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STEM CELLS

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By:

Joslyn Foley

Joon Lee

James Mike Watson

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APPROVED:

Prof. David S. Adams, Ph.D.
Project Advisor

ABSTRACT

Stem cells are undifferentiated cells with the ability to renew and divide indefinitely to generate specialized cells, thus they show medical potential for treating and curing currently untreatable diseases. This project investigated the different types of stem cells, how they have been used, and the effects of this new technology on society via ethical and legal issues.

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EXECUTIVE SUMMARY

Stem cells are undifferentiated cells with the capacity to grow indefinitely and to differentiate into tissues. Because of this regenerative capacity, stem cells have the potential to regenerate tissues, and is the basis for the new field of regenerative medicine. One common misconception is that all stem cells are alike, so one purpose of this IQP was to document in chapter-1 the various kinds of stem cells, including embryonic stem (ES) cells and various kinds of adult stem cells. Another source of misinformation is what has or has not been achieved with stem cells so far. Some observers argue that no human lives have yet to be saved with stem cells, yet they forget about the thousands of lives already saved with bone marrow transplants using hematopoietic stem cells. So the purpose of chapter-2 of this IQP was to document what has been done with stem cells in both humans and animals. The use of some stem cells can destroy human embryos, so chapter-3 focused on stem cells ethics, and the stances of the major world's religions. Finally, chapter-4 focused on U.S. and state laws governing stem cell use, comparing them to other countries.

Chapter-1 serves as an introduction to the different types and sources of stem cells, and provides some basic definitions. Stem cells share three common properties. All stem cells must be: 1) capable of renewing and dividing for extended periods of time, 2) unspecialized, and 3) able to give rise to specialized cells (*Stem Cell Basics*, 2005). A stem cell is often described in terms of its potency, or the number of different kinds of specialized cells that it has the ability to produce. Totipotency, meaning it has the ability to give rise to any embryonic or adult tissue cell, is a characteristic of a fertilized egg.

Embryonic stem (ES) cells are considered to be pluripotent, with the ability to make almost all kinds of cells in the body. Multipotent stem cells are capable of making various kinds of cells of one tissue, and unipotent stem cells are capable of forming only the same type of cell from a specific tissue.

Chapter-2 explores some of the possible applications for stem cells. For example hematopoietic stem cells (HSC) have been used for many years in Leukemia patients to reconstitute the cellular components of blood to send the Leukemia into an ultimate remission. Most of what we know about stem cells comes from animal studies, especially mice, and we document some key experiments in chapter-2. With respect to humans, ES cell experiments are only now in clinical trials, so researchers have yet to tap into the vast potential of using stem cells to fight many diseases. Diabetes could be fought with ES cell therapy where the cells could provide the necessary amount of insulin for survival. Stem cells could be transplanted to fight diseases of the human nervous system such as Parkinson's disease. Use of stem cells could also one day help repair the tissues of the heart which is so vital to our daily survival. These are but a few of the many potential benefits that the promise of stem cell research can bring.

Chapter-3 addresses the ethical concerns that have made this such a heated topic. The traditional Hindu belief is that life begins at conception, which is the point when a person is reborn from their previous life, or reincarnated. However, Swami Tyagananda, a Hindu chaplain at the MIT Religious Activities Center, argues that ES cell research and therapy may be justifiable as it is considered an "extraordinary, unavoidable circumstance," and an act done "for the greater good"(Reichhardt, 2004). Traditional Muslim belief supports ES cell research since they argue life begins forty days after

fertilization, well after blastocyst formation from which ES cells are obtained. Those of the Jewish faith believe that the human embryo is not given human status until the 40th day of gestation as well, permitting the use of ES cells provided that the fetus was aborted in accordance with Jewish law. Some Christians approve of ES cell research under certain conditions, while others believe that it is unethical under any circumstances. Catholic officials are strictly opposed to the destruction of human embryos under any conditions, ES cell research is “immoral, illegal, and unnecessary,” as said by the U.S. Roman Catholic Bishops (*Religious Views...*2001). All four of the world’s main religions support the use of adult stem cells to save lives, since no embryos are destroyed in the process.

Chapter-4 summarizes current stem cell legalities, and provides a historical perspective leading up to current U.S. policies. On August 9, 2001 President Bush arguing that destroying human embryos constituted murder, announced that he would allow federal funding only for stem cell lines derived before that date. The rationale was that although the initial embryos had already been destroyed, perhaps the cell lines derived from their demise could be used to save lives. Unfortunately this bill severely limited the number of ES cell lines available for research purposes, and curtailed US research efforts behind some other countries (Monitoring Stem Cell Research, 1994). The state of California became the first to legalize research on embryos, including cloned embryos, when Governor Gray Davis signed the new stem cell law SB 253 on September 23, 2002. In the state of Massachusetts, on May 31, 2005 an “Act Enhancing Regenerative Medicine in the Commonwealth”, including a chapter on biotechnology, passed both the Senate and the House of Representatives legalizing stem cell research.

The moratorium on the dispersing of funds for stem cell research in the European Union ended on December 31, 2003. Despite opposing views by member nations, the EU has taken the position of funding research on a case by case basis (*“EU to Fund Stem Cell Research Despite Split,”* 2003). Just last year on August 11, 2004, the United Kingdom issued a license to the Newcastle Center for life allowing them to create colonies of human stem cells for research (Garfinkle, 2004). A sensible legal approach loosening the current federal restrictions is critical for the US to remain competitive and stay on the leading edge of medical innovation.

PROJECT OBJECTIVES

The purpose of this IQP was to investigate the controversial topic of stem cells, providing information on the various kinds of stem cells and their applications to help dispell common myths about their use and potentials. The effect of stem cell technology on society was investigated in via ethical and legal topics. Finally, the research performed help the authors make their own conclusions and recommendations about this new technology.

Chapter 1: STEM CELL TYPES AND SOURCES

Stem Cell Definitions

The term stem cell is used most often by the press when referring to embryonic stem cells, which are undifferentiated cells that have been isolated from an embryo. But in reality there are many different types of stem cells with varying levels of potency and ability. All stem cells however must share three common properties. All stem cells must be: 1) capable of renewing and dividing for extended periods of time; 2) unspecialized; and 3) able to give rise to specialized cells (*Stem Cell Basics*, 2005). Stem cells are unspecialized, meaning that they do not participate in the functions performed by the cells that they give rise to. For example, hematopoietic stem cells do not transport oxygen through the bloodstream, although they give rise to the blood cells that do.

When stem cells give rise to specialized cells the process is called differentiation. This process is directed by internal signals encoded in the cells genes, and external signals which include chemicals, physical interactions with neighboring cells, and specific molecules in the cells microenvironment (*Stem Cell Basics*, 2005). Classically, differentiation was thought to irreversible, but recently experiments done transplanting the nucleus from certain differentiated cells into an oocyte (the egg) has shown that the totipotency of the nucleus can be re-established.

Unlike many specialized cells, stem cells have the ability to replicate themselves an unlimited number of times over the lifespan of an organism. Normally a cell divides into two identical daughter cells, each of which inherits a complete copy of the chromosomes from the original cell, this is called symmetric division. Symmetric

division occurs in specialized cells and embryonic stem cells, as each daughter cell is an exact copy of the parent. Conversely, when an adult stem cell divides one daughter cell will become a stem cell (and remain “immortal”) and the other will go through the process of determination where it will gain a specific function, this is called asymmetric division (*Stem Cells...* 2001). Asymmetric division allows for the renewal of specialized cells while maintaining a constant supply of new stem cells to continue the cycle.

Stem Cell Potencies

A stem cell is often described in terms of its potency, or the number of different kinds of specialized cells that it has the ability to produce (Figure 1). The fertilized egg, or zygote, is considered to be the ultimate “stem cell” (technically it is not a stem cell because it does not renew itself) because it is totipotent, meaning it has the ability to give rise to any embryonic or adult tissue cell, including germ cells, the placenta, and embryonic membrane. As the zygote continues to divide its potency diminishes. At around 5 days, a blastocyst forms consisting of an outer layer and an inner cell mass. The inner cell mass contains embryonic stem (ES) cells. These cells are pluripotent with the ability to make almost all kinds of cells in the body. An adult human has multipotent stem cells capable of making various kinds of cells of one tissue, for example hematopoietic stem cells (HSCs) that are capable of forming the cellular components of blood. In addition adults also have unipotent stem cells within certain tissues that are usually capable of forming only that same type of cell. Cells in this category include neuronal stem cells, and skin stem cells.

Traditionally scientists believed that no adult stem cells were pluripotent, making them less useful in medical treatments than embryonic stem cells. However, increasing evidence suggests that some adult stem cells, especially those found in bone marrow, may retain pluripotency (*Sell, 2004*).

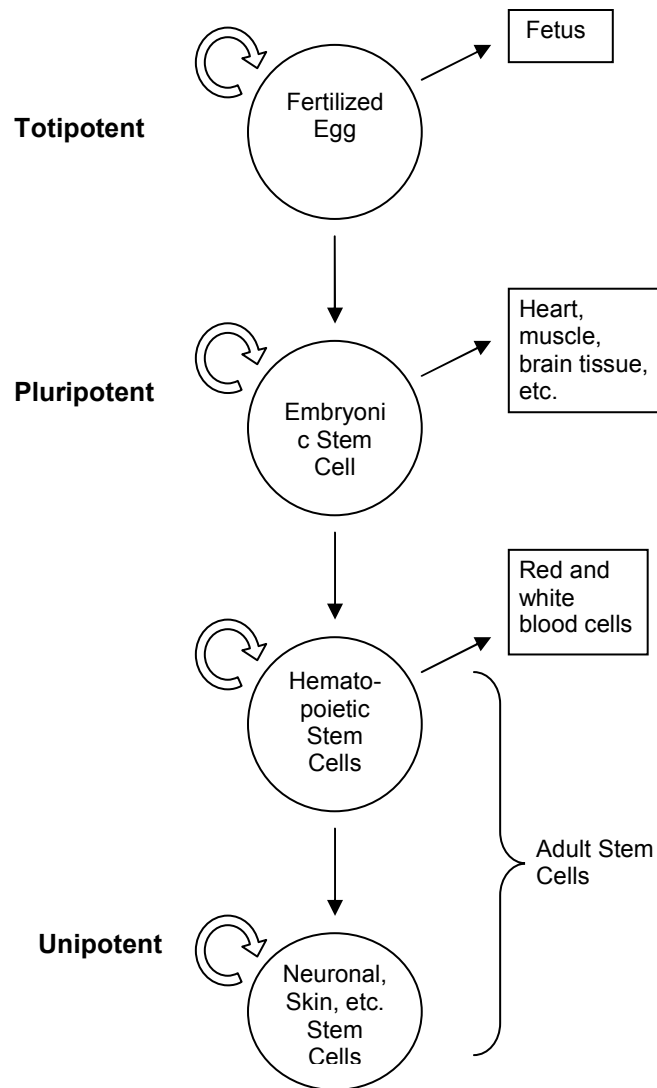


Figure 1. A diagram of diminishing stem cell potency as the fertilized egg develops into a specialized adult cell.

Stem cells can be found not only in developing embryos but also from the fetus, umbilical cord blood, the placenta, and many adult tissues. Scientists hope to use stem cells as a form of regenerative and reparative medicine to treat diseases such as Parkinson's, diabetes, and heart disease, as well as countless other types of injuries and illnesses. If procedures can be developed to prepare stem cells from a patient, the stem cell treatment would not require another donor, and would avoid the possibility of the rejection of tissues, cells, and organs by the recipient (Hwang et al, 2005). Stem cells also have the ability to divide indefinitely in culture, meaning that one line of stem cells can continue to make new stem cells, thus for example could produce a large amount of skin tissue for a burn patient.

Embryonic Stem Cells and Embryonic Germ Cells

Embryonic stem (ES) cells are defined by their origin in the blastocyst stage of the embryo. ES cells are pluripotent, not totipotent because unlike the fertilized egg, ES cells cannot by themselves produce a new organism. At this early stage they still have the ability to become any of the cells of the human body, but they are not totipotent as they can no longer become a part of the embryonic membrane or the placenta. Scientists have developed very specific criteria for defining ES cells. Austin Smith, a researcher of mouse ES cells, compiled the following list of characteristics necessary for defining ES cells:

Table I: Defining Properties of an Embryonic Stem Cell

- ^a Derived from the inner cell mass/epiblast of the blastocyst

- ^a Capable of undergoing an unlimited number of symmetrical divisions without differentiating (long-term self-renewal)
- Exhibit and maintain a stable full (diploid) normal complement [complement] of chromosomes (karyotype)
- Pluripotent ES cells can give rise to differentiated cell types that are derived from all three primary germ layers of the embryo (endoderm, mesoderm, and ectoderm)
- ^{a,b} Capable of integrating into all fetal tissues during development. (Mouse ES cells maintained in culture for long periods can still generate any tissue when they are reintroduced into an embryo to generate a chimeric animal.)
- ^{a,b} Capable of colonizing the germ line and giving rise to egg or sperm cells.
- ^a Clonogenic, that is a single ES cell can give rise to a colony of genetically identical cells, or clones, which have the same properties as the original cell.
- Express the transcription factor Oct-4, which then activates or inhibits a host of target genes and maintains ES cells in a proliferative, non-differentiating state.
- Can be induced to continue proliferating or to differentiate.
- Lack the G1 checkpoint in the cell cycle. ES cells spend most of their time in the S phase of the cell cycle, during which they synthesize DNA. Unlike differentiated somatic cells, ES cells do not require any external stimulus to initiate DNA replication.
- Do not show X inactivation. In every somatic cell of a female mammal, one of the two X chromosomes becomes permanently inactivated. X inactivation does not occur in undifferentiated ES cells.

(^a not shown in human EG cells. ^b Not shown in human ES cells. All of the criteria have been met by mouse ES cells) (Stem Cells... 2001)

As the zygote divides, the daughter cells produced are called blastomeres. When there are about 4-16 cells, they clump together to form a cluster called a morula. When number of cells reaches 40-150 blastomeres they form a hollow sphere, or blastocyst, the cavity of this sphere is called a blastocoele. The outer cells of the blastocyst, the trophoblast, will eventually form the embryonic membrane and placenta, while the inner cell mass (ICM) or embryoblast will form the embryo. (Figure 2) Through the process of gastrulation the ICM is then further divided into three germ layers, the ectoderm, mesoderm, and endoderm. Each of these layers will eventually develop into all of the tissues of the adult organism (*Mammalian embryogenesis*, 2005). The ectoderm layer will develop into skin, dermal appendages, and brain and neural tissue, the mesoderm layer becomes connective tissue, muscle, bone and blood vessels, and the endoderm layer gives rise to the gastrointestinal tract and internal glandular organs (*Sell*, 2004). Embryonic stem cells are derived from these inner cells of the blastocyst, at an early stage of the embryo before it is implanted in the uterine wall (*Stem Cells...* 2001).

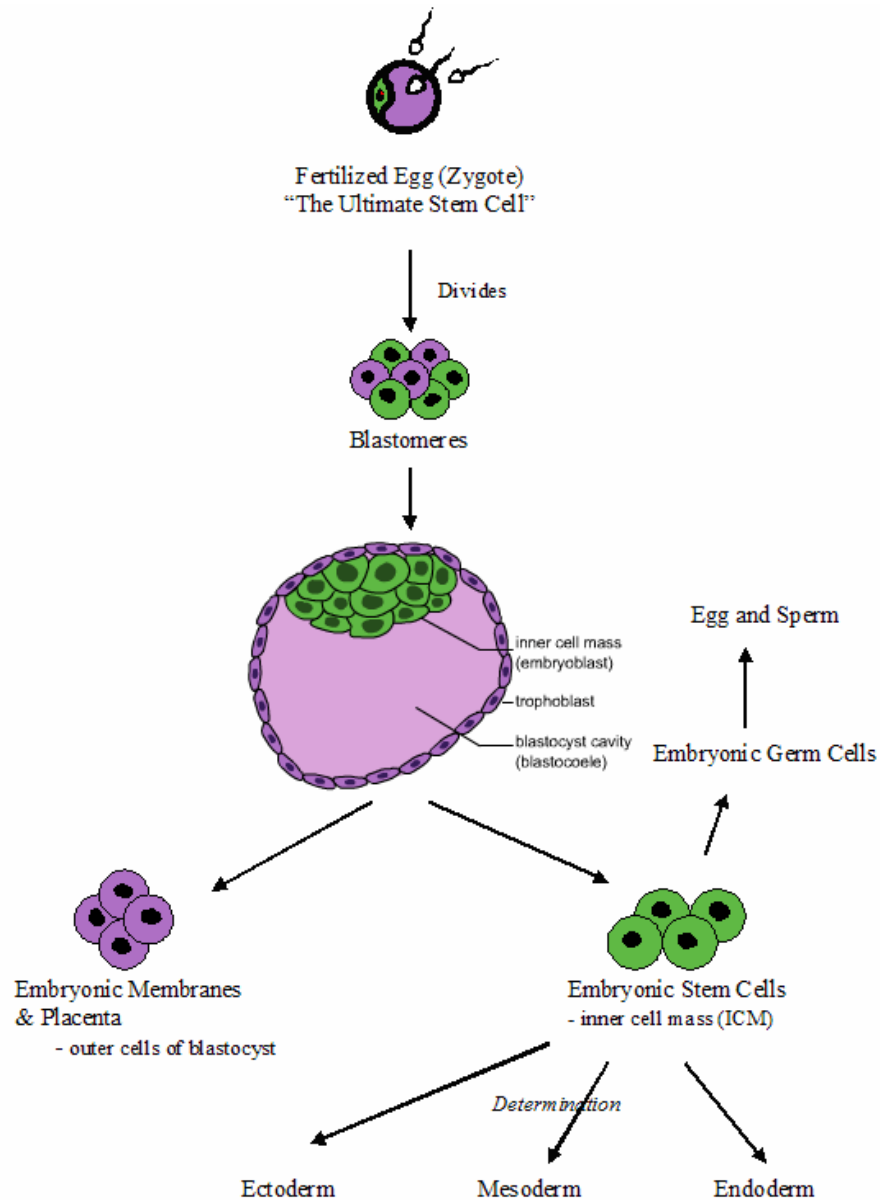


Figure 2. The development of the fertilized egg as it divides into blastomeres which then form the blastocyst from which embryonic stem cells are isolated.

Under certain conditions, such as the presence of LIF, leukemia inhibitory factor, ES cells can theoretically proliferate indefinitely. To this point researchers have maintained undifferentiated ES cells in culture for more than a year and up to 300 population doublings. However, if the ES cells are allowed to clump together to form

embryoid bodies they will begin to spontaneously differentiate into different types of specialized cells (*Stem Cell Basics*, 2005). It is unclear at this time what causes a stem cell to remain undifferentiated. Transcription factors such as Oct-4, expressed by human and mouse ES cells *in vivo*, as well as the cell cycle of the cell, are thought to play a role in maintaining the stem cells undifferentiated state.

Embryonic germ (EG) cells are isolated from the embryo or fetus, specifically from the gonadal ridge, and eventually form the germ cells of the organism. EG cells, derived from the primordial germ cells found in the gonadal ridge, are closely related to ES cells. Both are pluripotent, replicate for an extended period of time, and generate both male and female cell cultures. However, EG cells cannot be maintained in culture as long as ES cells and they do not produce teratomas, which are germ cell tumors made up of cells from all 3 germ layers, when injected into colonies of mice cells with compromised immune systems (*Stem Cells... 2001*).

Although ES and EG cells are the most potent type of stem cells known at this time, there is an ongoing debate about whether or not their potential in medicine should be further researched. Because the isolation of ES cells requires the destruction of an embryo or fetus, many view the scientific exploration of their properties and uses as unethical.

Adult Stem Cells

Adult stem cells, or somatic stem cells, are unspecialized cells that are found in specialized tissues, unlike ES cells they are not pluripotent, they only become specific types of cells. Although they are not pluripotent, adult stem cells do allow for tissue

renewal and growth. These stem cells are theorized to be located in certain areas of each tissue where they do not divide until they are triggered by injury or disease (*Stem Cell Basics*, 2005). They serve to maintain the constant functioning of the organism and, to an extent, to replace cells that die (*Stem Cells... 2001*). Adult stem cells, in comparison to other cells in the body, are rare. Only a small population of them can be found in adult tissues, and their origin is still uncertain in most tissues. Adult stem cells have been found in numerous places throughout the body, including the brain, bone marrow, peripheral blood, skeletal muscle, the spinal cord, blood vessels, dental pulp, retina, liver, pancreas, cornea, and epithelia of the skin and digestive system (*Stem Cells... 2001*).

Adult stem cells enter “normal differentiation pathways” where they divide and mature, eventually generating specialized cells specific to their type. The pathways of various kinds of adult stem cells are outlined as follows in *Stem Cell Basics* by the Department of Health and Human Services:

Stem Cell	Source	Types of Cells Produced
Hematopoietic	All types of blood cells	Red blood cells, B lymphocytes, T lymphocytes, natural killer cells, neutrophils, basophils, eosinophils, monocytes, macrophages, and platelets
Bone Marrow Stromal (mesenchymal)	Connective tissues	Tendons, osteocytes (bone cells), adipocytes (fat cells), and chondrocytes (cartilage cells)
Neural	Parts of the nervous system	neurons, astrocytes, and oligodendrocytes
Epithelial	Lining of the digestive tract	Absorptive cells, goblet cells, Paneth cells, and Enteroendocrine cells
Epidermal	Basal layer of the epidermis	Keratinocytes (forms the protective layer of the skin)
Follicular	Base of hair follicles	Hair follicles and the epidermis
Hepatic	Liver	Hepatocytes

Table 1. The normal differentiation pathways of adult stem cells. (*Stem Cell Basics*, 2005)

Adult Stem Cell Plasticity

Adult stem cells are normally thought to be “committed” to differentiating into a certain type of cell, but as mentioned earlier, recent experiments have suggested that even adult stem cells may retain some plasticity. Plasticity is the ability of a stem cell from one tissue to produce a differentiated cell of another type of tissue. This phenomenon reinforces the theory that some adult stem cells retain pluri/multi-potency throughout the life of the organism.

Some examples of this plasticity include hematopoietic stem cells that are able to differentiate into the three major types of brain cells, skeletal muscle cells, cardiac muscle cells, and liver cells, bone marrow stromal cells that are able to differentiate into cardiac and skeletal muscle cells, and brain stem cells that are able to differentiate into blood cells and skeletal muscle cells (Figure 3). If this plasticity can some day be controlled it could lead to new treatments where diseased or injured tissues can be replaced by healthy tissue (*Stem Cell Basics*, 2005) without having to use ES cells from embryos.

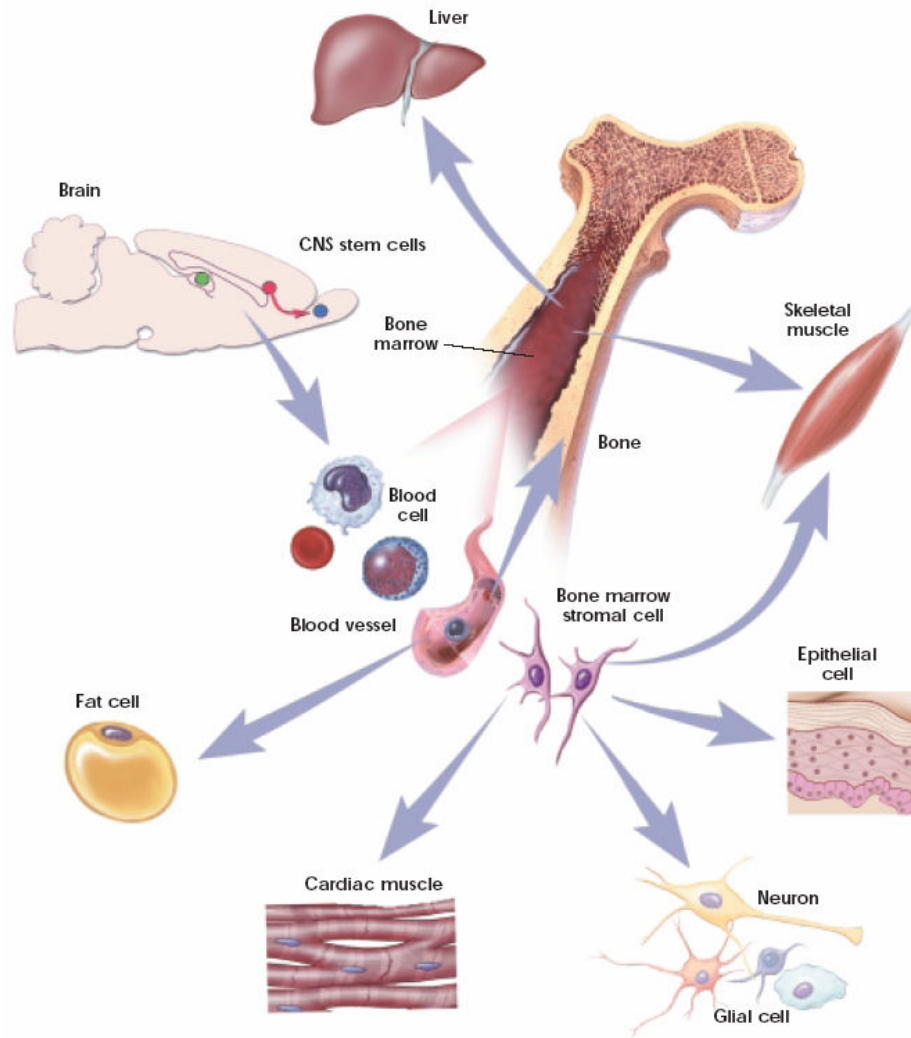


Figure 3. Diagram of plasticity in non-human adult stem cells (*Stem Cells.*, 2001).

Adult Stem Cell Isolation

Scientists hope to grow adult stem cells in culture and learn how to direct them to produce certain cell types that can be used to treat specific diseases or injuries, such as insulin producing cells for diabetics. It is difficult to identify adult stem cells, especially *in vivo* because it is nearly impossible to show that the cell is self-renewing throughout the entire life of a complex organism or that it is clonogenic, meaning that is able to

divide and produce a line of identical cells. Adult stem cells do not have the specific criteria as embryonic stem cells to identify and classify them, but certain methods have been developed by researchers to distinguish them from other types of cells. Often one of the following three methods is used: 1) labeling the cells with molecular markers and then determining the specialized cells they produce; 2) transplanting labeled cells from one living animal to another to determine if the cells repopulate their tissue of origin; and 3) isolating and growing the cells in culture and manipulating them to determine what types of cells they can generate (*Stem Cell Basics*, 2005).

Adult Hematopoietic Stem Cells

There are 5 sources of hematopoietic stem cells (HSCs): 1) bone marrow, 2) peripheral blood, 3) umbilical cord blood, 4) blood from the fetal hematopoietic system, and 5) ES and EG cells as they can potentially be manipulated to give rise to any kind of adult stem cell (*Stem Cells...* 2001). HSCs are most commonly isolated from bone marrow. They are responsible for the production on all of the types of blood cells found in the body. Of all of the different kinds of adult stem cells, HSCs are currently the best understood and the only kind of stem cell that is routinely used as treatment for cancer and other disorders affecting the blood and immune system. HSCs have been studied for over 50 years and the first successful bone marrow transplant in the United States took place in 1968. The first successful transplant between an unrelated donor and recipient was in 1973. Few members of the general public know that stem cells have been effectively used to treat diseases for over 30 years (*History of Stem Cell Transplants*, 2005). Originally HSCs were used in bone marrow transplants where the recipients own

hematopoietic system is irradiated to wipe out their own blood-producing cells and replaced with bone marrow from the donor. About 1 in every 10,000 to 15,000 cells in the bone marrow and 1 in every 100,000 in the peripheral blood is thought to be a hematopoietic stem cell. Now that a method of using a cytokine to urge the stem cells to migrate out of the marrow has been developed, peripheral blood is commonly used as it is a less invasive procedure. ES and EG cells as well as fetal blood are not currently used in HSC treatment due to the ethical issues that they incur.

Umbilical Cord Stem Cells

Stem cells isolated from the umbilical cord have the same multipotency as bone marrow HSCs, but do not have the potency of ES and EG cells, and the controversy of destroying an embryo is avoided. Although there have been suggestions of cord blood containing multipotent stem cells, to this point only hematopoietic cells have been identified. Stem cells from cord blood differ from those found in the bone marrow and peripheral blood: the potential for HSC's to repopulate the hematopoietic system after transplants tends to decrease as the cells age, thus cord HSCs are "younger" than marrow HSCs, and HSCs found in the umbilical cord are less likely to cause immune reactions in the recipient. In this way cord blood seems advantageous to other sources of HSCs, however, cord blood does not yield enough stem cells to use in an adult transplant, so some labs are developing ways to amplify cord HSCs for treating adult patients (Viacell, 2002).

Parthenotes

A possible alternative source of embryonic stem cells has recently been discovered. In certain invertebrate species (such as ants and bees) the female is able to reproduce without male fertilization, this is called parthenogenesis. Worker bees and ants are produced by this process. Parthenogenesis does not happen naturally in more complex organisms, such as humans, but it can be induced artificially. Scientists have used chemicals to imitate the fertilization of the egg by sperm, causing the egg to divide on its own (without eliminating half of its chromosomes) and develop into something very much like a normal embryo. In mammals the embryo that results from this treatment never develops past the early stages of the fetus, meaning they have no potential to become a living organism, they do however develop into a blastocyst from which ES cells have been derived in monkeys (Cibelli et al, 2002). The egg normally contains a full set of chromosomes until fertilization, when half of the chromosomes are expelled and the other half of the chromosomes are then supplied by the sperm, if this process of elimination is suppressed the egg will contain the full number of chromosomes. If the chromosomes from the egg are completely replaced by chromosomes from two of a male's sperm cells a male parthenote can also be created. Researchers have found that female parthenotes tend to generate brain and nerve cells, while male parthenotes tend to generate muscle cells (Pollack, 2001).

Scientists have successfully induced parthenogenesis in human eggs that developed to the blastocyst stage (Cibelli et al, 2001) but no human parthenote ES cell lines have been established yet. Parthenogenesis was induced in 77 macaque monkey eggs, and out of those one yielded a stable line of pluripotent stem cells (Cibelli et al,

2002; Holden, 2002). Researchers were then able to manipulate these stem cells into generating neurons, smooth muscle cells and heart-like cells (*Parthenogenic Stem Cells...*2002). At this time there are many unanswered questions about the usefulness of the stem cells isolated from parthenotes. Without the influence of both male and female chromosomes that mammals require it is possible that the stem cells will not develop normally, and some scientists doubt that they will prove useful in therapeutic cloning (Weiss, 2001). Parthenotes, if found to be a reliable source, seem to be an answer for resolving the ethical debate over embryonic stem cells, however new arguments have arisen around the religious association to “virgin births” and the public’s possible uneasiness with women donating eggs for this purpose and “the idea of producing a creature whose status as a life-form is entirely ambiguous” (Holden, 2002).

CHAPTER 2: STEM CELL APPLICATIONS

The human body houses approximately 220 different types of cells. These cells, when functioning properly, do their part to make the human body work as a fairly efficient machine. When even one type of cell does not appear to be in good working order, it is visibly evident in the health of the individual. It usually does not require a doctor to diagnose a person with some sort of disorder, but it would require one to explain and correct it. An attack on one type of cell could leave someone with a faulty nervous system or faulty heart, for example. Many of the problems are easily fixed through a surgery or some sort of antibiotic; but there are a handful of diseases that still leave doctor's scratching their heads.

Leukemia can be corrected through a long, arduous process. As far as diabetes is concerned, doctors are usually able to keep it in check as long as the patient takes their medicine regularly and on time. Parkinson's disease and cancer only sometimes respond to current therapies. As time passes, efforts are constantly made to identify new leads in cracking these puzzles. So complex are these puzzles that not even MENSA candidates could possibly decipher them. In the past few years, researchers have been able to elaborate greatly on the idea of stem cell research being the missing key in cracking the code for certain diseases and saving millions of human lives. The idea may have started out as a long-shot, but has quickly become the frontrunner in eradicating some of the world's more resilient diseases.

These diseases cause mutations in the body's cells making them act in a certain way as to disrupt the body's natural working order. In some cases, these diseases are

hereditary with a person's DNA containing the code for these diseases. DNA is a puzzle of its own with different sequence making a very unique masterpiece. When a disease mutates a piece or pieces of this masterpiece, there is a need for a correction to that piece or pieces. Stem cells can make that correction in order to restore the masterpiece that once was to its original working order. While research is being done to verify this hypothesis in human embryonic stem (ES) cells, we have already seen strong evidence that success can be achieved in humans with adult stem cells, or in animals with ES cells.

Hematopoietic Stem Cells and Leukemia

It is untrue that stem cells have yet to save human lives. The hematopoietic stem cell (HSC) has been used for many years in Leukemia patients to send the Leukemia into an ultimate remission. This type of stem cell can be found in bone marrow. As discussed in chapter 1, HSCs are multipotent, capable of generating all the various cellular components of the blood (figure 1). Since leukemia is a blood cell disease, it is a logical choice for HSC treatment. The HSC is capable of replicating for the entire life of the organism. A bone marrow registry has been setup for those Leukemia patients that may need a transplant to survive. The transplant calls for a donor match so none of the cells are rejected by the patient's immune system. Once the patient's bone marrow has been destroyed by radiation or chemotherapy, the new marrow HSCs replicate making red blood cells and white blood cells, all of which help in constant body maintenance.

Recently this process has been refined using HSCs isolated from umbilical cord blood. Cords are donated by the mother at time of birth, and the blood is frozen for

storage. Cord HSCs are more abundant than in bone marrow, and they are less likely to be rejected by the patient.

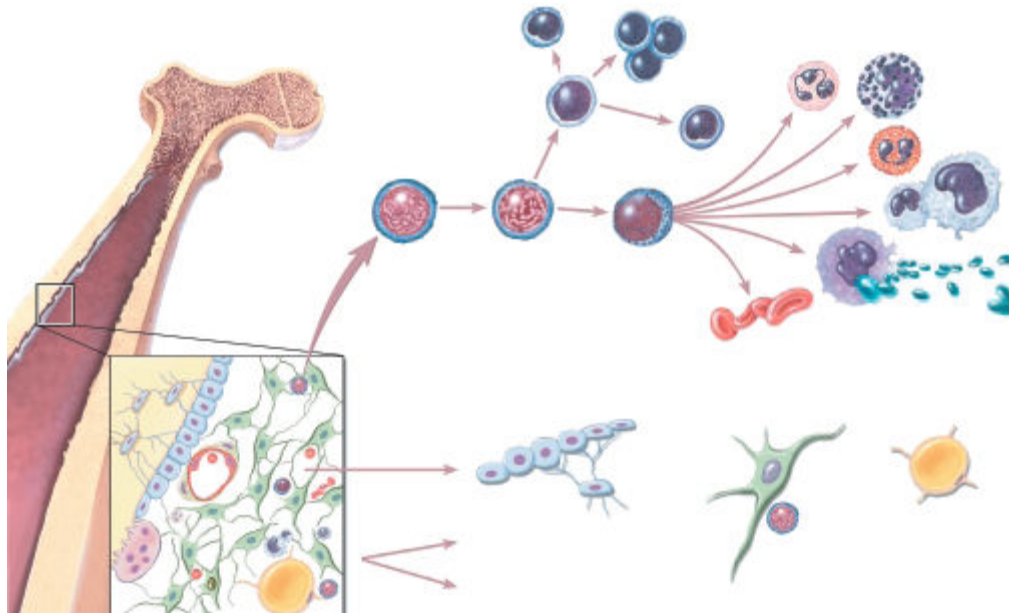


Figure 1: Diagram of Hematopoiesis, the Formation of Blood Cells by HSCs. The top lineage illustrates the differentiation possibilities for HSCs, while the bottom lineage illustrates the differentiation possibilities available for stromal stem cells (Hematopoietic Stem Cells, 2005).

Embryonic Stem Cells

A more powerful form of relief is contained within embryonic stem cells.

Although this method is highly controversial, the possibilities that lie within the heart of these cells are multitudinous in number. ES cells are the master cells that can differentiate into almost any type of cell in the human body.

While these cells are pluripotent, human life is too fragile to experiment with. Scientific testing usually begins with lab animals, mostly mice. Scientists have been able to culture mouse embryonic stem cells in the presence of low insulin concentrations. This prompted the cells to increase their insulin production almost sevenfold (Stem Cells and Diabetes, 2005). Therefore, ES cells seem to provide more of a hope in the fight

against the world's more threatening, and seemingly unbeatable, diseases. Their versatility is surpassed by nothing else. Lung cells, heart cells, liver cells, and muscle cells all can emerge from ES cells. Theoretically, this is the ultimate utility tool for fixing our fragile frames.

Diabetes

In the United States alone, approximately 18.2 million people have diabetes. Of those 18.2 million, 13 million are actually diagnosed with some form of diabetes; while the other 5.2 million are unfortunately unaware (All About Diabetes, 2005). A person who suffers from diabetes cannot produce a hormone called insulin. It is also possible that they can produce the insulin but the body may misuse it. Insulin in the body is used to convert sugars, starches and foods into energy (All About Diabetes, 2005).

Insulin is normally produced in the beta islet cells of the pancreas (Figure 2). Scientists, one day, hope to be able to coax ES cells into differentiating into insulin-producing beta cells (Kahn, 2005). The belief is that the effect of new, working beta cells will work as if they had been there the entire span of the patient's life. Once the cells have matured into pancreatic beta cells, they will begin to secrete insulin that will hopefully prove enough to control, and maybe eliminate, type 1 diabetes (Kahn, 2005). There is, however, a slight obstacle in following this line of thinking. Type 1 diabetes is an autoimmune disease. It can destroy new beta cells should they appear from a donor. This is not say that it will definitely happen every time a beta cell is transplanted to a person with type 1 diabetes. There have been plenty of successful transplants. This method is, unfortunately, limited due to a short supply of donors. There are about three to five thousand donors compared to the approximate 800,000 people diagnosed with

type 1 diabetes (Kahn, 2005). Recent ideas also focus on encapsulating the islet cells to prevent their destruction in the host from the autoimmune attack.

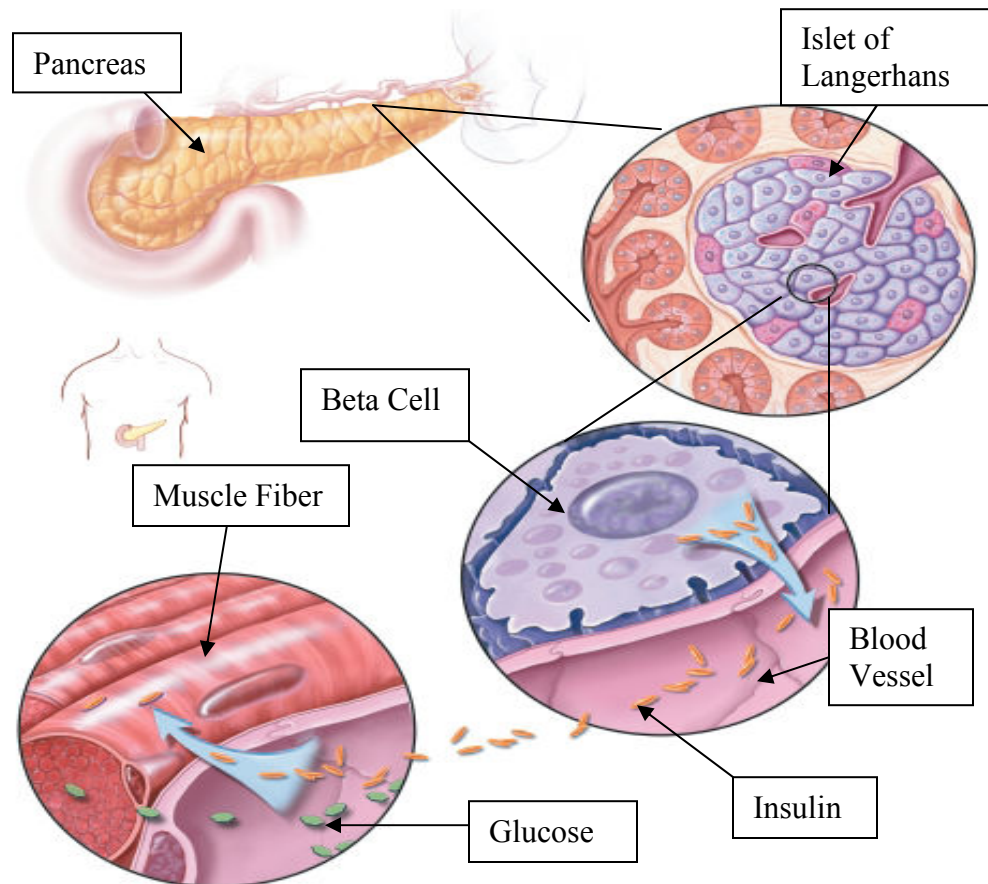


Figure 2. Insulin Production in the Human Pancreas. The pancreas is located in the abdomen, adjacent to the duodenum (the first portion of the small intestine). A cross-section of the pancreas shows the islet of Langerhans which is the functional unit of the endocrine pancreas. Encircled is the beta cell that synthesizes and secretes insulin. Beta cells are located adjacent to blood vessels and can easily respond to changes in blood glucose concentration by adjusting insulin production. Insulin facilitates the uptake of glucose, the main fuel source, into cells of tissues such as muscle (Stem Cells and Diabetes, 2005).

With transplant relief in such short supply, we are forced to find new ways of therapy that can allow for the supply to last a while longer. Researchers have had some success with obtaining islet cells from an adult cadaver and teasing them to express the PDX-1 gene, a characteristic gene of insulin-producing beta cells. A great deal of engineering is necessary for this step, but nothing is too much if it works in the end. The

big question with this method is under what conditions can these cells be cultured and coaxed into becoming efficient insulin secretors (Stem Cells and Diabetes, 2005).

The keyword here is efficient. Ron McKay and his colleagues were able to culture mouse ES cells into producing insulin; but, once introduced into a diabetic mouse, they were unable to reverse the diabetes. The silver lining to the experiments was that the cells did remain insulin producing cells, they just could not produce enough of the insulin needed for reversal (Stem Cells and Diabetes, 2005).

It is also possible to culture cadaver cells but it has been found through study that the cells that proliferate well don't produce insulin, and the ones that don't proliferate are very efficient insulin secretors. Ammon Peck, Vijayakumar Ramiya and their colleagues have recently been able to perform this procedure with the use of adult mouse cells. They were able to obtain islet-like clusters that consisted of the four main components excreted from the pancreas— insulin, glucagon, somatostatin, and pancreatic polypeptide. When these four substances were found to be present, it was not too long afterwards that the diabetes was reversed (Stem Cells and Diabetes, 2005).

Type 2 diabetes is unique in that it does not hurt the insulin-producing cells; but, rather, it is unaffected by the presence of insulin. It would appear that stem cell research cannot be of much assistance to the 90% of the people in the United States who are diagnosed with type 2 diabetes, never mind the entire world (Kahn, 2005). The prospects for alleviating type 1 diabetes, however, are not too far off in the future. The next obstacle seems to be overcoming the autoimmune system, and an answer may already be in the woodwork. Before transplantation, it's possible to dip the cells into a nonimmunogenic material so as to hide the cells from the body's immune system,

eliminating the need for the patient having to take immunosuppressant drugs for the duration of their life (Stem Cells and Diabetes, 2005).

Adult and ES Stem Cell Therapy of the Nervous System

If you were to get a cut, it would heal. It may take a few days, but it would heal. If you and your girlfriend or boyfriend broke up, you might be sad for a while; but, eventually, you would be fine again. Somewhere through the ages of time, the phrase, “Time heals all wounds”, was coined. Would the person who coined that phrase feel a little outdone when they look at degenerative nervous system diseases and how time cannot possibly cure them? As of now, there are still many unanswered questions on the path to finding a cure. The adult nervous system is only capable of small scale renovation, so when major damage happens like a large stroke or a disease such as Parkinson’s disease or Alzheimer’s diseases, whatever was damaged stays damaged. Recently, scientists have found a ray of light amongst the shadows that surrounded these debilitating illnesses. Neural stem cells have been found in the body, and researchers hope that maybe they can be of some assistance.

Parkinson’s Disease

Parkinson’s disease is a disorder that occurs when nerve cells in the substantia nigra part of the brain either become impaired or die (About Parkinson’s Disease, 2005). The substantia nigra is located in the middle region of the brain (Substantia Nigra, 2005) (Figure 3). This part of the brain is very important in that it allows for smooth

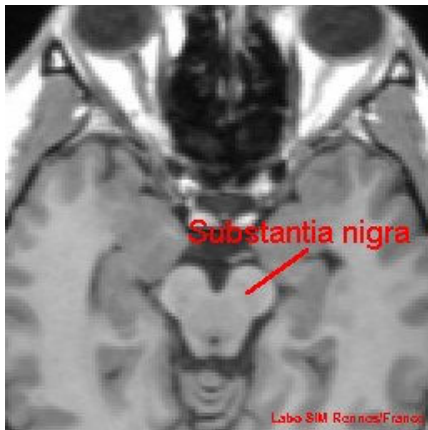


Figure 3. The Substantia Nigra
(Substantia Nigra, 2005)

functionality of the body's normal physical movements. It produces a chemical named dopamine to accomplish this task. Should the cells cease to make the dopamine, or at least 80% of the dopamine-excreting cells, symptoms of Parkinson's disease-- Tremors, stiffness and slowness of movement, to name a few-- will become evident (About Parkinson's Disease, 2005).

As of now, scientists have only been able to produce drugs that can temporarily ease the symptoms of Parkinson's disease. One of the most common treatments for this ailment is a drug known as Levodopa. The brain is able to change this drug into dopamine. Unfortunately, this is not a permanent solution. It works tremendously, initially; but as treatments using levodopa continue, the drug becomes less and less effective and the side effects become greater and greater (Rebuilding the Nervous System with Stem Cells, 2005). It's easy to say, not having experienced the disease; but it would appear that this is a losing battle in the fight against Parkinson's disease. A more drastic step in the fight against Parkinson's would be brain surgery (About Parkinson's Disease, 2005). It's not unheard of, but it is a step which must be carefully planned and carefully researched. A neurologist and a brain surgeon must be contacted and they both must specialize in Parkinson's. In the end it still only eases the symptoms (About Parkinson's Disease, 2005).

While it is comforting to know that there is some form of relief from this disease, it is still puzzling to realize that there has to be a way to put a stop to it all at once.

Scientists are looking towards two promising ideas that could bring an end to the helplessness that Parkinson's. The first is cell transplantation which involves implanting fetal cells and tissues (which include neuronal stem cells) into the brain to allow them to finish growing and inserting themselves into the patient's brain to produce dopamine. There have been mixed results with this method with many cases of improvement in a patient's condition (Rebuilding the Nervous System with Stem Cells, 2005).

While there have been rather noteworthy efforts using that fetal cell transplant technique, the public is strongly against using fetal cells for anything because fetal cells are even more mature than the blastocysts used to obtain ES cells, so the public argues they have higher moral status. Also, scientists would really like to know whether the cells can replicate to produce more dopaminergic neuronal cells to keep the patient free and clear of Parkinson's for the duration of their life.

The second method that scientists are researching at the moment is isolating and growing the recently discovered adult neuronal stem cells and implanting them in a patient's brain to be allowed to differentiate into dopamine-producing cells. This is exciting and it sounds like it is exactly what a doctor would order if they could order something to fix up this problem. The biggest obstacle, however, lies in culturing neuronal stem cells. They are very difficult to culture in a lab, at least not without some form of engineering being performed on them (Rebuilding the Nervous System with Stem Cells, 2005).

Well, when in doubt, look to the pluripotency of embryonic stem cells to save the day. In 1998, Ron McKay, of the National Institute of Health, and his colleagues were reported being able to culture and expand a group of neurons made from mouse

embryonic stem cells. These neurons found their way into the brain of an adult rat with Parkinson's. The results of this experiment show a great improvement in the rat's condition and a recession of the disease (Rebuilding the Nervous System with Stem Cells, 2005). Human testing cannot be too far into the future.

Adult and ES Stem Cells and the Heart

The heart is the driving force behind our very being. Should it cease to work, we would cease to exist. It is a well-oiled machine, when working properly. The heart pumps the blood throughout the body. If the pathways, or blood vessels, were to become impassable, important parts of the body would not be able to get the necessary nutrients needed to function correctly. When that happens, the heart must force itself to work harder and harder to push the blood past whatever is blocking its path. If the blockage were to happen in the heart, the heart's muscle cells, cardiomyocytes, would die off. If too many of them die off, a myocardial infarction occurs. Simply put, you would get a heart attack. Approximately 1.1 million people die from heart failure in the United States each year (Can Stem Cells Repair a Damaged Heart, 2005).

Imagine a world where congestive heart disease can be corrected after first onset. Generally, we are supposed to take care of our bodies so that heart disease and heart failure can be prevented, but these things happen and it is not always preventable. Heart disease can also be brought on by reasons such as hypertension (Can Stem Cells Repair a Damaged Heart, 2005). Researchers are currently exploring the possibility of using embryonic and adult stem cells to repair damage done to cardiomyocytes. The obvious

choice would be to start with the embryonic stem cells; but, in this case, that would be an incorrect assumption (Can Stem Cells Repair a Damaged Heart, 2005).

On February 17, 2003, sixteen year old Dimitri Bonnville underwent therapy for his heart attack after open heart surgery for an impaled nail from a nail gun. His parents were given the choice for a heart transplant or an experimental procedure involving stem cell therapy. Seeing the low risk versus great rewards attractiveness of the experimental procedure, his parents opted for the stem cell therapy. He was given drugs to coax his body to produce extra adult stem cells and after four days of production, these stem cells were harvested from his own blood stream with the use of a heart catheter. They were then injected into the bloodstream that supplies blood to the front of his heart, the part of his heart that was heavily damaged. Scientists didn't even need to worry about the immune system rejecting the cells because they were his own. One week following the treatment, he was released from the hospital and was finishing his recuperation in his home (Philipkoski, 2003).

This may be one isolated incident, but it may have been the spark needed to propel this portion of stem cell research. Sensing the potential in this field, Dr. Joshua Hare decided to spearhead a study at the Johns Hopkins Hospital in Baltimore, Maryland. Forty-eight patients will check in and they will participate in a study that will test the effects of adult stem cells on damaged areas of the heart. When the test was run on pigs, the experiment ran beautifully. Out of fourteen pigs, all with heart problems, half were given adult stem cells and the other half was given a placebo. The pigs that were given the adult stem cells had healed almost all of the scar tissue and had returned the heart contractions back to normal. Those that were given the placebo actually worsened in

their condition and eventually died (Trials to test safety of stem cell therapy for heart damage, 2005).

CHAPTER 3: STEM CELL ETHICS

Stem cells, although they carry with them a great potential power, also carry a great deal of ethical roadblocks, some types more so than others. Considering what is involved in working with stem cells, many people feel that certain types of work should be deemed unethical, immoral and, in some cases, murder. There has not been a situation this hotly debated for this length of time since Roe versus Wade, which still owns the title. From chapter 1, we know there are several types of stem cells. There are adult stem cells (such as hematopoietic stem cells, neuronal stem cells, stromal stem cells, and epithelial stem cells, etc) and embryonic stem (ES) cells. The latter are usually isolated from a blastocyst (an embryo about 5 days old, the size of the period at the end of this sentence), which has potential to become an adult, so some call its destruction murder.

In a more liberal world, researchers would have proposed that stem cells can cancel out diseases such as those discussed in chapter 2, and the entire nation would have stepped aside allowing their use arguing that researchers know more about this subject than the common individual. However, the world we live in allows scientist's work to be regulated by even the tiniest of voices. These voices, even though they are heard in the streets, can carry all the way to governmental offices.

The Present Policy

On August 9, 2001, President Bush took a stand on the issue of federal funding for stem cell research. He decreed that from that point forward, no new embryonic stem cell lines were to be opened. What that meant was that scientists and researchers would

not be able to obtain embryos from donors and use them for research purposes. The only embryos, at this point, that can possibly be used in this manner would be those obtained prior to the date of our present policy (Monitoring Stem Cell Research, 2004). The rationale, as we will discuss more in chapter 4 Stem Cell Legalities, is although the blastocysts were destroyed to obtain the ES cell lines, perhaps those existing cell lines can be used to save lives. The past cannot be tampered with. The administration, however, will not be a part of furthering the supply by lending federal funds for destroying more embryos. So the ethical debate for ES cells centers on whether the destruction of a blastocysts constitutes murder. To answer this question, we turn to the world's four major religions to see their stance on when life begins.

Number of Embryos Destroyed versus Lives Saved

Maybe it is possible that the general public is unaware of the awesome power that is at our disposal with stem cells. One human embryo can produce about forty stem cells (Weiss, 2005). As of the present moment, there is a huge fight about what to do about the approximate 400,000 frozen embryos that are in storage inside in vitro fertilization clinics (Freking, 2005). It is a stretch, but here is a crazy idea. We could use them to save someone's life from an unpleasant and abrupt end. In Seoul, South Korea, scientists have come up with a new method for the use of hES cells. Their original method used about 242 cells. Their new and improved method has cut this from 242 down to the use of about 20 hES cells (Scientists match stem cells to patients, 2005). Their work has been proven to be effective in human testing. The math works out to being able to save approximately 800,000 people. Call it a crazy idea, or even insane, but the numbers

speak for themselves. Those forty hES cells can be cultured in a medium and under the right conditions can produce millions of healthy cells and can replicate infinitely. The number of people that can be saved from these cells would be endless.

The thought of 400,000 lives being destroyed is a sore sight, from a conservative view. So if you look closely, every embryo has the potential to save multiple lives. Since the argument being thrown against the researchers is that we should not destroy nascent human life, why should we throw away existing lives for the sake of one potential life the size of a dot. All efforts until now have been the equivalent of a band-aid for a broken leg. Being allowed to complete this stem cell research would be the equivalent of mending the broken bone on the spot and the person being able to walk away.

Religious Stances on Stem Cells

Hinduism

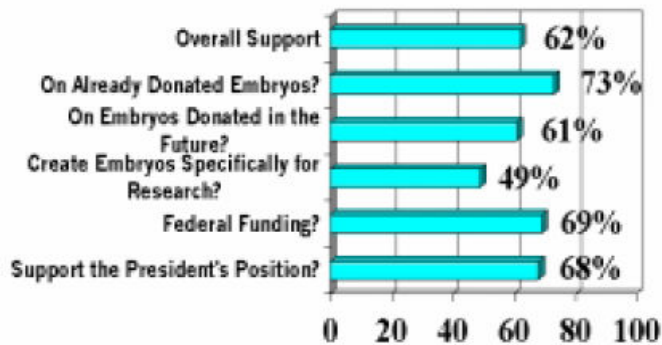
The traditional Hindu belief is that life begins at conception, which is the point when a person is reborn from their previous life, or reincarnated. Some believe that ‘ensoulment’ or the beginning of personhood takes place between the 3 and 5 month of gestation. However, Swami Tyagananda, a Hindu chaplain at the MIT Religious Activities Center, argues that ES cell research and therapy may be justifiable as it is considered an “extraordinary, unavoidable circumstance,” and an act done “for the greater good”(Reichhardt, 2004). While abortion and any other kind of killing of the fetus at any stage is considered murder, abortion is still practiced in Hindu culture in India because of the cultural preference for boys.

Islam

Traditional Muslim belief supports ES cell research for forty days after fertilization. Most Muslim's believe that it is after the blastocyst stage when the fetus becomes a person, and that 'ensoulment' is a developmental process that does not occur at the moment of conception. Although the embryo and fetus are considered sacred, and it is not acceptable to abort them, under certain circumstances it is permissible to use them to benefit the human population.

Studies done by the Islamic Institute polling the opinions of Muslim Americans show that the majority of the Muslim community in the United States supports ES cell research (Figure 1). Through the Islamic method of forming an opinion about controversial matters, *ijtihad*, where a panel of "qualified Islamic scholars" review current research, and through careful consideration decide on a position that conforms to Muslim belief (The Islamic Institute, 2001), it was decided that stem cell research should proceed. Although Muslim teachings inherently reject human cloning experimentation, the process of IVF is generally seen as a, "compassionate and humane scientific procedure to help infertile couples bear children," but only when they are preformed under strict guidelines, including that the couple must be married (The Islamic Institute, 2001). Because this procedure inevitably produces spare embryos, the Islamic Institute not only supports using these embryos as a source of ES cells, but feels that it is a, "societal obligation" (The Islamic Institute, 2001).

American Muslim Support for Stem Cell Research*



*10 Question Poll of 629 individuals

Figure 1. Poll of Muslim American's Opinion on ES Cell Research (The Islamic Institute, 2001).

Judaism

Judaism also teaches that life is acquired progressively; the embryo is not given human status until the 40th day of gestation (well past the blastocyst stage), once the embryo begins to take human form (Green, 2001b). The Union of Orthodox Jewish Congregations stated that, “an isolated fertilized egg does not enjoy the full status of personhood” (*Religious Views...2001*). In fact, some Jews believe that ‘ensoulment’ is not achieved until the moment of birth. So, while it is wrong to unnecessarily abort a fetus, it cannot be considered murder. However, an abortion is permitted if carrying the child is a threat to the mother’s health or if the fetus is “severely defective” or has a terminal illness (Dorff, 2002). In fact, due to Judaism’s emphasis on protecting and healing the body, “an abortion must be performed to save the life or the physical or mental health of the woman, for she is without question a full-fledged human being with all the protections of Jewish law, while the fetus is still only part of the woman’s body” (Dorff, 2002).

The Jewish faith also places a strong emphasis on human healing (Ayon, 2002). “What would be ‘immoral and unethical’ is cutting off funds for promising medical research,” says The Religious Action Center of Reform Judaism (*Religious Views...2001*). Judaism views our ability to heal as a gift from God and by not utilizing this gift is, “turning God down” (Ayon, 2002).

This support is conditional however; the embryo from which the stem cells are isolated must be aborted legitimately under Jewish law. They also support the use of excess embryos from IVF procedures, as embryos formed outside of a woman’s body have an even lower status than those in the first 40 days of gestation (Dorff, 2002). The subject of creating embryos specifically for research purposes is more difficult. Some Jews feel that this should never be permissible, while other believe that it can be permitted under the condition that the woman only does this once or twice in her life due to the increased risk of developing ovarian cancer from drugs causing hyper-ovulation (Dorff, 2002).

Christianity

Some Christians approve of ES cell research under certain conditions, while others believe that it is unethical under any circumstances. The majority of Christians believe that life begins at conception and is sacred from that moment on.

Catholic officials are strictly opposed to the destruction of embryo’s under any conditions, ES cell research is “immoral, illegal, and unnecessary,” as said by the U.S. Roman Catholic Bishops (*Religious Views...2001*). Catholicism is the only major religion that is opposed to the *in vitro* fertilization (IVF) methods which, along with

cloning, are the main sources for ES cells. The IVF clinics often destroy excess embryos, and these embryos could be used as a source of ES cells. This is a popular method for allowing infertile couples to have children, however, the Catholic Church believes that it, “breaks the God-given connection between sex and procreation” (Reichhardt, 2004).

The position of Protestant denominations ranges from the Southern Baptist Convention, who believe that the embryo is the “tiniest form of human life and should not be destroyed,” to the American Presbyterian Church, who support ES cell research, “if the goals cannot be reached in any other manner” (Green, 2001b). Although the group itself has no official position on stem cell research, the president of the Unitarian Universalist Association, William Sinkford stated his belief that there should not be a ban on stem cell research, but, “no human embryos should be created specifically for stem-cell experimentation, thus turning human life and human reproduction into a commodity — surely a clear affront to our first principle affirming the inherent dignity of human beings” (Reichhardt, 2004).

Even those Christians that do not believe that the embryo is fully human argue that they are still, “deserving of respect”. Nigel Cameron, a bioethicist at the Institute on Biotechnology and the Human Future in Chicago, Illinois, and an evangelical Christian believes that, “It is by no means necessary to take the view that the early embryo is a full human person in order to be convinced that deleterious experimentation is improper” (Reichhardt, 2004).

Thus in the end, three of the worlds four main religions and some Christians agree that working with ES cells is ethical so long as the cells are used to help save lives, and

so long as the embryos used to obtain them were not produced exclusively for that purpose.

Opposition's Views on Embryonic Stem Cell Research

Immoral, attack on innocent life, a form of abortion; these are phrases that can be heard throughout the streets. Embryos deserve a chance to become human life. Who are we to say that they are not to be allowed to live? We are not here to play God.

The Catholic Church stands against this research that utilizes and destroys the embryos. No price can be put on human life, living or nascent. These embryos can become a human life; and, therefore must be protected as if it already were a human soul. We have been put on this Earth to be fruitful and multiply. We are negatively contributing to the second part of that charge if we were to allow the research done upon these embryos. In a meeting with President Bush on July 23, 2001, the Pope stated, "In defending the right to life, in law and through a vibrant culture of life, America can show the world the path to a truly humane future in which man remains the master, not the product, of his technology (Pope John Paul II Addresses President Bush, 2001)." We should all heed these words, especially the part about being the master of our technology and not the product of it.

Parthenote Ethics

Parthenotes are eggs, embryos, or individuals that are created without fertilization. In a lab setting, parthenotes are created by chemically treating eggs so cell division initiates. Parthenotes appear to be the ideal answer to the stem cell debate, if

they prove to be a viable source of human ES cells. Regarding mammalian parthenotes, parthenote blastocysts have already been created in monkeys (Cibelli et al, 2002) and man (Cibelli et al, 2001), but so far ES cells have only been derived from parthenote blastocysts in monkeys (Cibelli et al, 2002). Mammalian parthenotes do not have the ability to develop past the early blastocyst stage, so they can not make an individual, thus they have lower moral status than an embryo obtained by fertilization. They do theoretically give rise to ES stem cells, although whether these stem cells could be successfully used in medical treatments has not been proven.

Three of the world's four main religions fully support the use of parthenote blastocysts as an alternative source of ES cells. Some in the Catholic Church are the exception, although not all Catholics agree. This support is based on the premise that no mammalian parthenote could ever develop past the blastocyst stage. Because parthenotes do not develop past this stage they have less moral status than embryos produced by fertilization. If scientists find a way to make mammalian parthenotes develop past this stage to become a fetus or be born, their moral status would increase and the validity of using parthenotes as an ethical alternative to embryos would need to be reassessed.

Those in the Catholic Church who do not support the use of parthenotes cite the Congregation for the Doctrine of Faith's *Donum vitae*, which teaches that any attempt to produce, "a human being without any connection with sexuality through 'twin fission,' cloning or parthenogenesis are to be considered contrary to the moral law, since they are in opposition to the dignity both of human procreation and of the conjugal union" (Latkovic, 2002) Their argument is that the Catholic faith is opposed to parthenogenesis in general because it is an attempt to unnaturally form a human being. This argument is

slightly confusing however, because the reasoning for using parthenotes rather than embryos as a source of ES cells is precisely that it would *not* be forming a human being.

Chapter Conclusion

The opposition would say that medical science, if they believe heavily in its strengths, is here to save lives not take them. Scientists would most likely not have to destroy the embryos if they can make life from it, should there be an alternative. Unfortunately, it seems that this provides the most promise at the moment. The time for “modern medicine” has arrived. The diseases do not seem to respond the way we would have hoped. It is time to look towards futuristic medicine to get the job done. It is time to consider stem cells penicillin for the 21st century.

To address the other option of possibly using the adult stem cells instead of the embryonic stem cells, all four major religions support their use so long as they are used to save lives. Unfortunately these cells do not have the pleuri-potencies of ES cells, but the authors of this IQP strongly support their use whenever possible.

The embryonic stem cells have been chosen for the bulk of the disease for a couple of reasons. The first reason is their ability to differentiate into almost any of the approximate 220 types of cells. Adult stem cells can differentiate into about six types of cells. Those six types of cells are limited to neuronal activity and the blood (Weiss, 2005), although more are being discovered all the time. The second reason is that the embryonic stem cells are a lot easier to culture and isolate than adult stem cells. Adult stem cells are scarcer in the body and, therefore, a lot harder to isolate.

The scrutiny that scientists have had to endure over this subject alone is enough to drive anyone insane. How is it possible to stand in front of someone and tell them that you don't think it is ethical to destroy embryos that have been fertilized on a lab bench and forget about the millions of existing lives that can be saved? How can someone call scientists murderers for destroying a cell mass barely visible, that has no brain or feeling, and protest in front of research labs? By shutting down their research isn't it possible that they are the bigger murders. Kill a few embryos or doom millions to a slow eventual death. Too many times, people have a tendency to think about the present when it should be time to think about the future.

It is comforting to see that people are starting to warm up to the idea of hES cell research. In a recent poll taken in Boston, MA from June 6, 2005 to June 12, 2005, sixty-seven percent of the residents polled said they were in favor of using taxpayer money to fund stem cell research. Forty percent said they were strongly in favor (Wallace, 2005). The poll had reached only 405 residents of the Hub, but this is at least an indication that the people of this country are slowly being educated on this subject. It wouldn't be too surprising to find out that those who protest this subject know very little about the details involved with stem cell research, especially adult stem cell research.

It is not just Boston who has started to learn about what we are dealing with, however. A Wisconsin senator tried to push for a ban in Wisconsin and at the University of Wisconsin-Madison on stem cell research. Senator Scott Fitzgerald was denied on both accounts (Still, 2005). There is even a recent push in the House of Representatives for federal funding on stem cell research. The most recent vote, in May 2005, was 238 to 194 in favor of federal funding for stem cell research. If this bill were to reach the

president's desk in the oval office, it will most likely be vetoed, but this does prove that people are warming up to the idea of using stem cells to help humanity to live longer (Still, 2005).

We can only hope that in the future things can be different and more ES cell lines can be established. These puzzles that have been most perplexing appear to be coming clear. These building blocks, these stem cells that we once were, can potentially be there to jump start us in the future. When people get a big head and think they are the authority on everything, I can only hope that something happens to make them change their minds.

Everything that can be done must be done now to prepare for the future. Who knows how many of us may develop one of these silent assassins, these killers that wish to bring us down from the inside. A strong foundation and resolve is needed to fight this war much like the wars fought with guns and ammunition. Scientists have nearly figured it out and now are just struggling to prove it, despite heavy opposition. We have learned how to survive as human beings. Now that we don't have to fight for as much these days, we have lost sight of things that should be really important, such as minimizing human suffering. There used to be threats just as great as these diseases and for things just as simple as the flu. We, as a whole, have lost sight of many things like what it means to fight to survive. No longer can we be so narrow-minded to think only of ourselves. Embryonic stem cell research is much like being family-oriented; and scientists have realized that, much like family, you can never forget your roots.

CHAPTER-4: STEM CELL LEGALITIES

Years of debate concerning the use of human embryos for the advancement of stem cell research have yet to reconcile our strong dissenting views and translate them into uniform laws governing appropriate uses for fetal tissue. Yet there is a growing sense of a need to have uniform laws, to have a standard in place that everyone can adhere to. The sense of urgency is made tangible by the Human Cloning Ban and Stem Cell Research Protection Act of 2005 (discussed below), which attempts to allay fears and doubts, while still encouraging the U.S. to stay competitive and continue advancing stem cell research. For the sake of saving human lives by stem cell treatments, it is vital that the world be able to reconcile the ethical issues and act cohesively to stay at the forefront of this technology.

Embryonic and Fetal Research Laws within the U.S.

To better understand current U.S. legislative policies concerning stem cell research, it is important to examine the historical debate surrounding federal funding of human embryo research.

- *January 22, 1973:* The Supreme Court decides on *Roe v. Wade* in favor of the nationwide legalization of abortion. Concerns over the use of aborted fetuses in scientific research prompt the Department of Health, Education and Welfare (DHEW) to initiate a temporary moratorium on federally funded fetal research (Monitoring Stem Cell Research, 1994).

- *July 12, 1974:* Congress passes the National Research Act of 1974, due largely in part to rage over the Tuskegee syphilis experiments (Boonstra, 2001). In addition to protecting the rights of human research subjects and forming the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the act codifies the policy of a temporary moratorium on federally funded fetal research supported by DHEW (Regulations and Ethical Guidelines).
- *1975:* The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research publishes their report *Research on the Fetus: Report and Recommendations*, which lifts the moratorium on fetal research and replaces it with regulations governing the use of federal funds for that research. The Commission “called for the establishment of a national Ethics Advisory Board within DHEW to propose standards and research protocols for potential federal funding of research using human embryos, and to consider particular applications for funding” (Regulations and Ethical Guidelines, 2005).
- *June 18, 1979:* The Ethics Advisory Board issues the “HEW Support of Human In Vitro Fertilization and Embryo Transfer: Report of the Ethics Advisory Board”, in which it deems in vitro fertilization and embryo research as acceptable, provided that the embryos are not beyond fourteen days of development, and that they are donated by married couples. However, the board refrains from advising the DHEW to support funding for such projects. As a result, when the DHEW was left with the fiscal decision, the department at this time refused to offer funds for human embryonic studies (Monitoring Stem Cell Research, 1994).

- *1980*: The Ethics Advisory Board's charter expires with no renewal or call for a replacement. As regulations required that all proposals for funding be reviewed by the board, this in effect put a ban on all embryo (and thus ES cell) funding throughout the 1980s (Monitoring Stem Cell Research, 1994).
- *1993*: Congress enacts the NIH Revitalization Act which negated the proposal review requirement for funds by the nonexistent Ethics Advisory Board. In theory, this new act would allow NIH funds to be appropriated for research using in vitro fertilized embryos (Monitoring Stem Cell Research, 1994).
- *1994*: The NIH convenes a Human Embryo Research Panel recommending that the creation of embryos purely for research purposes be supported under certain circumstances. President Clinton rejects funding the creation of embryos for research purposes, but permits the stipulation that research funds may be used for applications utilizing embryos to be discarded from in vitro fertilization procedures (Monitoring Stem Cell Research, 1994).
- *1995*: Congress attaches the "Dickey Amendment," named after Rep. Jay Dickey of Arkansas, to the 1996 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act and is subsequently attached to the Health and Human Services appropriations bill every year thereafter. The provision reads as follows:

None of the funds made available in this Act may be used for—

(1) the creation of a human embryo or embryos for research purposes; or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204 and 46.207, and subsection 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term ‘human embryo or embryos’ includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

This Dickey amendment in effect forbids the use of federal funds for research in which human embryos are subjected to a high degree of risk, while still allowing private funds to be appropriated for such endeavors (Monitoring Stem Cell Research, 1994).

- *1999*: The General Counsel of the Department of Health and Human Services argues that stem cells derived from embryos that have been destroyed using private funding should be eligible for federal funding. The Clinton administration adopted this stance, and drew up guidelines for implementing this policy, but never got a chance to act on it since it was already near the end of Clinton’s term in office (Monitoring Stem Cell Research, 1994).

Over the next few years the country continued to engage in the intense debate over embryonic stem cell research. Religious groups and radio talk show hosts alike

could be heard voicing their opinions, advocating their ethical views. Republicans called for a ban on all funding for stem cell research on July 2, 2001. On July 23 the Pope condemned embryonic stem cell research (Robinson, 2005). With so many intense emotions surrounding this issue, people anxiously awaited the official position from the new Bush administration.

Finally on August 9, 2001 President Bush announced that he would allow limited funding for stem cell research. He stipulated that funding would be restricted to embryonic stem cell lines derived before August 9, 2001, effectively limiting the supply to what the NIH now believes are seventy-eight human embryonic stem cell lines (or preparations) (Monitoring Stem Cell Research, 1994). Although these cell lines are eligible for research purposes, as of August 26, 2005 research indicates that many of the cell lines are genetically identical, and only twenty two are actually available to researchers (NIH, 2005). A report by the National Institute of Health in 2003 indicated several international organizations possessing eligible stem cell lines for federal US funding (shown in Table 1).

Table 1: International Human Stem Cell Derivations Eligible for Federal US Funding

Name	Number of Derivations
BresaGen, Inc. , Athens, Georgia	4
CyThera, Inc. , San Diego, California	9
ES Cell International , Melbourne, Australia	6
Geron Corporation , Menlo Park, California	7
Göteborg University , Göteborg, Sweden	19

Karolinska Institute , Stockholm, Sweden	6
Maria Biotech Co. Ltd. – Maria Infertility Hospital Medical Institute, Seoul, Korea	3
MizMedi Hospital – Seoul National University, Seoul, Korea	1
National Centre for Biological Sciences/ Tata Institute of Fundamental Research , Bangalore, India	3
Pochon CHA University , Seoul, Korea	2
Reliance Life Sciences , Mumbai, India	7
Technion University , Haifa, Israel	4
University of California , San Francisco, California	2
Wisconsin Alumni Research Foundation , Madison, Wisconsin	5

Source: Monitoring Stem Cell Research, 1994.

State Overrides of the Federal Ban for Funding New ES Research

Although embryonic stem cell research is not currently banned in the U.S., using federal funds to create new ES cell lines is banned. To compensate for this ban, the state of California became the first to legalize research on embryos, including cloned embryos, when Governor Gray Davis signed the new stem cell law SB 253 on September 23, 2002. The law prohibits reproductive cloning and does not directly appropriate funds for research. However on November 2, 2004, California voters approved Proposition 71 which allows the state to borrow \$3 billion for stem cell research. New Jersey became the second state to legalize stem cell research when Governor James E. McGreevey signed a law on January 2, 2004, permitting research and use of human embryonic stem cells, germ cells, and human adult stem cells from any source (Robinson, 2005).

California and New Jersey are considered to be at the forefront in stem cell research, which is exemplified by how much they encourage this technology. Other states vary widely in their approach. The following table illustrates just how diverse each state is in its policies towards embryonic stem cells.

Table 2: State Embryonic and Fetal Research Laws

State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Arizona §§36-2302, 2303	No	Yes, prohibits research on aborted living/non-living embryo or fetus	No	No	No
Arkansas §§20-17-802, 20-16-1001 to 1004	No	Yes, prohibits research on aborted live fetus	Yes, consent to conduct research on aborted fetus born dead	Yes, prohibits research on cloned embryos	Yes, prohibits sale of fetus/fetal tissue
California Health & Safety §§ 123440, 24185, 12115-7, 125300-320	Yes	Yes, prohibits research on aborted live fetus	Yes, consent to donate IVF embryo to research	No	Yes, prohibits sale for the purpose of reproductive cloning or for stem cell research
Connecticut 2005 SB 934	Yes, on embryos before gastrulation (a process during embryonic development)	No	Yes, consent to donate IVF embryo to research	No	Yes, prohibits payment for embryos, embryonic stem cells unfertilized eggs or sperm donated following IVF treatment
Florida §390.0111	No	Yes, prohibits on aborted live fetus	No	No	No
Illinois 720 ILCS 510/6, 510/12.1 Executive Order 6 (2005)	Yes, under E.O. 6 (2005) permits funding of research that involves adult stem cells, cord	Yes, prohibits on aborted living/nonliving fetus	Yes, written consent to perform research on cells or tissues from a dead fetus other	Yes, prohibits research on fetus/fertilized embryo; prohibits funding under E.O. 6	Yes, prohibits sale of fetus/fetal tissue; also prohibits award of funds for

	blood stem cells, pluripotent stem cells, totipotent stem cells, progenitor cells, the product of somatic cell nuclear transfer or any combination of those cells		than from an abortion	(2005) of research on fetuses from induced abortions and the creation of embryos through the combination of gametes solely for the purpose of research	stem cell research under E.O. 6 (2005) to a person who purchases or sells embryonic or fetal cadaveric tissue for research
State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Indiana §35-46-5-1, 2005 Senate Enrolled Act No. 268	Yes, permits fetal stem cell research on placenta, cord blood, amniotic fluid or fetal tissue	Yes, prohibits research on aborted living/non-living embryo or fetus	Yes, consent required for fetal stem cell research	Yes, prohibits research on cloned embryos	Yes, prohibits sale of human ovum, zygote, embryo or fetus
Iowa §707B.1-4	No	No	No	Yes, prohibits research on cloned embryos	Yes, prohibits transfer or receipt of oocyte, embryo or fetus for somatic cell nuclear transfer
Kentucky §436.026	No	No	No	No	Yes, prohibits sale of fetus/fetal tissue
Louisiana §14: 87.2	No	No	No	Yes, prohibits research on fetus/embryo in utero, in vitro fertilized embryo	No
Maine 22§1593	No	No	No	Yes, prohibits research on fetus/embryo born or extracted alive, only applies to in vitro fertilized embryos post-implantation	Yes, prohibits sale of fetus/fetal tissue

Massachusetts 112§12J, 2005 SB 2039	Yes, on embryos that have not experienced more than 14 days of development (not including days frozen)	Yes, prohibits research on embryo/live fetus	Yes, written consent to perform research on a dead fetus and informed consent to donate egg, sperm, or unused preimplantation embryos created for IVF	Yes, prohibits research on live embryo or fetus; also prohibits creation on fertilized embryo solely for research	Yes, prohibits sale of neonate, embryo or fetus for illegal purposes; prohibits sale of embryos, gametes or cadaveric tissue for research
State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/ embryo	Consent provisions to conduct research on fetus/embryo	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Michigan §§333.2687-2688, 333.16274-16275, 333.20197, 333.26401-26403, 750.430a	No	Yes, live embryo/fetus	Yes, written consent of mother to donate dead embryo, fetus or neonate to research	Yes, prohibits research on a live embryo or fetus, cloned embryo	No
Minnesota §§145.421, 422	No	No	No	Yes, prohibits research on a live embryo up to 265 post fertilization or fetus	Yes, permits the sale/purchase of cell culture lines from nonliving human conceptus
Missouri §§188.036, 037	No	Yes, prohibits research on a fetus alive pre-abortion	No	No	Yes, prohibits receipt of valuable consideration for aborted fetal organs or tissue
Montana §50-20-108(3)	No	Yes, prohibits research on a live fetus	No	No	No
Nebraska §§28-342, 346, 71-7606	No	Prohibits research on aborted live fetus or the use of state funds for research on fetal tissue obtained from an abortion	No	Yes, limits the use of state funds for embryonic stem cell research; restrictions only apply to state healthcare cash funds provided by tobacco settlement dollars	Yes, prohibits sale, distribution or donation of viable aborted child

New Hampshire §§ 168-B-1, 15	No	No	No	Yes, prohibits the maintenance of a unfrozen fertilized pre-embryo past 14 days	Yes
New Jersey 2002-2003 SB1909/AB2840	Yes	No	Yes	No	No
State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
New Mexico § 24-9A-1, 3, 5	No	No	No	Yes, prohibits research on a fetus/embryo born or extracted alive, only applies to in vitro fertilized embryos post-implantation	Yes, prohibits abortion for the purpose of selling the fetus to researchers
North Dakota § 14-02.2-01, 2 ; HB 1424	No	Yes, prohibits research on a living/non-living embryo or fetus	Yes, requires consent to conduct research on a nonliving fetus or embryo other than from an abortion	Yes, prohibits research on a fetus born or extracted alive; cloned embryos	Yes, prohibits the sale of a fetus to be used for illegal purposes
Ohio § 2919.14	No	Yes, prohibits research on a living/non-living embryo or fetus	No	No	Yes, prohibits sale of fetus or fetal remains from an abortion
Oklahoma 63 § 1-735	No	Yes, prohibits research on a fetus/embryo	No	No	Yes, prohibits sale of fetus or fetal remains
Pennsylvania 18 §§ 3203, 3216	No	Yes, prohibits research on a live embryo or fetus	Consideration may not be given to mothers consenting to research; in cases involving abortion, consent must be provided after decision to abort	No	Yes, consideration may not be given to mothers consenting to research or other transferring tissue except for expenses involved in actual retrieval,

					storage, etc.
State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/ embryo	Consent provisions to conduct research on fetus/embryo	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Rhode Island §11-54-1	No	No	Yes	Yes, prohibits research on a fetus/embryo born or extracted alive, only applies to in vitro fertilized embryos post-implantation	Yes, prohibits sale of neonate, embryo or fetus for illegal purposes
South Dakota §§34-14-16, 17, 20; 34-23A-17	No	Yes, prohibits research on a living/non-living embryo or fetus ¹⁵	No	Yes, prohibits research on embryo outside of a woman's body; research on cells or tissues derived from an embryo outside a woman's body	Yes, prohibits sale of embryo
Tennessee §39-15-208	No	No	Yes, consent required to conduct research on aborted fetus	No	Yes, prohibits sale of aborted fetus
Texas Penal Code §48.02	No	No	No	No	Prohibits sale of fetus/fetal tissue
Utah §§76-7-301, 310	No	No	No	Yes, prohibits research on a live fetus, fertilized embryo post-implantation ¹	Yes, prohibits sale of fetus/fetal tissue; also prohibits sale of live unborn children, which is not defined, but are referred to in abortion statute ¹
Virginia §32.1-162.32-2	No	No	No	May prohibit research on a	Yes, prohibits shipping or

				cloned embryo or fetus ²	receiving of the product of human cloning for commerce ²
State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Wyoming §35-6-115	No	No	No	No	Yes, prohibits sale, distribution or donation of live or viable aborted child, defined to include embryos, for experimentation

Source: Johnson, 2005

It should be noted that on May 31, 2005 an “Act Enhancing Regenerative Medicine in the Commonwealth”, including a chapter on biotechnology, passed both the Senate and the House of Representatives in the state of Massachusetts. This law says in part, that "it shall be the policy of the Commonwealth to actively foster research and therapies in the life sciences and regenerative medicine by permitting research and clinical applications involving the derivation and use of human embryonic stem cells, including research and clinical applications involving somatic cell nuclear transfer, placental and umbilical cord blood cells and human adult stem cells, and other mechanisms to create embryonic stem cells which are consistent with this act. It shall further be the policy of the commonwealth to prohibit human reproductive cloning"

(Chapter 27 of the Acts of 2005, 2005). As one of the three largest biotechnology sectors in the U.S., Massachusetts continues to be among the leaders of medical innovation.

World Embryonic Stem Cell Policies

Now we turn our attention to ES cell policies in some other representative countries. Figure-1 below denotes the relative permissiveness of various countries for ES cell research. The brown color denotes permissive policies (i.e. Japan, South Korea, China, India, Sweden, Finland, and England). The orange color denotes flexible policies (but not totally permissive) (i.e. Brazil, Canada, Spain, Russia, Australia). The yellow color denotes restrictive policies (i.e. U.S., Africa, Italy, Saudi Arabia, Malaysia). Representing 3.4 billion people, the map shows that over half the world's populations are either "flexible" or "permissive" in their policies on embryonic stem cell research.

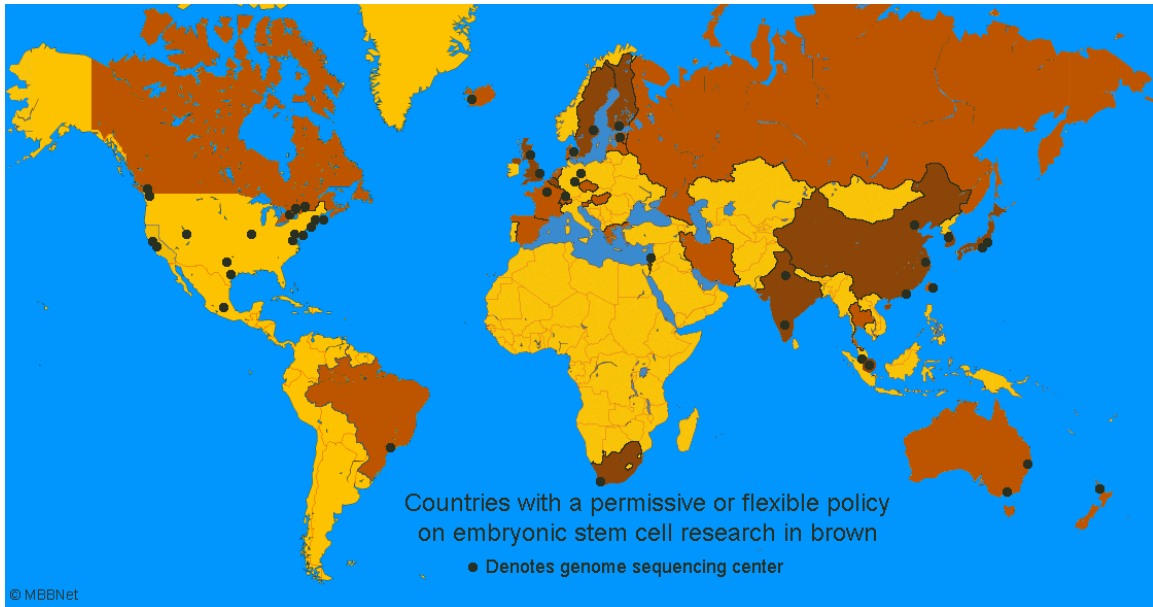


Fig. 1: World Stem Cell Map (Hoffman, 2005).

Map Explanation

- ■ **"permissive"** = various embryonic stem cell derivation techniques including somatic cell nuclear transfer (SCNT), also called research or therapeutic cloning. SCNT is the transfer of a cell nucleus from a somatic or body cell into an egg from which the nucleus has been removed. Countries in this category include the United Kingdom, Belgium, Sweden, Israel, India, Singapore, China, Japan, South Korea, South Africa, and others. [Walters, LeRoy, National Academy of Sciences, Oct. 12, 2004.] These countries represent a global population of approximately 2.7 billion people.
- ■ **"flexible"** = derivations from fertility clinic donations only, excluding SCNT, and often under certain restrictions. Countries in this category include Australia, Brazil, Canada, France, Spain, The Netherlands, Taiwan and others. [Walters, LeRoy, National Academy of Sciences, Oct. 12, 2004.] These countries represent a global population of approximately 700 million people.
- ■ **"restrictive"** = countries with restricted stem cell policies ranging from heavy stipulations to an outright ban on stem cell research. Countries include the U.S., many African countries, Italy, Saudi Arabia, and Malaysia.
- Map is designed to reflect **national policy** and whether or not public funds may be used to pursue stem cell research using IVF embryos donated from fertility clinics. (Hoffman)

The moratorium on the dispersing of funds for stem cell research in the European Union ended on December 31, 2003. Despite opposing views by member nations, the EU has taken the position of funding research on a case by case basis (*“EU to Fund Stem Cell Research Despite Split,”* 2003). Just last year on August 11, 2004, the United Kingdom issued a license to the Newcastle Center for life allowing them to create colonies of human stem cells for research (Garfinkle, 2004). It is strikingly clear that much of the world is gaining a foothold in stem cell research, and that legal measures should be taken to ensure U.S. competitiveness, while still balancing out the ethical concerns. Drafting a policy to allow the use of embryos taken from IVF clinics with parental consent, with no monetary inducement for the donors, and with embryos cultured for less than 14 days (which would include the blastocyst from which ES cells are obtained) seems to be a logical compromise supported by the authors of this IQP.

CONCLUSIONS

Stem cell research is possibly the most misunderstood and misrepresented area of science today. When the media makes reference to “stem cells”, they are usually referring to ES cells, a generalization that has led to controversy and misinformation. There are many types of stem cells, including those termed “adult stem cells”, which can be found in a grown human being. While these adult stem cells have less potential ability than ES cells, they may still provide cures from ruthless killers such as degenerative diseases. For example, adult neuronal stem cells may be able to regenerate fresh brain cells in a Parkinson’s patient.

ES cells are blank cells that can differentiate into almost any type of cell in a human body. They are capable of replicating much longer than any normal cell. Normal cells, after some time, are dictated by their biological makeup to stop replicating. Stem cells are not told to stop. This resume makes any sort of stem cell a viable candidate for becoming the foremost maintenance tool for the body. The world has seen much evidence to back up these claims, from using adult hematopoietic stem cells to send leukemia into full remission, to using ES cells to reverse diabetes in mice.

There have been many advances, but still U.S. stem cell research operates under overly strict regulations. It would be wise to allow this stem research to develop. Many oppose the use of embryos (from which ES cells are obtained) since they argue the embryos are “living entities”. However, three of the four major world’s religions support the use of ES cells since the blastocysts from which they are taken is no bigger than the period at the end of this sentence, and they argue life begins much later in the pregnancy. Some Catholics argue destroying blastocysts represent “murderous acts”, however even

Catholics are in favor of using adult stem cells, so long as they are used to support the common good. It is even possible that those who oppose ES cell research will be in need of stem cell assistance one day, and recognize that using one blastocyst with no feeling, no brain, no ensoulement, might be used to save hundreds of lives.

This world was made the way it is today through hard work and sacrifice. Too many times we forget the past, and how many before us have given up their lives so that our way of life can be preserved. Everything has its cost, and it is only fitting that there be a sacrifice to preserve humanity.

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