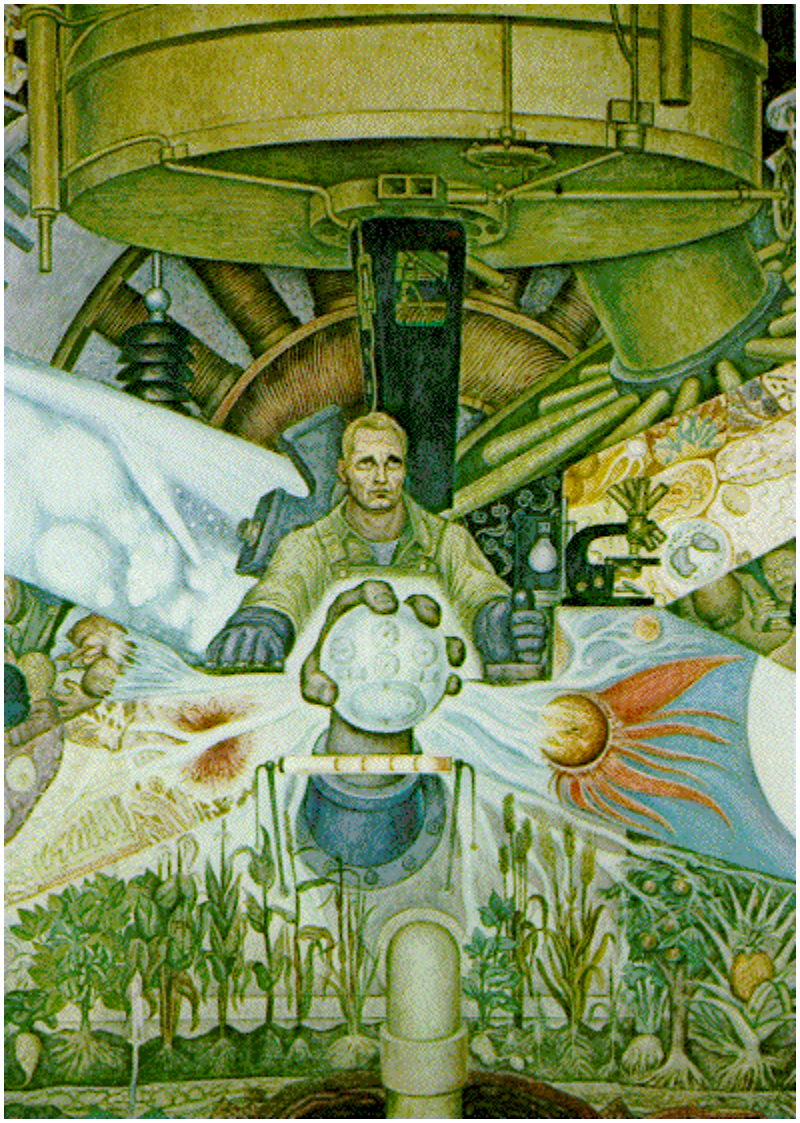
Human Embryonic Stem Cell Research



Thinking Points, Vol. 1, No. 5

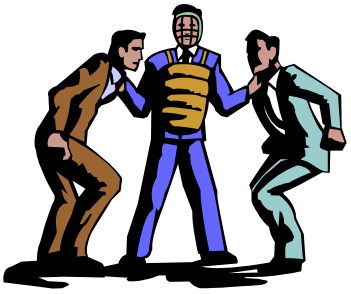
Prepared by the Republican House Policy Committee
United States Representative Thaddeus G. McCotter, Chair
110th Congress

Overture

So let's leave it alone
'Cause we can't see eye-to-eye
There ain't no good guy
There ain't no bad guy
There's only you and me
And we just disagree….

"We Just Disagree"
Dave Mason

Introduction



Human embryonic stem cell research is an issue of an age where the boundaries of science and their concomitant ethical questions are expanding in nanoseconds, and every American is being compelled to examine these developments in accordance with the dictates of their conscience. As every individual is unique, their determinations will vary. Thus, because our political party is comprised of citizens representative of the broader American public, when applying our shared convictions Republicans sometimes differ over the ethical rectitude of a new scientific development. So it is with human embryonic stem cell research. To pretend otherwise would silence an internal ethical and political debate, and violate members' inalienable right to freedom of conscience. Such an insistence on doctrinal conformity is anathema to our Republican Party. Therefore, human embryonic stem cell research is not and will not be (as some hope) an instance of ideological division or political disunity; it is an example of how a principled Republican Party possesses the moral and political vitality to respectfully disagree, debate, decide and, united, move forward. Consequently, this section will attempt to fairly present the differing Republican perspectives - and their common ground - on the issue of human embryonic stem cell research.

The sovereign American people deserve no less.

The Republican Consensus

America's Challenge

In 2006, the 109th Congress passed legislation permitting federal funding for research involving human embryos donated from infertility clinics. President Bush vetoed this legislation, and his action was sustained. Now, the new the 110th Congress will again be voting on a legislative initiative to provide federal funding for embryonic stem-cell research.

If enacted into law, such legislation would constitute an unprecedented authorization for tax dollars to be spent for the destruction of living human embryos. Nevertheless, those in favor of the legislation argue the authorization is ethically acceptable, since it "only" permits research on embryos "leftover" from in vitro fertility treatments. Since these embryos are allegedly doomed to die anyway, they are said to be eligible for destructive research. Applying this logic then, we could offer no principled argument in opposition to allegations of organ harvesting from political prisoners sentenced to death in communist China or elsewhere. True, no one would argue a human embryo of five days possesses the same capacity to experience pain as a human adult of fifty years. Still, the problem with this approach is how it distinguishes between human beings based on

arbitrary factors divorced from the reality of their inherent humanness. As Dr. Nigel Cameron, founder of the journal *Ethics and Medicine,* testified, "Our membership in the human species is enough to distinguish the human embryo from all other laboratory artifacts."

Alexander Pruss, Assistant Professor of Philosophy at Georgetown University, argues for the continuity of human life from conception to adulthood. We may categorize a human being as a blastocyst, embryo, fetus, infant, toddler, and child, yet there is no point at which these are names for anything other than a human being. Pruss refers to this continuum as an "essential property" of being human, as is human dignity, which Pruss defines as "a property of me which makes it wrong for another human being to set out to kill me when I am juridically innocent." Human dignity is not reserved for adult human beings. As Pruss writes, "if human dignity understood in this way is an essential property and I have it, then the fetus that I was also had it – otherwise it wouldn't be an essential property." Certainly, the same argument can be made on behalf of the embryo or blastocycst.

Yet rather than making this argument, proponents of the embryonic stem cell research bill claim it offers "real hope" for those suffering from debilitating diseases. This hope has so far proven illusory. Despite 25 years of animal research on embryonic stem cells, the dramatic predictions made by its proponents have not been realized. For example, in a recent study funded by the National Institutes of Health, fetal cells transplanted into the brains of Parkinson's patients did not result in measurable improvement of the patients'

symptoms. Instead, according to the Mt. Sinai School of Medicine, "in more than 50% of the patients the procedure has the side effect of producing potentially disabling involuntary movements…and in some instances was so severe as to necessitate an additional surgery."

Additionally, research using human embryonic stem cells has been plagued by problems relating to tissue rejection, and the tendency for tumor formation. This should be contrasted with the results of adult and cord blood stem cell research where there are currently treatments for seventy-two diseases that have shown a benefit for human patients. It should be added, none of these treatments have required the destruction of human embryos.

Again, ethical considerations must be weighed in light of the advances being made using adult stem cells, including those derived from cord blood. These advances are substantiated by peer review studies confirming improvement in many types of cancers, cerebral palsy, sickle cell anemia, paralyzing injuries, autoimmune diseases, metabolic disorders, neural degenerative diseases, and heart damage. The real treatments offered by adult and cord blood stem cell therapies were the impetus for two bills we cosponsored last year that will establish a national cord blood stem cell network and bank. The cord blood collected and stored through the network will be used for therapy as well as for research.

Moreover, a recent study published in the January 7, 2007 online edition of *Nature Biotechnology* found that amniotic fluid contains cells that can be cloned to produce stem cells that behave much like embryonic stem cells. Researchers tested the amniotic fluid-derived stem cells and found that they are "broad-spectrum multipotent (that is, pluripotent) stem cells." Anthony Atala, director of the Institute for Regenerative Medicine at Wake Forest University School of Medicine in Winston-Salem, N.C. notes that, contrary to embryonic stem cells, however, amniotic stem cells "remain stable for years without forming tumors."

Additionally, there are innovative technologies by which we may obtain pluripotent stem cells – cells that are able to differentiate into any type of human cell. These cells would have the potential advantages of embryonic stem cells, but without destroying human beings in the process of obtaining them. Early research shows that pluripotent cells derived from alternate sources do not have the negative side effects associated with human embryonic stem cells. Also, recent studies have shown that several of the alternate sources of pluripotent cells discussed by the President's Council on Bioethics demonstrate tremendous potential for research. A set of companion bills introduced during the 109th Congress by Roscoe Bartlett in the House and Rick Santorum and Arlen Specter in the Senate would have promoted the derivation of pluripotent stem cell lines from alternative sources that do not require the destruction of human embryos. As Dr. Hadley Arkes, Edward N. Ney Professor of Jurisprudence and American Institutions, posits, "Given a choice between a therapy that happens to be lethal for human subjects and one that is not, wouldn't we be inclined to favor the therapy that is not lethal?"

Still, some have maintained a singular focus on stem cell research that entails the destruction of human embryos. This has, unfortunately, all too often involved claims that using IVF embryos will guarantee much-awaited cures for virtually every debilitating condition known to man. If we could just access this allegedly vast, untapped resource, we could drink from the fountain of youth itself. This of course raises the question: exactly how large is the fountain? In other words, are there enough embryos in suspended animation to satisfy our research needs and, if not, where will the next crop of human subjects come from?

A joint study by the Society for Assisted Reproductive Technology (SART) and the RAND Corporation found that of the roughly 400,000 human embryos currently in frozen storage, only 2.8 percent have been designated for research. The remainder is being held for future family building. Even with the 11,000 embryos that would be available for research, the SART/RAND study maintained that "the actual number of embryos that might be converted into stem cell lines is likely to be substantially lower." In-vitro fertility treatments use the highest quality embryos for implantation and those which are "leftover" may not be suitable for research. The SART/RAND study estimated that only about 65 percent of the 11,000 embryos would survive the thawing process and of those, only 25 percent would survive to the 5-day blastocyst stage necessary to derive embryonic stem cells. Since each embryonic stem cell line requires somewhere from 18 to 40 blastocysts, even if all the embryos designated for research in the United States

were to be used to derive embryonic stem cells, at most, 275 new stem cell lines could be created. The actual number of new lines would likely be much smaller.

Nevertheless, even if embryonic stem cell research should someday prove effective in some cases, the destruction of one class of human beings (distinguished in this case by size and location) for the benefit of another class of human beings raises the most telling ethical considerations. We must never fall prey to the ethical failures exemplified by the Tuskegee experiments where nearly 400 subjects, most of them poor black sharecroppers, were left to die from the ravages of syphilis – under the pretense of free medical care, and supposedly for the advancement of medical science. It is crucial for us as a nation to stand firm for an ethos that the protection of innocent human life should be protected as an end in itself. As Dr. Arkes notes, "there [are] moral constraints that properly [limit] the passion of science 'to know'."

The dictates of conscience require we Americans – *we human beings* – secure the moral constraints on unethical science; and ensure our country and humanity is never ushered into Aldous Huxley's brave new world.

Republican Principles

- Americans are endowed with the inalienable right to life, liberty, and the pursuit of happiness.

- Because it intrinsically involves the destruction of innocent human life, human embryonic stem cell research is inherently unethical.

- As the fiduciary custodian of the public's tax dollars, the federal government must not use taxpayers' money to fund unethical research. Instead, the federal government should facilitate and fund only ethical research to help alleviate human suffering.

- The federal government must concentrate public funding on those areas where ethical private research demonstrates the greatest advances, in order to speed the alleviation of human suffering.

Republican Policies

Ever mindful this complex issue is often inaccurately depicted in the court of public opinion, Republicans must emphasize we do not oppose all stem cell research; but we (and some Democrats, as well) do oppose federally funding inherently unethical human embryonic stem cell research, where currently no federal restrictions exist. We must also emphasize we do support federal funding of research into adult stem cells and other alternatives – where the greatest advances are being demonstrated – in order to alleviate human suffering. This position is both eminently principled *and practical*: it focuses federal funding on those stem cell research areas demonstrating the greatest promise; encourages the ethical development of alternative methods of deriving embryo-like stem cells; and, thus, hastens the advance and increases the ability of medical science to alleviate human suffering.

Advancing American Exceptionalism

Supporters of human embryonic stem cell research fear the United States will "fall behind" if we do not fund research that destroys human subjects. This argument is not well founded. As a consequence of an alliance of European leftists, Greens and women's groups, the regulatory restrictions in much of Europe are tighter than those in the United States. In 1991, for example, Germany enacted the Embryo Protection Act, which prohibits the fertilization of eggs "which are not intended for implantation within one cycle." This law clearly prohibits even the incidental creation of human embryos to be consumed for research purposes.

In an article published in the July 1, 2006 volume of the *German Law Journal*, Professor of Public Law at the University of Goettingen Christian Starck notes that "the freedom of scientific research is not unlimited. Scientific research is obliged to respect human dignity and life, physical integrity and freedom of the person." Starck concludes, "Not even the highest-ranking objectives of medical research (developing therapies for grave illnesses, prolonging human lives) can justify the consumption of human life." This is consistent with the Kantian notion that human beings are not to be viewed as mere objects or means to an end – a concept reflected in European Human Rights law, which contains explicit protections for the human embryo and the integrity of human life.

The May/June 2005 issue of *Foreign Policy* points out how, "Europe still trains large numbers of highly skilled scientists, yet thousands come to the United States every year to seek advanced study or employment, and more than 70 percent never return." It must also be kept in mind the legislation before the Congress only relates to federal subsidies for embryonic stem cell research and does not affect private financing where the United States has a considerable advantage over its trading partners.

True scientific progress entails evaluating not only what we can do, but also what we should do. In this regard, public policy should reflect support for research that has demonstrated empirical effectiveness as well as respect for the weak and defenseless among us.

All of us have a stake in the therapies promised by stem cell researchers. We are advocates of such research – so long as it does not destroy human lives in the process. History is replete with examples of the horrors that befall societies which make human rights contingent on arbitrary factors such as race, gender, or beliefs. Let us not add size or location to the list of superficial criteria for fundamental human rights lest, one cruel tomorrow, we find we have lost all of our rights as a free and ethical people.

Contributing Republican House Policy Committee Members

Hon. Michael Burgess (TX)

Hon. Dan Lungren (CA)

Hon. Thaddeus McCotter (MI)

Hon. Dave Weldon (FL)

Another Republican Perspective

America's Challenge

One of the most promising areas of medical research according to the world's leading scientists and Nobel Laureates is that of embryonic stem cell research. Embryonic stem cells are considered the "master cells" of our bodies and eventually develop into the 200 different stem cells, which govern how our body works and grows. There is consensus in the scientific community that such cells could be used in regenerative medicine -- to replace failed insulin producing or dopamine producing cells for diabetic patients or Parkinson's' patients, for example, or to repair damaged cells for patients with heart disease. It is also believed that these cells can be used as testing models for drug development as well as answer some of our most basic questions about how diseases and tumors form and grow.

Embryonic stem cells were first discovered in 1998 by Dr. Jamie Thompson at the University of Wisconsin. Embryonic stem cells come from the inner cell mass of 5 to 8 day old blastocysts, or embryos no bigger than the tip of a pencil, which are created for the purposes of in vitro fertilization, but will never be implanted in a woman. These embryos would otherwise be discarded as medical waste. Because the process whereby the parents create the embryo can be tedious and uncomfortable for the woman, the

fertility specialist tries to make as many embryos as possible at a single time. Then through the natural selection process to implant the "best" embryos, some are discarded immediately and others are frozen for future use. After the couple is finished with their family building, they make the decision about whether to discard the embryos as medical waste, to give those embryos to another family (known as embryo adoption and rarely done), or to keep them frozen. If the couple decides to discard the embryos as medical waste, at that point they could be donated to research. The researchers extract the inner stem cells and grow these cells into colonies or stem cell lines, with which they can conduct experiments. A recent study by the American Society of Reproductive Medicine accounts for over 400,000 frozen embryos stored in fertility clinics around the U.S.

As President Bill Clinton was finishing his Presidency, his Administration began to address whether or not the federal government would fund such research as part of the $28 billion National Institutes of Health portfolio. However, before any decision was made, President George W. Bush took office and in August, 2001, he made the landmark decision to allow federally-funded research to move forward on stem cell lines created prior to that date. At that time, there were thought to be 60 such stem cell lines available, the number grew to 78, and now five years later, only 22 lines are available for research. Unfortunately, all of these lines have been compromised with mouse feeder cells, meaning they can never be used in clinical applications. Since that time, there is thought to be over 150 new lines developed worldwide, some of which are disease specific lines. Yet none of these new lines qualify for federally funded research, because current federal

policy on human embryonic stem cell research allows federally funded research to be conducted only on those stem cells derived before August 9, 2001.

In the 109th Congress, the United States Congress passed H.R. 810, The Stem Cell Research Enhancement Act, which lifted the August 9, 2001 date restriction; allowed federally funded scientists to research a greater number of stem cell lines; and, on those stem cell lines eligible for funding, provided strong ethical guidelines, including donor consent and certification embryos donated are in excess of clinical need and would be otherwise discarded. In the end, the President vetoed this legislation, and Congress could not muster the two-thirds votes in the House and Senate needed to override this veto.

Republican Principles

- Embryonic stem cell research holds enormous promise for easing human suffering, and federal support is critical to its success.

- As with all scientific endeavors, the limitless bounds of science do not infringe on the beliefs that we hold as ethical human beings.

- America must remain the world leader in advancing the boundaries to medical science to enhance human life.

Republican Policies

Congress must pass and the President must enact into law legislation modeled on H.R. 810, the Stem Cell Research Enhancement Act of 2005. Again, this legislation expands the number of stem cell lines eligible for federally funded research, thereby accelerating scientific progress toward cures and treatments for a wide range of diseases and debilitating health conditions. Specifically, the bill allows federal funds to be expended for human embryonic stem cell research on those stem cell lines derived after August 9, 2001. The bill also enables parents to make a choice between keeping their embryos frozen; donating them to research; providing them to another couple for adoption (snowflake baby program); or discarding them as medical waste. Finally, the bill contains strong ethical safeguards. The Secretary of Health and Human Services ("The Secretary") must conduct and support research on stem cells derived from embryos to see if the following requirements are met: embryos used to derive stem cells were originally created for fertility treatment purposes and are in excess of clinical need; individuals seeking fertility treatments for whom the embryos were created have determined the embryos will not be implanted in a woman and will otherwise be discarded; and the individuals for whom the embryos were created have provided written consent for embryo donation. Moreover, the Secretary, in consultation with the Director of the National Institutes of Health ("NIH") must issue guidelines within 60 days after the legislation's enactment into law. These guidelines shall ensure federally funded researchers adhere to ethical considerations. Finally, the Secretary shall annually report to Congress about NIH stem cell research.

In addition, Congress must not terminate but must continue to fund human embryonic stem cell research on those stem cell lines derived prior to August 9, 2001. Medical researchers believe embryonic stem cell research has the potential to change the face of human disease. A number of current treatments already exist, although the majority of them are not commonly used because they tend to be experimental and not very cost-effective. Medical researchers anticipate being able to use technologies derived from stem cell research to treat cancer, Parkinson's disease, spinal cord injuries, and muscle damage, amongst a number of other diseases, impairments and conditions. Therefore, federal research funding for all stem cell research must be permitted and enhanced.

As stem cell research continues and expands, Congress must be ever vigilant for instances where additional ethical safeguards are required; and must continue to categorically oppose the harvesting of embryos for scientific research as well as any attempt to use our scientific knowledge to clone human beings. As with all scientific endeavors, the limitless bounds of science must not infringe on the beliefs we hold as ethical human beings.

Given numerous instances of state involvement in the issue of stem cell research, and the ethical stakes involved, Congress must implement a uniform federal standard to avoid the creation of a patchwork approach to research. Such a segmented approach without publishing requirements prevents all scientists from participating in stem cell research. As a consequence, this segmented approach will not advance science, but will hinder it.

Advancing American Exceptionalism

TIME Magazine published a feature story on the growing biotechnology business in Singapore, where there is a 2 million square foot facility, known as the Biopolis, which focuses solely on stem cell research. "It's impossible to witness the buzz at Biopolis or meet scientists who have chosen Southeast Asia over Stanford and not wonder how much the U.S. could achieve if it were as science mad as this city-state of 4.4 million," reads one line in the story.

This situation greatly concerns us. The world needs the muscle of the NIH to coordinate this research. But because of the lack of federal investment in this research, it is quite likely the United States will only continue to fall behind other countries moving forward with this embryonic stem cell research, such as Great Britain, Singapore and Israel. Clearly, embryos created as a by-product of in vitro fertilization, which would otherwise be destroyed, should be allowed to provide greater insight into the myriad afflictions which can potentially be alleviated through stem cell research –

And allow America to remain the world leader in advancing the boundaries to medical science to enhance human life.

Contributing Republican House Policy Committee Members

Hon. Ginny Brown-Waite (FL)

Hon. Jon Porter (NV)

Republican Common Ground

America's Challenge

The very words, "Regenerative medicine," speak to the great hope among patients and healers and patients of realizing the day when some of the most tragic human afflictions are relieved. These words, too, constitute a powerful lure to participants on both sides of the human embryonic stem cell debate.

Thus, the question: Do the differing sides share any common ground from which to mutually pursue stem cell research; advance medical science; and alleviate human suffering?

Yes.

For almost a decade, clinicians have practiced "pre-implantation" genetics, where a single cell is taken from an early gestation without causing harm to the donor embryo. The single cell is then used for genetic studies. This same procedure could be used to create new ESC lines in a manner morally and ethically acceptable to all Americans.

In the 109th Congress, federal funding for this approach was proposed by Representative Roscoe Bartlett in his H.R. 5526, "The Alternative Pluripotent Stem Cell Therapies Enhancement Act." Congress should again consider such an approach - especially given the recent discovery of pleuripotent epithelial cells in ammonic fluid, which readily demonstrates how quickly the world has changed since Congress last debated this issue less than a year ago. In fact, on January 8, 2007, the Washington Post reported researchers at the Institute for Regenerative Medicine at Wake Forest University's School of Medicine discovered pleuripotent epithelial cells can adapt and form other types of tissues, such as brain, muscle, and skeletal cells, and can remain stable for years without forming tumors. This innovative, developing regenerative medical technology provides common ground, because it respects everyone's dictates of conscience.

As we have repeatedly seen throughout human history, too often technology surpasses morality; and technology almost always surpasses legislative proceedings. Consequently, in seeking and sharing our common ground on the issue of human embryonic stem cell research, we should accept and honor the Inaugural invitation of President John F. Kennedy: "Let both sides seek to invoke the wonders of science, instead of its terrors."

Republican Principles

- Americans are endowed with the inalienable right to life, liberty, and the pursuit of happiness.

- As the fiduciary custodian of the public's tax dollars, the federal government must not use taxpayers' money to fund unethical research. Instead, the federal government should facilitate and fund only ethical research to help alleviate human suffering.

- As with all scientific endeavors, the limitless bounds of science do not infringe on the beliefs that we hold as ethical human beings.

- The federal government must concentrate public funding on those areas where ethical private research demonstrates the greatest advances, in order to speed the alleviation of human suffering.

America must remain the world leader in advancing the boundaries of medical science to enhance human life.

Republican Policies

Congress should continue to support mutually agreed upon stem cell research legislation, such as the bill introduced in the 109th Congress by Representative Roscoe Bartlett. His "Alternative Pluripotent Stem Cell Therapies Enhancement Act" (H.R. 5526) would have funded efforts to derive and study cells which have the capabilities of embryonic stem cells, but are not obtained from a human embryo (e.g., reprogrammed adult stem cells); and would have allowed appropriations for animal trials on new techniques for extracting stem cells. Further, the bill would have required the Secretary of Health and Human Services ("the Secretary") to provide guidance concerning the next steps required for additional research; prioritize research with the greatest potential for near-term clinical benefit; and take into account techniques outlined by the President's Council on Bioethics and any other appropriate techniques and research. Finally, the legislation included ethical protections to prevent funding to any techniques which would harm or destroy human embryos. The phrase "human embryo or embryos" is defined as "any human organism that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes." Examples of stem cell research permitted funding under the bill included: dedifferentiation, in which effort recent studies have shown promise in converting adult tissue cells back into a more flexible state; and pleuripotent Adult (Non-embryonic) Stem Cells, in which more adult and cord blood stem cells have demonstrated the same flexibility as embryonic stem cells.

Advancing American Exceptionalism

As is clearly evinced above, while the issue of human embryonic stem cell research is fraught with strong passions and sharp disagreements, this need not always be the case. Common ground can be attained, when principled people agree the goals of curing disease, promoting scientific knowledge, and respecting human life are not mutually exclusive.

Indeed, nowhere is this quest for and the achievement of such common ground more fruitfully pursued than within the American political system. When combined, our God-given, constitutionally recognized liberty and our equality before the law foster a desire to express the dictates of our consciences; a respect of our fellow citizens' views; and a yearning to find equitable consensus amongst ourselves. Such is the strength of our revolutionary republic: We, the people, in expressing our views on such a difficult and often divisive issue, can ensure America remains both the world leader in ethical medical research; and the world leader in democracy.

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