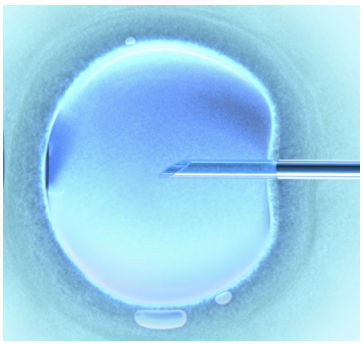

Stem Cells and Biomedical Research in Texas

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Stem Cells and Biomedical Research in Texas

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Online version of this report is available on the Baker Institute website at
www.bakerinstitute.org/publications/texasstemcellreport.

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EXECUTIVE SUMMARY

The Science of Stem Cells and their Uses

- Stem cells are unspecialized cells that have the ability to replicate and become different cell types.
- There are several different types of stem cells: embryonic stem cells (derived from five- to six-day-old embryos); adult stem cells (found in most of the major organs in the body); cord blood stem cells (found in umbilical cord blood and the placenta); and induced pluripotent stem cells (created when adult cells, like skin cells, are manipulated to return to a stem cell–like state by activating specific genes).
- Stem cells have the potential to cure many different types of diseases and disorders, such as Parkinson's disease, diabetes, and multiple sclerosis.
- Scientists believe that no one type of stem cell will be the cure-all and that multiple types of stem cells will be needed for research.

U.S. Federal Stem Cell Policy

- The Dickey-Wicker Amendment is an appropriations rider attached each year to the bill passed by Congress to fund the U.S. Department of Health and Human Services (DHHS). This rider bans federal funding for creating or destroying human embryos for research.
- From 2001 to 2009, President George W. Bush allowed federal funding for human embryonic stem cell research using 21 stem cell lines created before August 2001.
- In 2009, President Barack Obama rescinded Bush's policy and removed the cutoff date, allowing funding of research on stem cell lines created after 2001.
- In 2009, the National Institutes of Health (NIH) developed guidelines permitting funding of research on embryonic stem cell lines that are generated from embryos created for reproductive purposes using nonfederal funds and donated freely with proper informed consent.
- Federal funding is not allowed for the creation of human embryonic stem cell lines or research on human embryonic stem cell lines from sources other than embryos no longer needed for *in vitro* fertilization (IVF).
- The NIH guidelines are currently being challenged in court, in the case *Sherley v. Sebelius*, to determine if they conflict with the Dickey-Wicker Amendment. If the legal challenge is successful, it would halt funding for all NIH human embryonic stem cell research including research approved during the Bush administration.

State Stem Cell Policies

- States have different policies and views of human embryonic stem cells. California and Maryland, for example, appropriate state funds to conduct embryonic stem cell research. Others, such as Massachusetts, have permissive policies but do not fund research. A few, including South Dakota, ban embryonic stem cell research. Texas is one of many states that has no specific policy.

Texas Stem Cell Politics and Policies

- Numerous bills have been proposed in the Texas state legislature regarding human embryonic stem cell research but none have passed.

Biomedical Research and Biotechnology Industry in Texas

- The biotechnology industry in Texas employs more than 100,000 people with an economic impact of approximately $75 billion.
- Texas has several programs for promoting research and business development including the Texas Enterprise Fund ($93.1 million used for biotechnology projects), the Texas Emerging Technology Fund ($171 million used for biotechnology projects), and the Cancer Prevention and Research Institute of Texas ($3 billion used for cancer research).
- In 2010, Texas ranked fourth in the nation for total research and development funding ($17.9 billion) and fifth in the nation in funding from NIH ($1.1 billion). In 2007, it was estimated that for every $1 of NIH funding, Texas generated $2.49 in economic activity, the highest return in the nation.
- Overall, it has been projected that the number of patients treated with stem cell therapies will rise from 20,000 in 2007 to 9.4 million in 2020.
- Revenues from stem cell products are predicted to increase from $12.6 million in 2007 to $16.3 billion in 2020.

Stem Cells and Texas

- Creating policies that will inhibit areas of biomedical and biotechnological development could negatively impact all the work done to promote new business within the state, as well as Texas as a hub for biomedical research.

INTRODUCTION

Stem cells and regenerative medicine are exciting and emerging fields of biomedical research. Many applications for stem cells have been proposed to help cure or treat conditions such as diabetes, blindness, and heart disease. The impact of these treatments could be revolutionary for medicine and biotechnology. But more research still needs to be done to utilize these cells for therapies.

There are also external factors that limit or stall research. Ethical issues surrounding human embryonic stem cells, policy issues determining science funding and regulation, and economic pressures all play a role in federal and state decisions to either prohibit or support types of stem cell research. Determining the best policy for Texas requires thoughtful analysis of these issues and consideration of how other states have addressed these issues and the impacts their decisions have had.

The goal of this report is to provide an overview of stem cell biology, government policies, and economic data in the state of Texas. The report is guided by research from the Baker Institute International Stem Cell Policy Program, which has published reports and hosted events on stem cell policy since 2004.[1] It is not the intention of the report to make specific recommendations for policy in Texas, but rather to give information regarding the current status of stem cell research in light of current economic conditions and government policy. By analyzing stem cell research in Texas, the authors hope to highlight the future potential for a positive impact on medicine and on the state of Texas.

The Baker Institute International Stem Cell Policy Program

The mission of the Baker Institute International Stem Cell Policy Program is to bring together scientists, ethicists, policymakers, media experts, and community and business leaders to find new ways to engage the general public in a dialogue on international stem cell policies and the ethical use of stem cells for research. It is a part of the Baker Institute Science and Technology Policy Program.

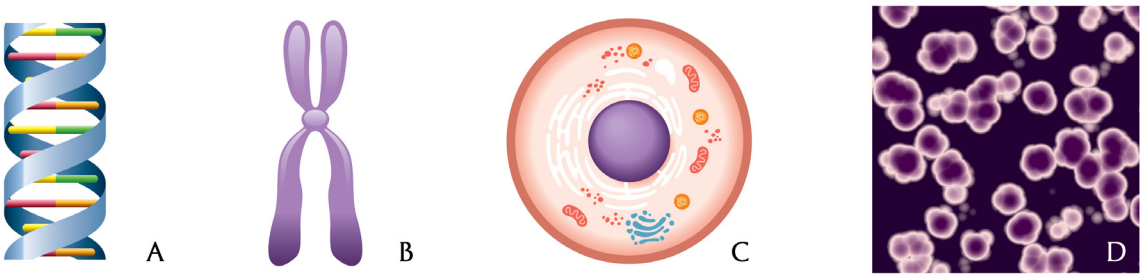
Additional information can be found online at **www.science.bakerinstitute.org.**

THE SCIENCE OF STEM CELLS AND THEIR USES

Cells are the building blocks of the human body. Genes, which are made of DNA (deoxyribonucleic acid), hold all of the inheritable or genetic information of the cell, and are packaged in chromosomes (see Figure 1). Every cell in the body begins as the same type of cell containing the same genetic information. However, during the developmental process, cells receive signals and cues from their environment that cause them to turn into specific cell types such as muscle or nerve cells. Cells that have not yet become a specialized cell type are termed stem cells.

[1] Information on the Baker Institute Science and Technology Policy Program, which runs the International Stem Cell Policy Program, can be found online at www.science.bakerinstitute.org.

Figure 1: The Building Blocks of the Human Body
a) DNA; b) chromosome; c) human cell (nucleus [DNA] colored purple); d) human cells under a microscope



Stem cells play a critical role in the human body. They can replicate themselves indefinitely and have the ability to become multiple cell types, a process termed differentiation.[2] These properties make them essential for human growth and development, as well as for the normal repair and replacement of diseased or damaged tissues. They are derived from various sources, and each type of stem cell has its own unique set of characteristics. Types of stem cells include embryonic, adult, cord blood (a subtype of adult), and induced pluripotent stem cells.

Embryonic stem cells are typically isolated from a blastocyst, the scientific term for an embryo five to six days after fertilization and before implantation, created *in vitro* or in the lab (see Figure 2).[3] Scientists are also trying to obtain embryonic stem cells from earlier embryonic stages, such as the eight-cell stage when one cell can be removed without damaging the rest of the embryo (see Figure 3).[4] In addition, scientists have attempted to create human embryonic stem cells through a technique called somatic cell nuclear transfer (SCNT), sometimes referred to as therapeutic cloning. SCNT involves removing the nucleus (or DNA) from an unfertilized egg, replacing it with the nucleus from a normal cell (such as a skin cell) and activating the egg to grow. While scientists have been unable to use SCNT to create human cells, the process has been successfully used to create animal cells.

Embryonic stem cells are uniquely valuable to scientists and physicians because they can generate every cell in the human body. This gives scientists the ability to create cell types and tissues, which are usually difficult to obtain because of their location or small population size. It is thought that cell therapies derived from embryonic stem cells have the potential to treat various diseases and heal conditions that have no existing cure, such as spinal cord injury.

Another type of stem cell is an adult stem cell, which can be found in several adult organs and tissues including bone marrow, muscle, and the brain. The adult stem cell's main function is to repair tissue damaged by the normal wear and tear of the body. Adult stem cells reside in special compartments in tissues and organs called niches. They leave their niche and become

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2 "Stem Cell Basics: What are stem cells, and why are they important?" National Institutes of Health, U.S. Department of Health and Human Services, http://stemcells.nih.gov/info/basics/basics1.asp.

3 Ibid.

4 Kirstin R.W. Matthews, "Stem Cell Research: A Science and Policy Overview" (paper published by the James A. Baker III Institute for Public Policy, Rice University, Houston, Texas, September 2009), http://www.bakerinstitute.org/publications/stemcell-intro-0208.pdf.

more specialized cells in the tissue when activated by an injury or other similar event.[5] However, adult stem cells are more limited than embryonic cells. They can only become specialized cells of specific, predefined lineages. For instance, a blood-forming stem cell can become a red blood cell but not a liver cell. They are also hard to collect because they are present in the human body in small numbers in their respective niches.

A third type of stem cell is a cord blood stem cell. These stem cells are located in the umbilical cord and placenta, which are often discarded after birth. Cord blood contains many different populations of stem cells including bone stem cells, blood stem cells, and blood vessel stem cells, all of which have the potential to differentiate into multiple lineages.[6] Cord blood stem cells are less mature than adult stem cells from other sources so they proliferate faster and can be grown longer in cultures, which is advantageous in research as well as in some therapeutic applications.

The fourth type of stem cell, which is created in a lab, is called an induced pluripotent stem (iPS) cell. These cells are created by activating specific genes within normal cells, a process that effectively reprograms a cell to become pluripotent, meaning it has the ability to differentiate into all cell types. The cell "looks" and acts similar to an embryonic stem cell, and theoretically can be turned into any cell in the body. iPS cells can be used to create patient- or disease-specific cell lines. This would prevent immune rejection if they were to be used to replace damaged tissues. This same technique of activating specific genes within normal cells is also being adapted to create cells at other developmental stages. For instance, scientists could, in principle, change a skin cell into a neural cell or muscle cell directly. This would help limit the amount of manipulation to the cells and reduce risks of contamination or damaging genetic alterations.

Figure 2: Human Embryonic Stem Cells
a) human blastocyst; b) embryonic stem cells in culture

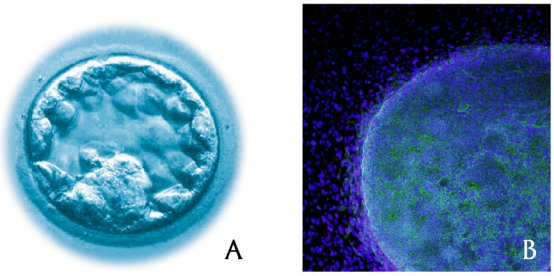
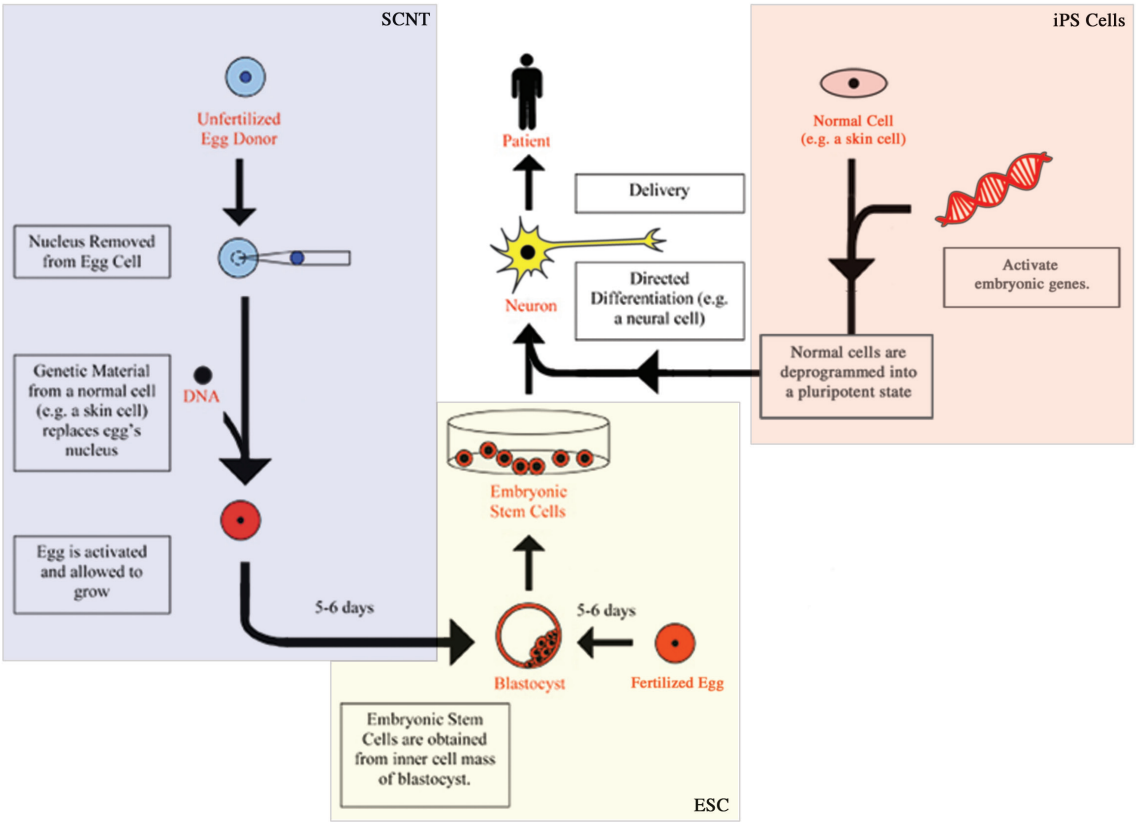


Image B courtesy of the California Institute for Regenerative Medicine.

[5] "Stem Cell Basics: What are adult stem cells?" U.S. Department of Health and Human Services, National Institutes of Health, accessed July 14, 2010, http://stemcells.nih.gov/info/basics/basics4.

[6] A. Buchheiser et al., "Cord blood for tissue regeneration," *J. Cell. Biochem.* 108 (2009): 762-768.

Figure 3: Pathways to Pluripotent Cells: hESCs, SCNT, iPS Cells



The iPS technique has problematic aspects, however. To reprogram the cells, genes are introduced into the cells by way of a virus (which can insert its DNA into the cell's nucleus), which might cause adverse effects clinically since viruses sometimes have unintended consequences. Additionally, one of the genes necessary for the process can contribute to unrestrained cell growth or cancer. Also, some researchers have had difficulty differentiating the iPS cells into lineages different from the origin cell, such as turning a skin-iPS cell into a heart cell, potentially limiting the number of therapeutic applications for which they can be used.

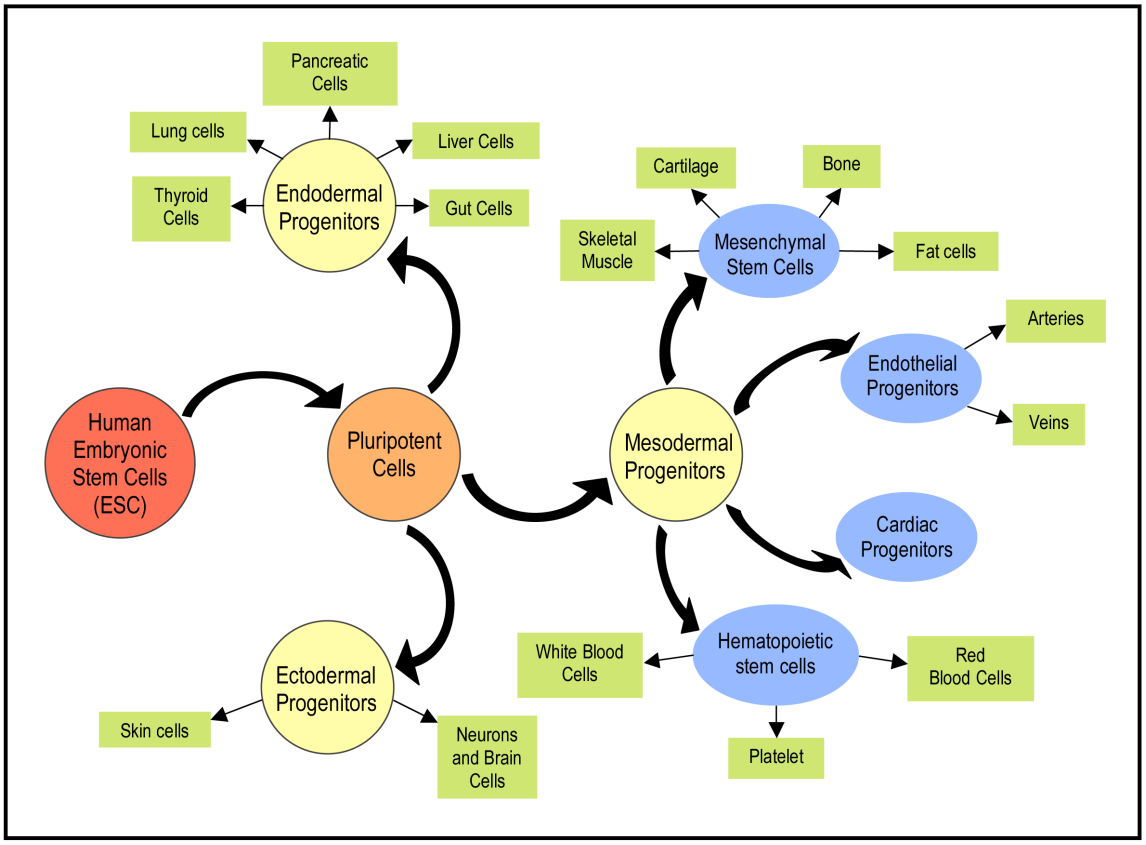
However, research is currently being conducted to find alternative methods of reprogramming, such as using chemicals instead of viruses, to "turn on" key genes. More information on how to differentiate cells might increase the number and types of cells iPS cells can change into. If scientists can resolve these issues, iPS cells could be a valuable source for cell therapies because donor stem cells could be reconfigured to genetically match the recipient's cells, eliminating the risk of immune rejection.

Differences Between Stem Cell Types

The biggest difference between embryonic and adult stem cells is their relative flexibility and the types of cells that they can become. Embryonic stem cells (and iPS cells) are pluripotent, which means they can be induced to differentiate into any cell type (see Figure 4).[7] However, most adult stem cells (including cord blood) are multipotent, which means they can only differentiate into the types of cells found in their environment or in the particular tissue or organ where they reside.

Another key difference is the number of cells that can be isolated and grown *in vitro* (in the lab). Large numbers of embryonic stem cells can be grown *in vitro* from a single blastocyst. Scientists have also refined the techniques required to produce iPS cells and can readily expand them in the lab. By contrast, adult stem cells are rare and methods of growing them still need to be perfected. Furthermore, due to their limited numbers, it is difficult to obtain a group of pure adult stem cells; a mixture of stem cells and other, more differentiated, cell types are typically collected during the isolation procedure.

Figure 4: Potential Uses of Human Embryonic Stem Cells



[7] Matthews, "Stem Cell Research."

However, adult stem cells, unlike embryonic stem cells, have already proven successful in the clinic; blood stem cells have been used to treat blood diseases for more than 40 years. Adult stem cells may also prove ideal for other treatments because a patient's own cells can be used, thus preventing an immune response or rejection.

Unfortunately, some tissues and organs do not have a sufficient population of adult stem cells, so the only method to create a cell-based treatment would be to utilize embryonic or iPS cells. In theory, iPS cells will be advantageous for this purpose, because they can be generated from the patient's own cells.

Conditions that Stem Cell Research Could Potentially Help:

Parkinson's
Multiple Sclerosis
Alzheimer's
Spinal Cord Injury
Stroke
Burns
Heart Disease
Diabetes
Osteoarthritis
Rheumatoid Arthritis
Birth Defects
Infertility
Pregnancy Loss
Leukemia
Brain Cancer
Muscular Dystrophy
Sickle Cell Anemia
Brain Trauma/Damage
Liver Disease
Metabolic Disorders
Deafness
Macular Degeneration
Retinitis Pigmentosa
Organ Donation

While embryonic and iPS cells have great potential, there has not been enough research conducted to determine how useful they will be therapeutically. Although iPS cells appear to function similarly to embryonic stem cells, more research needs to be done. In the meantime, embryonic stem cells are still considered the gold standard for stem cell research. They are necessary as a control to determine the pluripotent ability of induced cells. And only embryonic stem cells can be used to study early development because adult stem cells have progressed too far into a differentiated state, and induced pluripotent cells have been artificially manipulated.

While embryonic stem cells hold great promise, they are also controversial because a human embryo is destroyed in the process of creating the cell lines. The debate revolves around the fundamental question of when life begins. Opponents believe that life begins when an egg is fertilized, and thus, a life is destroyed in the creation of embryonic stem cell lines. Proponents of embryonic stem cell research have differing opinions. Some believe that life begins much later than fertilization, while others see the sacrifice of embryos as something that can be tolerated for the sake of treating diseases/disorders afflicting millions of people. This moral dilemma has affected embryonic stem cell research in several countries including the United States. iPS cells could be a solution but the research is still in its infancy, and it remains to be seen whether these cells are as promising as true embryonic stem cells.

Another ethical issue is the use of therapeutic cloning, or SCNT, to create embryonic stem cell lines, though, as of yet, this has not been achieved using human cells. SCNT uses the same scientific techniques as reproductive cloning—used in the 1996 birth of Dolly the sheep, the first cloned mammal—but for a much different end. Critics are concerned with the slippery slope that could develop if SCNT becomes the main method of creating embryonic stem cell lines. They are apprehensive that once this technology is available, it could be used to create humans—a process that would require numerous failures to perfect and is regarded by scientists and ethicists alike as unethical.

Clinical Uses of Stem Cells

Due to their unique characteristics, stem cells promise to play a significant role in science and medicine. Stem cells can be used to investigate the process of basic human development and expand our knowledge about cell division, including abnormal cell division associated with cancer. This knowledge may prove critical in diagnosing and treating cancer. Studying stem cells provides insight into how cells become more specialized, or differentiate, and how tissues are repaired after damage or injury. Furthermore, by thoroughly understanding these processes, stem cells can be used clinically to potentially cure diseases—instead of just treating their symptoms—and advance the field of regenerative medicine.

Regenerative medicine is the replacement—or regeneration—of cells, tissues, or organs to restore or establish normal function.[8] Tissue-engineered products (a combination of cells and materials used to create functional tissues), cell therapies (therapies that employ cells to repair or regenerate aged or diseased tissues), and regenerative compounds (compounds that trigger regeneration) all fall under the category of regenerative medicine. The utilization of stem cells could become a major tool in regenerative medicine.

Therapies developed from stem cells and engineered tissues already exist. Adult stem cells from the bone marrow were first successfully transplanted in 1968.[9] Blood stem cells have been used for years to treat cancers and problems that affect the immune system. There is also a stem cell therapy that helps regenerate damaged cells in the eye to restore sight.[10] In addition, tissue-engineered skin is available commercially, and doctors successfully transplanted a tissue-engineered human trachea in 2008.[11,12] A tissue-engineered human bladder is currently in the final stages of clinical trials.[13] The use of stem cells in treating other diseases and conditions, such as heart and liver disease, is being investigated.

Similar to adult stem cells, cord blood stem cells have been found to be effective in therapeutic applications as an alternative to bone marrow transplants for blood cancers and diseases.[14] They are easier to obtain and require less stringent immunological matches.[15] However, because of their immature status and small numbers in a single cord sample, multiple cords,

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[8] C. Mason et al., "Regenerative Medicine Glossary," *Regen. Med.* 4, no. 4 (2009).

[9] J.A. Hansen, "In Memoriam: Robert A. Good, M.D., Ph.D.," *J. Clin. Imm.* 23, no. 6 (2003): 539–40.

[10] Li et al., "Niche regulation of corneal epithelial stem cells at the limbus," *Cell Research* 17 (2007): 26–36.

[11] S. MacNeil, "Progress and opportunities for tissue engineered skin," *Nature* 445 (2007): 874–880.

[12] P. Macchiarini et al., "Clinical transplantation of a tissue-engineered airway," *Lancet* 372, no. 9655 (2008): 2023–2030.

[13] A. Atala et al., "Tissue-engineered autologous bladders for patients needing cystoplasty," *Lancet* 367, no. 9518 (2006): 1241–1246.

[14] S.M. Watt and M. Contreras, "Stem cell medicine: umbilical cord blood and its stem cell potential," *Semin. Fetal. Neonatal. Med.* 10 (2005): 209–220.

[15] V. Rocha et al., "Graft-versus-host disease in children who have received a cord-blood or bone marrow transplant from an HLA-identical sibling." *N. Engl. J. Med.* 342 (2000): 1846–1854.

as well as some laboratory manipulation, are required in order for them to achieve similar results to bone marrow transplants.

In contrast, the first human embryonic stem cell was isolated in 1998, almost 50 years after the adult stem cell, so the field is still in its early stages.[16] Currently, embryonic stem cells are being tested as a therapy for several conditions. In January 2009, the U.S. Food and Drug Administration (FDA) approved the first clinical trials using nerve cells generated from human embryonic stem cells to treat acute spinal cord injuries.[17] Embryonic stem cells also have been differentiated into cardiac muscle cells and implanted after a heart attack to prevent cardiac cell death and heart damage, both of which can lead to heart failure. This research was conducted using an animal model, but could have great potential if successful in humans.[18]

Several companies, including Viacyte (formerly Novocell), ES Cell International, Advanced Cell Technology (ACT), and Pfizer currently conduct and invest in stem cell research. Viacyte, in collaboration with Pfizer, is using human embryonic stem cells to develop a treatment that would potentially cure insulin-dependent diabetes.[19] Researchers hope to restore normal pancreatic function in diabetic patients by differentiating human embryonic stem cells into ß-islet cells, which produce insulin, eliminating the need for frequent insulin injections. ES Cell International is investigating the use of embryonic stem cells for repairing heart muscle cells.[20] Pfizer and ACT are focused on a therapy to restore vision in patients suffering from age-related macular degeneration.[21] Restoring retinal pigment epithelial cells can prevent patients from becoming blind. In November 2010, the FDA approved the treatment for Phase I clinical trials, making it the second U.S. clinical trial using human embryonic stem cells.

Induced pluripotent cells are the newest cell type to be studied—the first human cells were created in 2007.[22,23] They have yet to be utilized for therapeutic research, because scientists are in the early stages of understanding their properties and how to manipulate them. Before they are ready for clinical use, researchers need to refine their methods for reprogramming the cells into a certain specialization without negative side effects.

Many scientists have stated that no one stem cell type will be a panacea. All types (embryonic, adult, cord, induced pluripotent) are valuable and different therapies might require different cell types depending on the tissue or condition. While there have been some successful applications in regenerative medicine, the full potential for stem cell research has yet to be realized.

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16 J.A. Thomson et al., "Embryonic stem cell lines derived from human blastocysts," *Science* 282, no. 5391(1998): 1145–7, PMID 9804556.

17 J. Alper, "Geron gets green light for human trial of ES cell-derived product," *Nature Biotechnology* 27 (2009): 213–214.

18 H. Vidarsson et al., "Differentiation of human embryonic stem cells to cardiomyocytes for *in vitro* and *in vivo* applications," *Stem Cell Reviews* 6(1): 108–120, PMID 20091143.

19 E.E. Baetge, "Production of beta-cells from human embryonic stem cells," *Diabetes, Obesity, and Metabolism* 10 (supplement 4): 186–194, PMID 18824446.

20 A. Sahoo, "Stem Cells: Therapeutic Markets," Kalorama Information, February 2009.

21 B. Lu et al., "Long-term safety and function of RPE from human embryonic stem cells in pre-clinical models of macular degeneration," *Stem Cells* 27: 2126–2135, PMID 19521979.

22 K. Takahashi et al., "Induction of pluripotent stem cells from adult human fibroblasts by defined factors," *Cell* 131, no. 5 (2007): 861–72, PMID 18035408.

23 J. Yu et al., "Induced pluripotent stem cell lines derived from human somatic cells," *Science* 318, no. 5858 (2007): 1917–20, PMID 18029452.

Regenerative medicine and stem cell therapies hold out hope to millions of patients, as well as their families and caregivers. However, patients must be cautious of over-hyped and unregulated stem cell therapies offered around the globe. There are currently clinics advertising stem cell therapies on the Internet for a range of diseases and conditions. An unknown number of patients travel to these private clinics for treatments that have not been approved by the FDA or its equivalent. In addition, some clinics are charging patients thousands of dollars for treatments that are considered unproven and sometimes unsafe. An investigation of the claims of some of these clinics found no scientific evidence to support statements made by the clinics regarding the efficacy of their stem cell therapies.[24] Another study of a clinic claiming to use stem cell therapy to treat spinal cord injuries determined that none of the patients had significant improvements after receiving treatments and several had serious complications.[25] Many physicians and scientists are concerned about the safety of the treatments offered at these clinics. As a result, the International Society for Stem Cell Research (ISSCR) recently established a website, which offers information to help evaluate the claims of these clinics and gives advice on stem cell treatments in general.[26]

All types (embryonic, adult, cord, induced pluripotent) are valuable and different therapies might require different cell types depending on the tissue or condition. While there have been some successful applications in regenerative medicine, the full potential for stem cell research has yet to be realized.

U.S. Federal Stem Cell Policy

Federal stem cell policy is governed by two regulations: the Dickey-Wicker Amendment attached to National Institutes of Health (NIH) funding and the NIH guidelines for human embryonic stem cell research. These regulations impact all federal funding, but do not affect privately funded or state- or local government- funded human embryonic stem cell research. At present, no federal law restricts human embryonic stem cell research or even reproductive cloning so long as nonfederal funds are used. Despite the lack of a federal law regulating nonfederally funded stem cell research, any human testing of a new medical treatment or therapy, whether based on stem cells or any other untested therapy, is subject to regulation by the FDA and must follow the standard clinical trial procedure.

The Dickey-Wicker Amendment, named for its authors, U.S. Representatives Jay Dickey (R-AK) and Roger Wicker (R-MS), is an appropriations rider attached each year, since 1996, to the Department of Health and Human Services (DHHS) funding bill. NIH, the U.S. biomedical research funding agency, resides within the DHHS, and therefore the amendment impacts all federally funded biomedical research. The amendment bans federal funding for "the creation of a human embryo or embryos for research purposes" and research where a human embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death." Therefore, no

[24] D. Lau, et al., "Stem cell clinics online: The direct-to-consumer portrayal of stem cell medicine," *Cell Stem Cell* 3 (2008): 591-594.

[25] B.H. Dobkin et al., "Cellular transplants in China: Observational study from the largest human experiment in chronic spinal cord injury," *Neurorehabil Neural Repair* 20, no. 1 (2006): 5-13.

[26] International Society for Stem Cell Research, "A closer look at stem cell treatments," http://www.closerlookatstemcells.org/.

federal funding is allowed for research on a human embryo or for the creation of human embryonic stem cell lines, which results in the destruction of a human embryo. Less clear is whether this law prohibits research on embryonic stem cell lines that were created with nonfederal funding, as will be discussed below.

NIH guidelines for human embryonic stem cell research were released in July 2009 after Obama mandated their development in his executive order on March 9, 2009.[27] During George W. Bush's administration, federal funding was available for research using 21 human embryonic stem cell lines created before August 2001. No federal funding was available to develop new lines or carry out research on lines made after that date, regardless of how they were created. Obama's executive order rescinded Bush's policy and removed the cutoff date for federal funding of human embryonic stem cell research.

The guidelines apply to stem cell lines created after these federal guidelines were released as well as already existing lines. Consistent with the DHHS legal interpretation of the Dickey–Wicker Amendment, the guidelines do not allow federal funding for the creation of a human embryonic stem cell line (see Table I). In addition, human embryonic stem cells from certain other sources, such as somatic cell nuclear transfer (SCNT or therapeutic cloning), parthenogenesis (the development of an embryo from an unfertilized egg), or any IVF embryos created for research (not reproductive) purposes are ineligible for NIH funding.

Table I: Federal Funding Guidelines

The Dickey–Wicker Amendment Prohibits:
The creation of human embryos for research.
The destruction of human embryos in research.
The creation of human embryonic stem cell lines.
NIH Guidelines for Human Embryonic Stem Cell Research:
Lines must be derived from leftover embryos that were created for reproductive purposes.
The embryos must be donated with proper consent.
No payment for the embryos is allowed.
NIH reviews lines before they can be used.

[27] The White House, Office of the Press Secretary, "Removing Barriers for Responsible Scientific Research Involving Human Stem Cells," news release, March 9, 2009, http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-cells/.

In order for new human embryonic stem cells lines to be eligible for NIH funding, they must be generated from embryos that are created for reproductive purposes (through *in vitro* fertilization or IVF) using nonfederal funds, and donated with proper consent. As part of the consent, the NIH requires that no payments or free services are given in exchange for donation, and that there is a clear separation between the IVF procedure and the decision to donate. The donor also must be informed about the use of the embryo and that personal information (such as genetic information or disease history) might be provided to the researcher.

For already existing lines, an NIH review committee examines documentation to determine if the investigators followed the spirit and intent of the guidelines. In addition, the investigators must demonstrate that the lines were created from leftover IVF embryos and that donors gave informed consent.

The new NIH guidelines and how the DHHS interprets the Dickey-Wicker Amendment are being challenged in court in the case *Sherley v. Sebelius*. On August 23, 2010, U.S. federal judge Royce Lamberth ruled that the Dickey-Wicker Amendment prohibited both the creation of human embryonic stem cells and their usage.[28] The court issued an injunction blocking all NIH funding for human embryonic stem cell research. This resulted in NIH removing all human embryonic stem cell grants from review and blocking funding to already approved grants. Research within NIH's campus in Bethesda, Maryland, was halted as well. In response, the U.S. Department of Justice appealed the injunction ruling, and a federal appeals court lifted the injunction pending the outcome of the federal court case, allowing federally funded human embryonic stem cell research to proceed for the time being. The ultimate fate of human embryonic stem cell research in the United States could depend on *Sherley v. Sebelius*, which might not be resolved for several years due to potential appeals. However, bills have been created in both the House and Senate that, if passed, could overturn Lamberth's ruling.

State Stem Cell Policies

In part because of the lack of comprehensive stem cell legislation on the federal level, states have been more proactive in regulating stem cell research (see Figure 5: State Stem Cell Policies).[29] Some states, such as South Dakota, chose to pass legislation restricting or banning human embryonic stem cell research. Other states adopted permissive legislation, such as Massachusetts, Missouri, and, more recently, Michigan. A few states, such as California, even appropriated funds to support in-state human embryonic stem cell research. But many states, including Texas and Wisconsin, have no stem cell policy at all—although Wisconsin does have several state-supported projects that provide assistance to stem cell researchers.

Table II outlines research and development (R&D), NIH funding, and NIH stem cell funding for selected states with varying stem cell policies.[30,31] California and Massachusetts lead the nation in R&D and NIH funding, and both have a strong policy position supporting all types of stem cell research. Michigan recently overturned a law that banned the use of embryos for research, making it legal to create human embryonic stem cell lines and conduct human

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[28] *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010), https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv1575-44.

[29] Matthews, "Stem Cell Research."

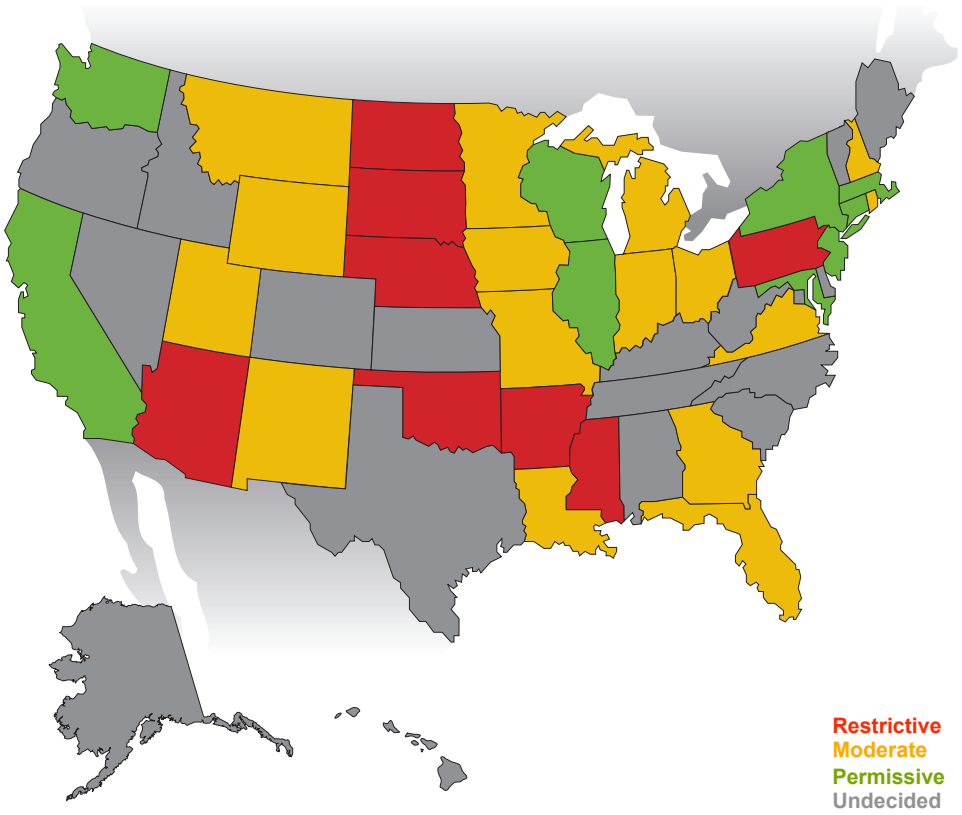
[30] NIH Research Portfolio Online Reporting Tools (RePORT), http://report.nih.gov/award/trends/State_Congressional/StateOverview.cfm.

[31] "Science and Engineering Indicators 2010: Financial Research and Development Inputs," National Science Foundation, http://www.nsf.gov/statistics/seind10/c8/c8s4o33.htm.

embryonic stem cell research as long as certain criteria are met in regard to the embryo. Missouri added a constitutional amendment to permit any stem cell research that is allowed under federal law. All of these states outlaw reproductive cloning and the buying or selling of embryos. South Dakota ranks low in the nation in R&D and NIH funding and has a very restrictive embryonic stem cell policy. It prohibits research on both embryos and embryonic stem cell lines while allowing all types of adult stem cell research.

Figure 5: State Stem Cell Policies

Out of the 50 states, 32 have some legislation in effect that addresses stem cell research. Of those 32, 17 specifically prohibit reproductive cloning, 13 ban therapeutic cloning, and 18 prohibit embryonic stem cell research. By contrast, 13 states have appropriated state funding toward some form of stem cell research. The remaining 18 states, including Texas, have no specific stem cell policy.



Texas Stem Cell Policies and Politics

Texas is a national leader in R&D and fourth in the nation for funding (see Table II).[32] It also ranks fifth for NIH funding at over $1 billion.[33] But these rankings are lower than expected considering that Texas is second nationally in population and gross state product.

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[32] National Science Foundation, "Science and Engineering Indicators 2010."

[33] "Dollars Awarded by State for 2009," NIH Research Portfolio Online Reporting Tools (RePORT), http://report.nih.gov/award/trends/State_Congressional/StateOverview.cfm.

Table II: Selected State Research and Development Funding, 2009

	R&D (in billions)*	NIH (in billions)**	NIH Stem Cells (in millions)
California	$ 77.6 (1st)	$ 3.2 (1st)	$ 203
Massachusetts	$ 24.6 (2nd)	$ 2.3 (2nd)	$ 141
Texas	$ 17.9 (4th)	$ 1.1 (5th)	$ 59
Michigan	$ 17.4 (5th)	$ 0.59 (11th)	$ 23.3
Missouri	$ 3.8 (24th)	$ 0.47 (12th)	$ 16.8
Wisconsin	$ 4.6 (21st)	$ 0.38 (17th)	$ 30
South Dakota	$ 0.24 (49th)	$ 0.02 (46th)	$ 0.20

*Notes: *Data from 2007, which includes both public and private funding;*
***Does not include projects funded by the Recovery Act.*

Research on stem cells is popular within the state. In 2009, Texas scientists received $59 million in NIH funding specifically for stem cell research; $6.6 million was categorized as grants for human embryonic stem cell research (including stimulus funding).[34] But Texas has no policy regarding stem cells, even though there has been much debate on the subject throughout the state.

Since 2003, numerous bills regarding embryonic stem cell research, both restrictive and permissive, have been authored but none have passed. The bills proposed have been mostly prohibitive. Several criminalized human embryonic stem cell research or made it illegal to receive therapies derived from human embryonic stem cells, regardless of where the procedure occurred. In recent years, there have been bills that ban both funding for human embryonic stem cells research as well as appropriations to state institutions conducting human embryonic stem cells research.

[Texas] ranks fifth for NIH funding at over $1 billion.

In 2005, state legislators began to propose bills that were more permissive to human embryonic stem cell research. These bills would have allowed research and provided methods to regulate the research through ethical guidelines. They would have also banned human reproductive cloning, established an oversight committee to monitor research, and funded research using human embryonic stem cells. However, none of these embryonic stem cell bills have passed, and Texas Governor Rick Perry has vowed to veto any bill that dedicates state funds to human embryonic stem cell research.[35]

[34] "Estimates of Funding for Various Research, Condition, and Disease Categories," NIH Research Portfolio Online Reporting Tools (RePORT), http://report.nih.gov/rcdc/categories/.

[35] "Gov. Rick Perry on Pro-Life Policy," Perry for Governor 2010, http://www.rickperry.org/issues/social_conservative.

Perry has, however, expressed support for adult stem cell research, especially as an alternative to embryonic stem cells.[36] In 2009, State Senator Jane Nelson (R–Grapevine), chair of the Health and Human Services Committee, proposed a bill (Senate Bill 73) to create a research program to help fund and oversee adult stem cell research in Texas. The bill passed the Senate, but did not come up for a vote in the House.[37] Nelson has indicated that she will resubmit it in the 2011 legislative session.

Also in the 2009 legislative session, State Senator Steve Ogden (R–Bryan), chairman of the Senate Finance Committee, proposed Senate Bill 1695, which prohibited the use of state funds or facilities for research involving the destruction of human embryos including human embryonic stem cells research. In addition, Ogden added an amendment to the Senate 2009 General Appropriations Act that banned state funds from being used to support any activity where a human embryo was destroyed. Both the Senate bill and appropriations amendment would have curtailed all human embryonic stem cells research, even on the lines approved by the Bush administration. Ogden did not seek a hearing for Senate Bill 1695 and withdrew his amendment to the General Appropriations Act. To increase awareness of current embryonic stem cell research, Ogden proposed a new bill, which requested reports from all publicly funded projects using human embryonic stem cells. This bill did not pass either.

Ogden also introduced Senate Bill 2573, which authorized a study of how to collect data on research being conducted throughout Texas. Though this did not pass, it was implemented as an amendment to House Bill 51, which did pass. This bill required an interim committee to study the feasibility of collecting data and maintaining a searchable database related to technology research performed in public universities. The committee includes representatives from the major public universities in Texas as well as members chosen by the Texas Higher Education Coordinating Board. The committee gathered data from universities throughout the state during the period between sessions.

In 2009, Texas scientists received $59 million in NIH funding specifically for stem cell research; $6.6 million was categorized as grants for human embryonic stem cell research (including stimulus funding).

Biomedical Research and the Biotechnology Industry in Texas

Biotechnology is a growing industry both globally and nationally. It is defined as "a collection of technologies that capitalize on the attributes of cells, such as their manufacturing capabilities, and put biological molecules, such as DNA and proteins, to work for us."[38] This definition includes aspects of numerous industries such as pharmaceuticals, medicine, defense, and agriculture. In 2009, the United States had 313 publicly traded biotech companies with revenues totaling $57 billion.[39] While the economic crisis affected the industry significantly in 2009, there were positive signs as the profitability of publicly traded U.S. biotechnology

[36] Perry for Governor 2010, "Gov. Rick Perry on Pro-Life Policy."

[37] "Texas State Senate Bill 73," Texas Legislature Online, 2009 legislative session, http://www.legis.state.tx.us/BillLookup/History.aspx?LegSess=81R&Bill=SB73.

[38] "Biotechnology: A collection of technologies," Biotechnology Industry Organization, http://www.bio.org/speeches/pubs/er/technology_collection.asp, accessed August 25, 2010.

[39] Jaggi Gautum, ed., *Beyond Borders, Global Technology Report 2010*, Ernst and Young, April 28, 2010.

companies increased from $400 million to $3.7 billion. In addition, U.S. contributions helped the global community, which is predominantly the United States, Europe, Australia, and Canada, reach a positive profit for the first time ever.

In Texas, the biotechnology industry has an economic impact of approximately $75 billion.[40] The industry itself employs over 100,000 people at an average salary of $67,000, which is higher than the state average. The Texas government has been very supportive of the biotechnology industry and has devoted parts of the budget specifically to its development. In 2004, Governor Perry designated biotechnology as one of six key target areas for economic growth in Texas, and he pledged to use state resources to help leverage private investment.[41,42] Over the past decade, numerous programs have been created to promote R&D and business development in Texas. The Texas Enterprise Fund (TEF), the Texas Emerging Technology Fund (TETF), and the Cancer Prevention and Research Institute of Texas (CPRIT) have all helped the biotechnology industry.

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Perry and the Texas legislature established the TEF in 2003. This $295 million "deal-closing fund" devotes state resources to attract new business to the state or expand existing businesses to recruit talent.[43] The fund may also be used for infrastructure and community development, business incentives, and job-training programs.[44] As of March 2010, the Texas Enterprise Fund had devoted $93.1 million to biotechnology-related projects to create over 10,000 jobs (See Table III).

The $200 million TETF was created in 2005 to aid in the development and commercialization process of new technologies in Texas.[45] The program aims to increase collaboration through the formation of seven "Regional Centers of Innovation and Commercialization," matching the funding of research grants, rewarding universities for attracting top talent to the state, and investing in small businesses with promising new technologies. TETF created the Texas Life Science Regional Center of Innovation and Commercialization, which acts as a gateway for all biotechnology TETF-funded projects. As of April 2010, $171 million from the fund has been devoted to biotechnology projects; $65 million of this is for commercialization at start-up companies and $106 million is for universities.[46]

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[40] Office of the Governor Rick Perry, *Texas Biotechnology Industry Report*, April 2010.

[41] Office of the Governor Rick Perry, "Gov. Rick Perry Announces Strategic Plan to Create Jobs," news release, October 20, 2004, http://governor.state.tx.us/news/press-release/4530/.

[42] Bernard Weinstein and Terry Clower. "The Economic Development Potential of Stem Cell Research in Texas," (report prepared for The Alliance for Medical Research, Houston, Texas, March 2007).

[43] Office of the Governor, *Texas Biotechnology*.

[44] "Texas Enterprise Fund," Office of the Governor, http://governor.state.tx.us/priorities/economy/investing_for_growth/texas_enterprise_fund/.

[45] "Texas Emerging Technology Fund," http://members.texasone.us/site/PageServer?pagename=tetf_homepage.

[46] Office of the Governor, *Texas Biotechnology*.

Additionally, in 2007, voters passed Proposition 15, which established CPRIT.[47] This initiative devoted $3 billion to cancer research and prevention over 10 years and started funding awards in 2009.[48] CPRIT grants support basic research, the commercialization of technologies, training of young researchers, and the recruitment of new scientists. As of July 2010, 155 awards were granted totaling over $200 million. Examples of projects awarded include a Baylor College of Medicine grant for $900,000 to develop a vaccine for cancer and a Texas Tech University grant for $200,000 to research a device to screen tumor cells for their ability to migrate in the body.[49]

Table III: Biotechnology Projects Supported by the Texas Enterprise Fund

	Jobs	***Funding (in millions)***
Baylor College of Medicine	N/A	$ 2.0
Cardiovascular Systems	100	$ 0.6
Grifols, Inc.	190	$ 0.5
Hanger Orthopedic Group	236	$ 1.5
Medtronic, Inc	1,384	$ 6.0
Scott & White*	1,485	$ 7.5
TIGM**	5,000	$ 50
UTHSCH**†	2,252	$ 25
TOTALS	10,647	$ 93.1

Notes: * *Includes Scott & White (S&W) Memorial Hospital and Scott, Sherwood & Brindley Foundation*

** *Includes Texas Institute for Genomic Medicine (TIGM) and Lexicon Genetics.*

† *Includes The University of Texas Health Science Center at Houston, The University of Texas MD Anderson Cancer Center, and G.E. Healthcare.*

According to Drs. Bernard Weinstein and Terry Clower, professors of applied economics at the University of North Texas, economic development relies on scientific research.[50] Research performed in university laboratories often leads to the launch of start-up companies. They are the main route to commercializing these technologies, and they may be the only way for such technologies to reach the market. Start-up companies can provide huge returns on investment, as was the case with the Internet giant Google. They are also responsible for new net job growth in the United States, and the jobs they create have a lasting positive impact on

[47] Cancer Prevention and Research Initiative of Texas, http://www.cprit.state.tx.us/.

[48] Office of the Governor, *Texas Biotechnology*.

[49] "Funded Grants," Cancer Prevention and Research Institute of Texas, http://www.cprit.state.tx.us/funded-grants/.

[50] Weinstein and Clower. "The Economic Development Potential."

the economy.[51] By generating funding for basic research both at the state and federal level, laboratories can advance a technology significantly enough to make it a viable product for a start-up. For basic R&D, Texas receives funding for biomedical research from the National Institutes of Health (NIH). In 2010, Texas ranked fifth in the nation in awards, collecting over $1 billion in the form of 2,264 grants. In 2007, for every $1 of NIH funding, Texas generated an estimated $2.49 in economic activity, the highest in the country (South Dakota had the lowest at $1.66).[52] Additionally, NIH funds accounted for the creation of over 20,000 jobs in Texas in 2007 at an average wage of $50,299, almost 20 percent above the national average wage of $42,000.[53] NIH funding contributes heavily to the Texas economy, and thus it is imperative for Texas to maximize federal funding by supporting research in the state.

Recently, the NIH has begun to invest increasing research dollars in stem cells. The funding of stem cell research increased from $643 million in 2006 to $1.1 billion in 2010.[54] These numbers include grants aimed at several Texas research institutions including Baylor College of Medicine, Rice University, Texas Heart Institute, several institutions in The University of Texas System, and Texas A&M University Health Science Center. The research conducted at these and other Texas institutions varies and includes all types of stem cells and applications. Projects range from studying how embryonic stem cells are regulated and exploring the role of neural stem cells in treating trauma injuries to understanding the reprogramming and aging of cells.[55]

Stem cells are considered a critical part of the advancement of the biotechnology industry, particularly for future regenerative medicine applications. Adult bone marrow stem cells have been used to treat blood cancers for many years and are being investigated for their ability to treat other diseases. This year, the Geron Corporation is beginning the first human embryonic stem cell clinical trial with a treatment for spinal cord injuries, and Advanced Cell Technology (ACT) has just been approved for clinical trials to restore retinal cells, derived from human embryonic stem cells, in patients suffering from macular degeneration. These applications represent a handful of stem cell-based therapies. Billions of dollars have been invested into basic stem cell research in hopes of developing new treatments and establishing a new marketplace.

NIH funds accounted for the creation of over 20,000 jobs in Texas in 2007 at an average wage of $50,299, almost 20 percent above the national average wage of $42,000.

[51] Michael Horrell and Robert Litan, *After Inception, How Endearing is Job Creation by Startups?* (Kansas City, MO: Ewing Marion Kauffman Foundation, July 2010).

[52] Families USA Global Health Initiative, *In Your Own Backyard: How NIH Funding Helps Your State's Economy*, June 2008.

[53] Ibid.

[54] NIH RePORT, "Estimates of Funding."

[55] Ibid.

An analysis of the therapeutic market of stem cells, conducted in 2009, projected that, in a best-case scenario, treatments using proprietary stem cells will rise from 20,000 in 2007 to 9.4 million in 2020. These numbers do not include bone marrow transplants for the treatment of blood cancers. Additionally, revenues from stem cell products are projected to increase from $12.6 million in 2007 to $16.3 billion in 2020. The report also offers its view on the most likely scenario: the treatment of 5.1 million patients with revenues of $8.9 billion in 2020. The analysis attributes the discrepancies between the two forecasts to the nascent state of stem cell technologies.[56]

It is important that Texas does not miss the opportunity to attract more federal dollars and biotechnology companies to the state. Without any type of policy firmly in place regarding stem cell research, researchers and industry leaders may be hesitant to invest in Texas or pursue groundbreaking research that could be considered controversial. Furthermore, by placing a ban on some types of stem cell research, Texas legislators would not only prevent this type of research from being conducted but also have the potential to affect other parts of biomedical research and industry. Prohibitive legislation portrays the state as unsupportive of developing biotechnology. It may also discourage companies or researchers from coming to Texas for fear that their product development or research areas will be banned in the future.

Stem Cells and Texas

Stem cells and regenerative medicine are exciting and emerging fields of biomedical research. However, the development of new therapies and cures is not only limited by scientific breakthroughs but also by politics. By most estimates, it takes at least 10 years before new therapies achieved in the lab are ready for clinical use. This is related to the long and thorough process required by the FDA to determine clinical safety and efficacy of treatments.

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Delays in research are also a result of policies implemented at the state and federal level. The more limited and restrictive the federal funding for stem cell research is, the fewer scientists will move into the field and the less research is attempted. The less research, the less likely therapies will be developed, at least by American researchers. While U.S. scientists are now limited on the types of federally funded stem cell research they can pursue, other countries such as the United Kingdom and China are pursuing a full range of projects. This could result in the United States playing a less significant role in the patenting and licenses of new treatments, which would lead to Americans paying royalties to the other countries that develop treatments first.

Much of Texas' economic success has been related to its business-friendly environment. Creating policies that will inhibit areas of biomedical and biotechnological development could negatively impact all of the work done to promote new business within the state and to make Texas a hub for biomedical research. By reaching out to the public, scientists, and policy experts, Texas legislators can craft a policy that respects the feelings of Texans, permits research to be conducted ethically, and enables the Texas economy to push forward.

[56] Sahoo, "Stem Cells."

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FREQUENTLY ASKED QUESTIONS

What research is President Barack Obama funding?

In March 2009, President Obama signed an executive order that removed the date restriction on embryonic stem cell lines. This allows research on lines created after 2001. The president asked the National Institutes of Health (NIH)—the agency responsible for funding the majority of U.S. biomedical research—to create guidelines for this new research. The guidelines, released in July 2009, allow federal funding for research on embryonic stem cells that were obtained using private funding from leftover *in vitro* fertilized eggs with proper informed consent. But they do not allow funding for research using cells that were obtained from fertilized eggs created for research purposes or other methods or cells obtained without proper documented informed consent from both the egg and sperm donor.

Can researchers use federal funds to destroy embryos and create embryonic stem cells?

No. Every year since 1996, the U.S. Congress has passed an amendment on the funding allocated to NIH that bans the destruction or harm of embryos for research. This amendment, called the Dickey-Wicker Amendment after the two representatives who wrote it, prohibits the use of federal funds to obtain embryonic stem cells but does not apply to private funding.

How is the Obama policy different from the Bush policy?

The new guidelines allow the use of cell lines created after 2001, but only if they follow a rigorous informed consent process. Any lines created in the future must follow current guidelines and previously existing lines must be reviewed and approved by an NIH panel of experts to determine if the informed consent process was upheld. This is more rigorous than the process for the approved Bush lines.

How does the Obama policy impact Texas?

With the expansion of cells eligible for federal funding, researchers across the country—including in Texas—can apply for money from the government to use embryonic stem cells that were created in private labs during the past 10 years. This would bring more federal dollars into the state, create more jobs, stimulate the Texas economy, allow researchers in Texas to participate in this revolutionary approach to health care, and free up private funding to be used in other areas of research.

How much stem cell research is going on in Texas?

The state of Texas receives approximately $1 billion from NIH for biomedical research each year. Of this, approximately $59 million was used for stem cell research in 2009 (including American Recovery and Reinvestment Act funds), with $6.5 million spent on human embryonic stem cell research (utilizing lines approved during the Bush administration and including Recovery Act funds). As of December 2010, no human embryonic stem cell lines created in Texas were approved by NIH for federal funding. The amount of private funding for human embryonic stem cell research within the state is unknown.

What would happen if Texas banned state funding for embryonic stem cell research?

The state of Texas does not currently fund embryonic stem cell research, but a ban could affect the use of state facilities. The ban would apply to any research currently underway, as well as federally funded biomedical research using cells approved during the Bush administration. It would also prevent researchers from applying for additional funds on newer lines.

How would a ban impact Texas' economy?

If a ban on embryonic stem cells were implemented in Texas, many researchers who are working in the field would likely leave the state to find new positions where there is more permissive regulation. In addition, a ban would create the perception that the state is anti-science and would hurt recruiting, especially of high-profile researchers. This could negatively impact the amount of federal funding brought into the state. Currently, Texas is fourth largest recipient of federal research and development dollars. As noted previously, Texas received more than $1 billion annually in federal funding from the NIH. This makes Texas fifth in the nation for biomedical research funding but only sixth for stem cell and eighth for human embryonic stem cell research.

A full FAQ for stem cell research can be found on the Baker Institute website at **www.bakerinstitute.org/publications/stemcellFAQ**.

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