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STEM CELLS

An Interactive Qualifying Project Report

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ABSTRACT

The use of stem cells to treat a wide range of injuries and degenerative diseases is currently one of the most exciting topics in the medical and scientific worlds. The potential for success of this type of treatment seems extremely promising, however moral and ethical opposition has impeded the advancement of stem cell research. This paper touches upon the various types of stem cells, their applications, as well as the ethical and legal issues surrounding this topic.

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EXECUTIVE SUMMARY

Stem cells are at the forefront of regenerative medicine. Their capability to regenerate indefinitely and change into many different cell types shows good reason why stem cell research has grown so considerably in the past decade. This report discusses all aspects of stem cell research, from what they are and where they are found, to applications, ethics and national and state laws regulating their use. Although the full potential of stem cells is great, they are actually quite delicate, and very difficult to derive and differentiate.

Chapter-1: The first chapter of this report discusses the main ideas behind what a stem cell is and where they are found in the human body. Many types of stem cells exist. Adult stem cells are derived from tissues in an adult organism. Such cells can be derived from the brain, bone marrow, liver and even in one's eyes. Adult stem cells are simply undifferentiated cells with renewal potential found inside some of our tissues. These cells are used for specific tissue regeneration purposes when needed. For example, if red blood cells are needed, hematopoietic stem cells are prepared from bone marrow or cord blood, and these cells will differentiate into all the cellular components of blood, including red blood cells, white blood cells, and platelets. Human embryonic stem cells (hES cells) are similar to adult stem cells in that they have regenerative capacity, however they have the potential to differentiate into a large variety of tissues, thus the medical community is strongly interested in these cells. ES cells are derived from the inner cell mass of a blastocyst, so unfortunately their isolation usually destroys an embryo, thus ES cells have strong ethical constraints on their use. Currently less invasive methods of derivation are in trial phases.

Much misinformation has occurred on exactly what can and can not be achieved using stem cells, so the purpose of Chapter-2 was to document the various applications of different types of stem cells. It is not true, as is often perceived, that no lives have been saved with stem cells. Thousands of lives have been saved with bone marrow transplants over the past 30 years, while treating cancer patients undergoing radiation or chemotherapy. Much information on stem cell use was originally obtained with animal research, and this knowledge is now being applied to humans. Although adult stem cells were the initiating factor in stem cell research, the future rests in embryonic stem (ES) cell research. Research has shown that ES cells may be capable of repairing and growing various types of tissues in the human body. This could lead to the treatment of diseases that were once thought to be life ending. ES cells may also be used to grow entire organs which could be used in organ transplants. The process would allow the organ to be specifically engineered for a patient using nuclei isolated from their skin cells, thus eliminating the possibility of auto-immune rejection. Scientists are also currently investigating the possibility of using ES cells as a delivery system for drugs and proteins, able to treat diseases in a manner that has never been done before. The possibilities of ES cells seem endless, and further investigation will certainly lead to more promising applications.

Chapter-3: The third chapter of this report explores ethical and moral issues concerning stem cells. Adult stem cell therapies have been in practice for decades, and do not currently have much controversy. All four major world religions support the use of adult stem cells to save lives. However, ES cells are relatively new to the world, and have stirred up much debate and opposition. Some are opposed to the further progression

of ES cell research because not enough is currently know about the effects of putting such cells into humans, side effects and mutations may be inevitable. The four major religions of the world all have their own unique view on stem cells applications, but three are not fully against the idea because they know that lives will be saved and humankind will benefit from ES treatments. As compared to the rest of the world, the United States appears to have the most closed minded view on stem cell research. Countries throughout Europe and Asia are far more willing to further explore the idea of ES cell therapies.

Chapter 4 discusses various laws regulating stem cell uses. On a world scale the United States falls into a moderate category when discussing stem cell legislation. The Clinton Administration started the push for advancements in stem cell legislation by asking the National Bioethics Advisory Commission (NBAC) to write a report on stem cell research in the U.S. Near the end of his second term in office, the report was finished and viewed by both Pres. Clinton and Bush. This report proposed 13 guidelines that established what was acceptable for federally funded researchers. Unlike some countries ES cell research is legal in the U.S., although it is not currently fundable with federal money. The U.S. also differs from the rest of the world when it comes to legislation because not only does the U.S. have a national policy, state governments are also allowed to make their own rules regarding ES research. Currently some states have floated bonds to pay for stem cell research, California was the first, followed by New Jersey and Massachusetts. While the U.S. has a moderate policy in place, many scientists argue the lack of federal funds will eventually choke U.S. research, and other coutrires will eventually surpass us in this area. The national government needs to coordinate with

local governments to organize a more nationally accepted policy, laws that would hopefully allow the U.S. to remain one of the top stem cell and bioscience researching countries.

In conclusion, this report covers the science of stem cell research and its impact on society. Subjects that were discussed are as direct as what a stem cell is and where they are found, but also as complex as their applications, the ethics behind using them, and the laws that govern researchers. The authors of this IQP agrue that the advancement of stem cell technology is something the U.S. should strongly support. The potential that these cells have in regenerative medicine is possibly the most important biological discovery in this century.

PROJECT OBJECTIVE

The purpose of this project was to investigate the new technology of stem cells, and describe their impact on society. The objective of chapter-1 was to discuss the various types of stem cells and where each one is found. Chapter-2's objective was to demonstrate the different applications for each stem cell type. The ethical and moral issues surrounding this topic are presented in chapter-3. The goal of chapter-4 was to document the different laws regarding stem cell use. The final section contains the author's conclusions on this controversial subject.

CHAPTER-1: STEM CELL TYPES AND LOCATIONS

What is a stem cell? Stem cells are immortal cells that have the ability to self renew, and to change into other types of cells. All mammalian organisms have stem cells, from mice to humans. The environment in which the cell is grown and nurtured will dictate what type of stem cell it is. These environments created a huge range of stem cells, some more complicated than others, and some more useful. The two main groups of stem cells are adult stem cells (AS cells) that are obtained from an adult, and embryonic stem cells (ES cells) that are obtained from day-5 embryos.

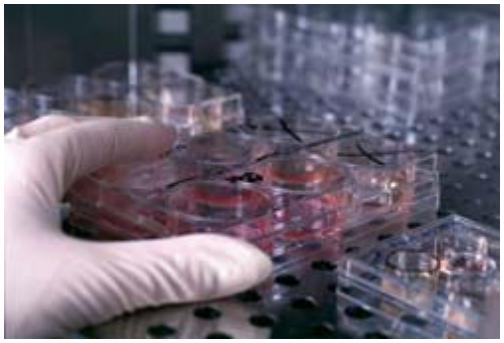

Figure 1: hES cell culture dishes

One of the special qualities of stem cells is their ability regenerate itself for extended periods of time; this process is known as proliferation. This feature is unique to these cells because as proliferation continues, if cultured correctly, millions of cells will be made that carry no specific purpose or task. This characteristic also allows stem cells to be able to remain in certain tissues until they are need for more specific purposes. If cultured properly in labs, stem cells can proliferate and stay unspecialized almost indefinitely.

The second feature of stem cells is their ability to differentiate into other types of cells, or cells with a more specialized function. For example, bone marrow hematopoietic stem cells (HSCs) have the capacity to create blood cells (red and white) and platelets. Differentiation is the process a stem cell will undergo as it changes from an unspecialized cell into a cell that is going to be used a specific purpose. The ability for stem cells to differentiate is the reason medical researchers are so interested in them. Such cells form the basis of the new field of regenerative medicine.

Adult Stem Cells

AS cells are stem cells found in specific tissues within adult mammals. Scioentists are still debating which adult tissues contain them, and whether such cells have the capacity to save lives, but their use does not destroy an embryo. One drawback however is they can only differentiate into one tissue type, usually the one they were isolated from.

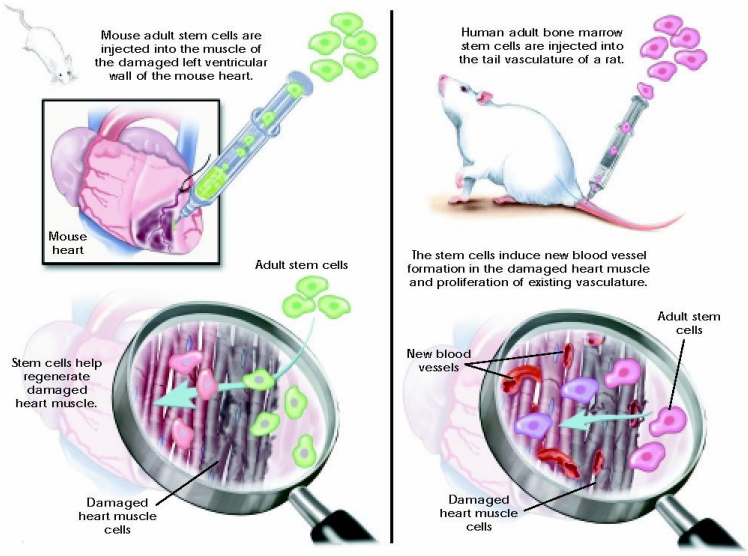

Figure 2: Demonstration of the regenerative ability of AS cells.

Figure 2 illustrates progress that is being made in this area, adult bone marrow stem cells are being differentiated in various environments into cell types that will aid in getting the tissues back to a healthy status.

Unlike stem cells, regular cells within our body are used to their fullest and then disposed. When these cells die off, new ones are sometimes created to take their place. This is why AS cells are so important to our well being.

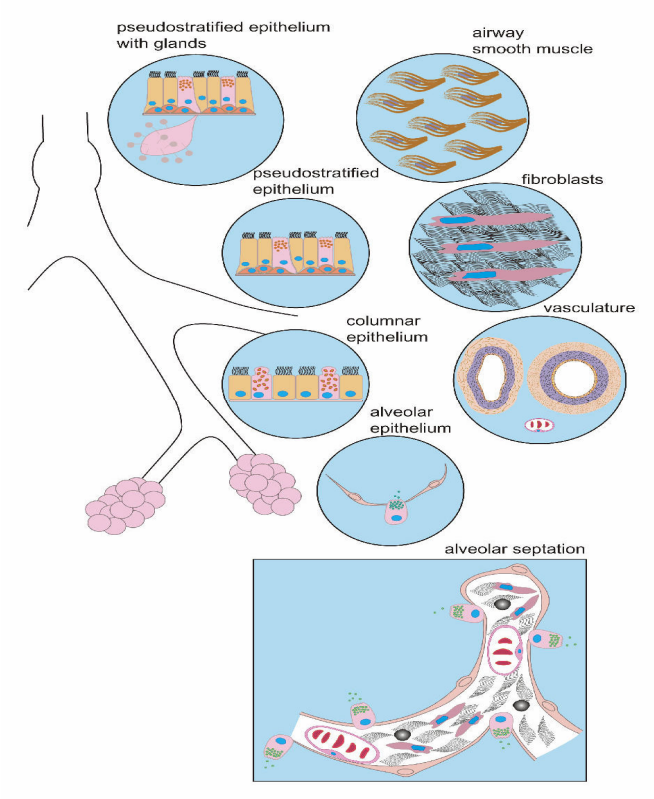

Figure 3: Differentiated pulmonary stem cells.

As an example of adult stem cells, the best characterized are the hemopoietic stem cells (HSCs). Everyday 300 billion HSCs are differentiated into platelets, and red and white blood cells. The human body also contains more specific adult stem cells, such as

bronchial or alveolar stem cells. In Figure 3, specific destinations are shown for the new cells created by differentiated mesoderm stem cells. These tissues are necessary for the function of the lungs. Other major adult stem cells include: endothelial stem cells, epidermal stem cells, gastrointestinal stem cells, liver stem cells, kidney or renal stem cells, lung or pulmonary stem cells, neural crest stem cells, neuronal stem cells, pancreatic stem cells, prostate stem cells and retinal stem cells. These AS cells and many others keep humans breathing, seeing and walking. Possibly in the future stem cells will allow diseased people to do these things again.

Embryonic Stem Cells

ES cells are the main basis for regenerative medicine. ES applications are being found to cure simple colds or something as complex as Alzheimer's Disease. As stated previously, ES cells have very much in common with AS cells, such as their ability to proliferate indefinitely in an undifferentiated state, but they can differentiate into a variety of tissues. ES cells are obtained from in vitro fertilized eggs grown for about 5 days to the blastocyst stage (see Figure-5). This "hollow microscopic ball of cells" is made up of three main parts. The outermost layer is the trophoblast, mainly a protective and sensory layer for the organism. Inside this layer is a fluid filled cavity called the blastocoele. Within this blastocoele lies the most important part, the inner cell mass. The inner cells mass is comparable to a yolk of an egg. At this stage, the ES cells constitute the inner cell mass. Their isolation destroys the embryo. The extracted ES cells are put into a new environment in order to proliferate, and eventually be differentiated. Figure 4 shows one form of external culture environment, a mictotiter culture dish.

Figure 4: Culture dish being examined for irregularities in stem cell growth.

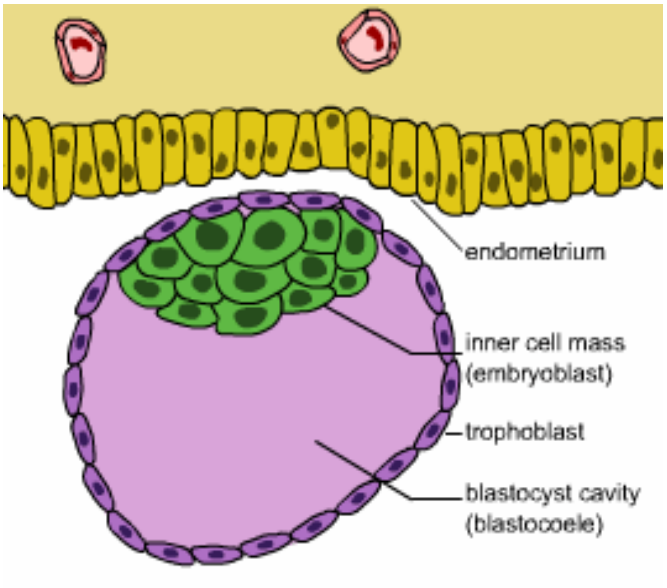

Figure 5: Diagram of a blastocyst and its various tissues.

ES cells if cultured correctly have to ability to take on the structure and purpose of any other cell in the human body. After proper culturing and proliferation, thirty ES cells could yield millions of cells.

The culturing process is not easy. Scientists and researchers spent twenty years struggling to grow ES cells in lab cultures. The process all starts with the extraction of the stem cells from the ICM, inner cell mass. Once the cells are gathered, they are placed into cultures with a specific culture medium or fluid. The culture dishes are also lined with what is called a feeder layer. This layer, usually mouse fibroblast cells (and more recently human fibroblast cells), is used to provide growth factors and attachment sites, much like the lining of a uterus. As cultures fill with new cells, they are separated into numerous different dishes and allowed to continue proliferating. When enough cells have been made, they are then differentiated into certain cell types controlled by the scientists working with the cells.

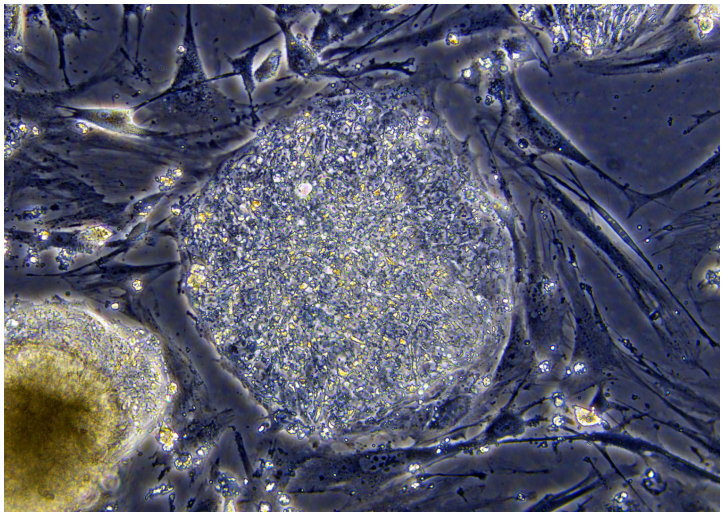

Figure 6: 20x view of human ES cells. hES cell are the dense clusters located in the center of the figure. The long skinny cells are the "feeder layer".

hES cells are also important to research because they allow information to be gathered about early cell development. Unfortunately this type of cell is falling far behind in the race of regenerative medicine, due to ethical and moral issues surrounding their use. These will be discussed in chapter-3.

CHAPTER TWO: STEM CELL APPLICATIONS

Stem cells are the key to opening a new door for regenerative medicine. Because the public often argues that stem cell research is "pie in the sky" and has yet to save any lives, the purpose of this chapter is to document the kinds of experiments that have already been successfully performed with stem cells.

Therapies using adult stem cells have been in use for over forty years, successfully treating patients with various types of autoimmune diseases (University of Minnesota, 2005). Although the use of embryonic stem (ES) cell therapy on humans is not yet permitted throughout most of the world, animal studies have proven that these types of cells will advance the medical world significantly. Many incurable diseases and permanent injuries could be treated with stem cell therapies, and further investigation of these cells may allow the mechanisms of tissue development and specialization to be mastered by scientists and engineers worldwide (National Research Council, 2003).

Adult Stem Cell Treatments

The first successful human stem cell therapy occurred in 1968, wherein adult bone marrow stem cells were transplanted from a donor. The bone marrow of an infant boy had been destroyed by radiation and chemotherapy while undergoing therapies to treat his sickle-cell anemia. The allogeneic (tissue matched) transplant allowed the donated adult hematopoietic stem cells (HSCs) to regenerate the boy's blood and to allow his immune system to once again function properly. Umbilical cord blood also contains adult HSCs that can be used to treat autoimmune diseases (Viacell, 2005). Because these cord HSCs are obtained from "younger tissue", they display less graft-versus-host disease

than bone marrow HSCs. Stem cells are labeled "adult" when they are harvested from a human after birth, so cord HSCs are actually considered "adult" to distinguish them from ES cells. Umbilical cord blood transplants are the preferred method of treatment because this process posses less of a risk and has a higher success rate. Despite the method chosen, once the donated adult stem cells have been placed into the patient, the cells immediately go to work, replenishing the patient's blood and immune system. A simple blood transfusion could provide temporary relief to certain patients, but stem cells harvested from umbilical cord blood settle deep into the patient's bone marrow, producing all the components of blood for the entire life of the patient. Both umbilical cord blood and bone marrow stem cells have been used to effectively treat various types of cancer. Clinical studies have involved patients with Non-Hodgkin's Lymphoma, Pancreatic, and Ovarian cancers. After each study most patients have improved conditions and reduced symptoms. Figure-1 below illustrates the proteins provided by an immune system after adult stem cell therapy. The patient's immune system would have produced very little to none of the disease fighting proteins before the therapy (Weiss, 2005).

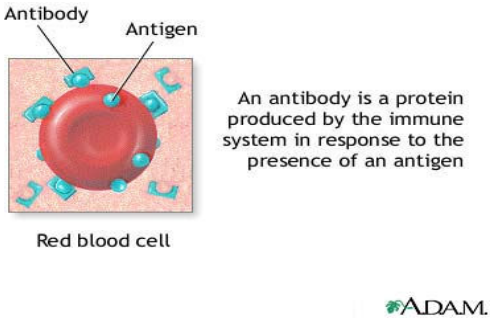

Figure 1: Red Blood cell shown with disease fighting antibodies, provided by the hematopoietic stem cell transfusion. Image provided by www.allrefer.com.

Adult Stem Cells harvested from the patients own body can also be used to battle certain autoimmune diseases. If the patient is suffering from a disease that does not affect their bone marrow, healthy stem cells will be used as treatment and an autologous (same patient) transplant will occur. In some trial cases, Lupus patients would have stem cells harvested from their own healthy bone marrow and injected into locations affected by the disease. The result of this therapy was the healing of what other doctors had called "irreversible damage". Seventy-five percent of the patients treated in this study experienced remission from the disease for two to three years (Weiss, 2005).

At an Italian eye bank, stem cells were harvested from a patient's healthy eye, and injected into the other damaged eye. The adult stem cells were taken from a part of the cornea called the limbus. The cells were then used to form a transparent membrane over the damaged portion of the unhealthy eye. The arrow in Figure-2 indicates the damaged portion of the cornea, which was treated with this procedure. A tear or a burn may have caused the damaged corneal tissue. The stem cell-formed membrane produces fresh and healthy tissue. The most unique aspect of this therapy is that the stem cells actually located the damaged portion of the cornea and were furtively instructed to perfectly repair the eye. This form of treatment is far more effective than any other known cornea related procedure, but little documentation has been made about why the cells behave in the manor that they do (Holland, 2005).

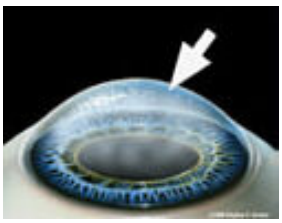

Figure 2: A damaged cornea to be treated using the patients own stem cells. The hazy portion of the cornea represents the unhealthy tissue. This image provided by www.schultze-eye.com.

The therapies that utilize adult stem cells are relatively new but with further research and testing, these types of cells may have more abilities than previously thought. In one clinical trial stem cells harvested from bone marrow were used to treat patients who had recently experienced a heart attack or heart failure. The stem cells were injected into the arteries of the heart, and the patients' cardiac functions and health was reported to have improved dramatically. Scientists are not sure if the stem cells formed new cardiac cells, but they most certainly are promoting healing and new growth.

Individuals with rheumatoid arthritis have also participated in trials with adult stem cells. The cells were used to jump start the repair of the eroded tissue between joints. Patients treated claimed that the pain from the arthritis had become dramatically less severe and stated "the relief was better than any drug ever taken" (Hall, 2005). Figure-3 below illustrated the damaged cartilage of a rheumatoid patient; adult stem cell therapy may provide just enough cartilage growth for a significant amount of pain reduction (Hall, 2005).

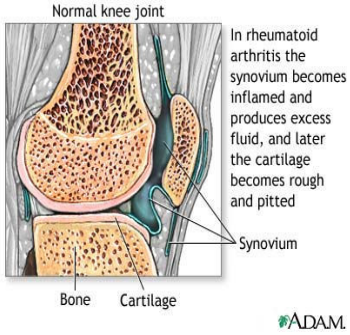

Figure 3: A knee damaged by rheumatoid arthritis will be treated with adult stem cell therapy, providing pain relief and aiding in tissue growth. Image provided by www.health.allrefer.com.

Adult stem cells taken from the bone marrow of healthy donors have provided an enormous amount of information about the multipotency of adult stem cells. In various

labs all over the world, these types of stem cells have been manipulated to grow several different types of cells and tissues; including the three major types of brain cells (neurons, glia, astrocytes). This could lead to newer and more refined therapies used to treat Alzheimer's and other brain degenerative diseases. Stem cells harvested from the human brain have also been found to produce blood and muscle cells. Adult stem cells are wonderfully useful in medicine and scientific research, but they are incredibly hard to obtain. Research thus far has shown that adult stem cells are limited as to how far they can go in terms of regenerative medicine. While stem cells have been used to treat cancer patients and others with autoimmune diseases, it is extremely difficult to pair up some patients with a donor carrying the correct histocompatible antigens. Isolating an adult stem cell in the human body is not only a lengthy process, but also an extraordinarily expensive one. Figure-4 below illustrates a stem cell found in the bone marrow of a human. Searching for these cells is quite literally like looking for a needle in a haystack (National Research Council, 2003).

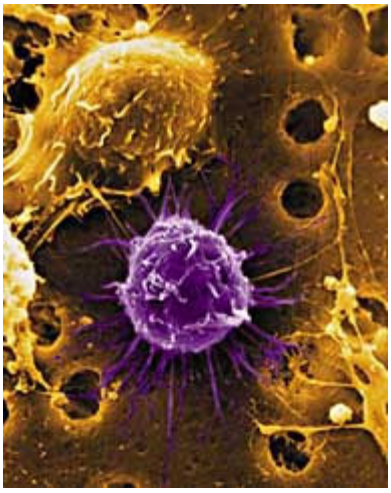

Figure 4: A microscopic stem cell rests within a vast jungle of bone marrow. The isolation and removal of these types of cells is a tedious and arduous procedure. Image provided by www.stanfordalumni.org.

Embryonic Stem Cell Therapies

Although adult stem cells were the initiating factor in stem cell research, the future rests in embryonic stem (ES) cells. This form of therapy is not yet legal in the United States for human testing, but extensive lab work and animal investigation has given researchers much optimism. Embryonic stem cells are easier to harvest directly and if eventually legalized, regenerative medicine will change the world.

One major difference between ES and adult stem cells is that adult stem cells are very useful for therapeutic replacement of damaged or diseased cells, but they cannot grow and replace complete damaged organs. In the laboratory ES cells have been manipulated to grow various types of tissues, and for the most part the cells have always been self-renewing (National Research Council, 2003). For example, when scientists transplanted neuronal ES cells into the damaged brain of a mouse, the stem cells not only survived but also worked along side the existing neurons of the mouse's brain. The cells then worked with the existing neuronal tissue to repair lesions and promote re-growth of damaged cells. Stem cells injected into the brain of mice have successfully located and repaired damaged tissue in several trials. Scientists believe that this process may also prevent neurodegenerative disease as well as promote healing. This application in humans could be incredibly useful in treating various illnesses such as Parkinson's and Alzheimer's disease, brain damage, genetic disorders, and possibly even spinal cord injuries. Figure-5 below shows a senile plaque formed on a brain from the toxic protein amyloid in Alzheimer's patients. Treatment with neuronal cell transplants could possibly repair the plaques and tangles associated with this degenerative disease, slowing the progression of the illness (Weiss, 2005).

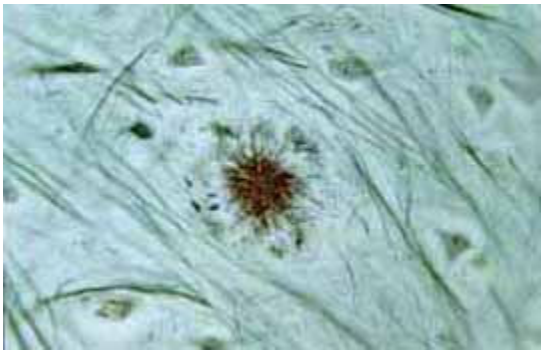

Figure 5: A brain damaged by Alzheimer's shows various lesions caused by a toxic protein. Neuronal stem cell treatment could repair damaged areas and prevent further progression of the disease. Image provided by (Brain…1999).

Embryonic stem cells have also experienced much success in animal studies with treating degenerative muscular disease. Individuals suffering from Duchene Muscular Dystrophy may someday undergo a therapy in which embryonic stem cells are used to grow and replace the muscle that has been deteriorated by the disease. When mice with Duchene's were treated with the stem cells, the muscle growth that occurred was miraculous. The mice not only grew back the muscle they had lost because of the disease, but they continued to grow becoming larger and more muscular than even the healthy mice. Figure-6 below shows a before and after scan of the leg of a mouse treated with this therapy, the green represents new muscle growth. This treatment was also performed on dogs with muscular dystrophy, and again the dogs grew larger and stronger than normal animals. This provided enough information for scientists and engineers to conclude that the stem cells promoted growth in the animals' own muscles, forming new tissue and building up the old host fibers (Potten, 1997).

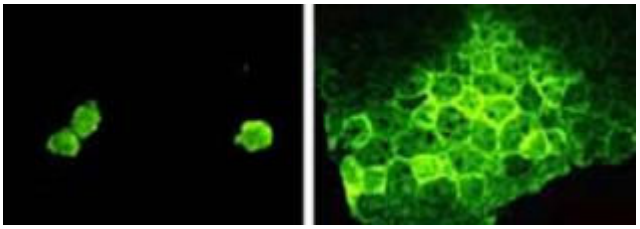

Figure 6: The image on the left is a scan of new muscle growth in the leg of a mouse before stem cell therapy. The image on the left clearly illustrates the large amount of new muscle growth after the embryonic stem cells were introduced to the host fibers. Image provided by (Researchers Reveal, 2005).

Spinal cord injuries are among the most life changing and emotionally devastating injuries, leading to paralysis and a dramatic change in lifestyle. Extensive research has been conducted concerning stem cells and the spine. Laboratory mice were manipulated such that their spine was carefully severed leaving the mouse paralyzed in the rear legs and tail. Scientists then created a specialized formula from an embryonic stem cell. After the mouse was injected with the therapy, the scientist could not believe the results. The spine and nerves which had been severed had re-grown, and the mouse was now able to walk with it's rear legs and movement was visible in the tail. The recovery was not full, a slight shuffle was present, but the ability to travel was regained. Several other studies have been completed all with promising results. Further research and a change of policies could lead to paralysis becoming an issue of the past (Weiss, 2005).

Organ transplants are another area in which ES cell research has been applied. The process of matching a donor with a patient is often difficult, and patients may wait months or years to find the correct match. Even after a match has been made and the transplant completed, the road to recovery is not an easy one. The recipient will need to take immune suppressive drugs so that their body does not reject the new organ. These drugs are often incredibly harsh on the body and sometimes cause sickness and anxiety that is unbearable. Prior to stem cell therapies, scientists were investing a process where

a biopsy was taken from the unhealthy organ. The cells removed from the organ were then grown and fed on a collagen scaffold. The hope was that the cells would form into a new and healthy organ; but limited success occurred. The grown organs are not useful to the human body due to the fact that the body will not absorb tissue that does not contain blood vessels. Another set back to this procedure is that the faulty organ is often so damaged that there is not enough healthy tissue to take a biopsy from. Embryonic stem cells could completely change this, allowing for perfectly functional organs to be created that are an exact histological match to specific patients. The need for immune suppressing drugs would no longer exist, and virtually every person needing an organ of some nature would be fulfilled. In a California laboratory, ES cells have been manipulated under very specific conditions to form masses of heart muscle that beat in perfect unison (Hall, 2005). Further improvement upon this research could lead to the development of specialized organs and tissues, used as transplants or as treatment to other degenerative diseases. Figure-7 shows two different types of tissues successfully grown in the laboratory from stem cells.

Figure 7: The image above is a photograph of tissues grown using embryonic stem cells. The image on the left is of epithelial cells, and the image on the right shows neuronal cells. Figure provided by www.itb.cnr.

Stem Cells as Delivery Systems

Stem cells manipulated by scientists not only grow various types of tissues but also act as drug and therapeutic protein carriers and producers. In turn, this means that stem cell therapy could be used to treat degenerative disease as well as viruses and other infectious agents. Muscle stem cells have been engineered to successfully carry and deliver Human Growth Hormone to mice in the laboratory. This system is possible because once the stem cell is injected into the host muscle it has direct access to vascular circulation. The multipotency of stem cells is quite apparent once again, now not only can muscle stem cells be used to treat degenerative disease but they can also be used as a drug delivery system (Potten, 1997). Muscle stem cells are not alone in this category; engineers strongly believe that neuronal stem cells could also be manipulated in this manor. More specifically they are currently working on using embryonic fetal tissue, along with a patient's on neuronal stem cells to treat patients with Parkinson's disease. The hope is that if the stem cells are matured properly they may be able to form the dopamine producing cells that are destroyed by this disease. Various attempts have been made to produce this type of cell, but the success rate thus far has been fairly low (Weiss, 2005).

Similar studies are currently underway to use embryonic stem cells as a treatment for Type I Diabetes. The medical world has been working on discovering a way to create the insulin-producing cells that are destroyed by the patients' own immune system. Scientists are currently working on "training" stem cells to mimic the behavior of the pancreatic islet cells that produce insulin, which without a doubt would have a profound affect on the disease. Recent developments using specialized proteins to spur cell

differentiation are believed to aid in making this therapy a reality (Holland, 2005). A group of American scientists working in Britain were able to use a concoction of chemicals to convert a brain stem cell into the insulin producing islet cells. When injected into a mouse and tested four weeks later, the brain stem cell was still alive and the insulin production of the mouse had increased drastically (Brain Stem Cells…2005). Just last year in Spain, scientists completely reversed the symptoms of diabetes in a sick mouse utilizing embryonic stem cells. They used a process that manipulated the DNA of the insulin gene and then inserted that into an embryonic mouse stem cell. The hybrid stem cell was then cloned and injected into the mouse, curing it of diabetes. Figure-8 illustrates the steps that the scientists took and also provides a graphical representation of the change insulin production (Cancer Facts…2004).

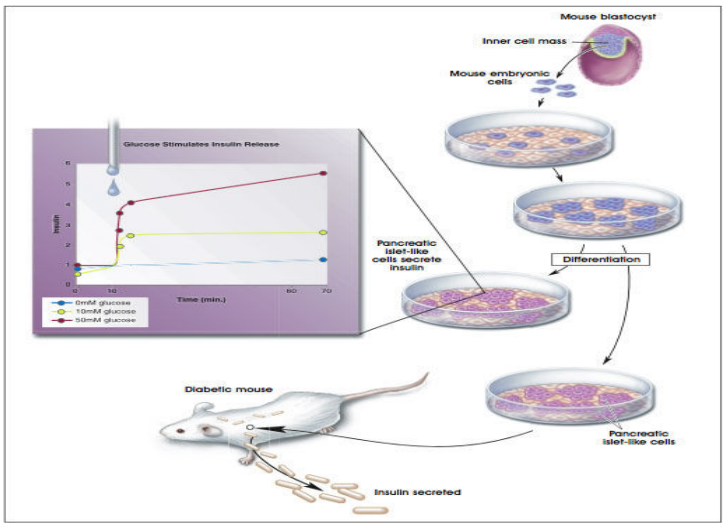

Figure 8: Careful manipulation of the insulin gene and embryonic stem cells allowed Spanish scientists to cure a mouse of diabetes. Above are the major steps they took and a graphical representation of insulin production. Image provided by (Stem Cells and Diabetes, 2005).

Stem cells of all types are useful as therapeutic treatments, but also can be studied and tested to provide information furthering the medical world. Stem cells could revile the unknown regenerative properties of the liver and skin tissue, and also provide further

information into the process of cell differentiation (National Research Council, 2003). Permanent injuries and untreatable diseases have been reversed in laboratories all over the world using stem cell therapies. Millions could be treated suffering from a wide range of medical issues, anything from Parkinson's disease to severe burns. Specific lines of stem cells harboring certain abnormalities would allow testing and therapies to unveil new methods of treating those suffering from disease and sickness. Further investigation into adult stem cells may lead to the discovery of new cells readily available in the human body, without destroying an embryo to obtain them. The birth of the a new age in medicine and science using stem cells has just barely began, and certainly the world will benefit dramatically from this new kind of therapy.

CHAPTER-3: STEM CELL ETHICS

The scientific and medical worlds have always sparked controversy and given rise to ethical questioning. New developments and cutting edge technologies are usually the targets of social unrest, usually because the general public is fearful of what it not well understood and widely accepted as the "norm". Today it is hard to pick up a medical journal and not find research or information relating to the topic of stem cells. Adult stem cell therapies have been in use for years, but the focus on the potential of embryonic stem (ES) cells has caused much incongruity. Political and social views on the this topic have significantly impeded the progression of ES cell applications, particularly in the United States; while other locations throughout the world are quickly gaining momentum in the world of regenerative medicine.

The use of adult stem cells to treat patients suffering from a wide range of illnesses has been in practice for decades. Initially, as with all pioneering medical applications, ethical issues were raised as to how safe these processes and procedures actually were. Initial success in the laboratory using animals is now being followed by human clinical trials. This highly documented and regulated progression brought ease to most of the ethical and moral qualms surrounding adult stem cells. In current times, procedures such as bone marrow transplants, are a common everyday practice; it is understood that therapies such as these save lives while not destroying an embryo to obtain the stem cells. In fact, all four of the world's main religions support the use of adult stem cells for improving the common good. However, adult stem cells have fewer

regenerative capacities than ES cells, and all eyes are on the applications of embryonic stem cells.

ESC research is highly controversial, raising both moral and ethical opposition. Most of this unrest is due to the fact that an embryo about day-5 of creation is destroyed in order to harvest ESCs. This opposition has severely slowed further advancement on research that is needed to fully understand the applications of these mysterious cells; cells that could lead to the curing of many degenerative diseases, and possibly even tissue or full organ growth and replacement. Figure-1 is a photograph of an embryonic stem cell, the topic of much debate (National Research Council, 2003).

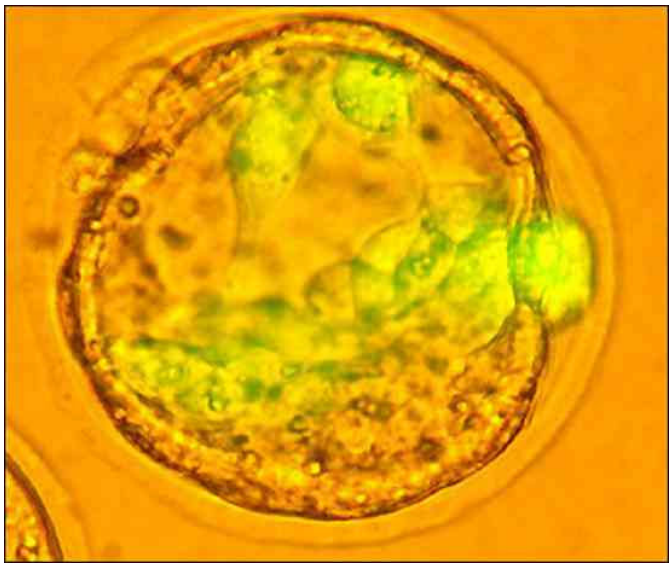

Figure 7: The photograph above shows an embryonic stem cell, this microscopic cell causes much controversy and ethical questioning. Image provided by www.allhatnocattle.com.

Opposition from Scientists and Engineers

The most feasible and well supported argument against ESC applications has come from the scientific and medical worlds. ESC research is groundbreaking and therefore has many loopholes that have people questioning the safety and morality behind

their use. The most serious concern of stem cell applications comes from the possibility that all ES cell lines eventually will change and mutate into potentially harmful ones. The technology of inducing immortalized cell lines has long been accepted as common practice, but these cell lines are not used for organ replacements in which mutations could have serious consequences. Scientists fear that if large banks of stem cells are used in therapeutic applications, mutations and abnormalities could lead to unwanted and dangerous side affects. For example, if a stem cell is harvested from an individual who is the carrier of a genetic disease, each cell derived from that stem cell would also carry the harmful mutation (National Research Council, 2003). However it has yet to be seen whether ES cell lines spontaneously mutate when taken from healthy volunteers.

The multipotency of stem cells has also raised much concern over their applications. Even with much research and clinical trials, scientists have not been able to fully control the ability of stem cells to form into many different types of tissues. The best example of this occurred in the laboratory on a mouse. A human ESC was injected into the mouse, and this caused the formation of various types of growths such as fatty tissue, hair, teeth, and lung tissue. This result was promising in that various types of tissues formed from one cell, but on the other hand the results were unpredictable and dangerous. These results in human applications could result in cancerous growths and may lead to sickness or even death; which quite obviously has raised many ethical and moral issues. There is also a concern with the actual injection of the stem cells into a patient; the wrong location could lead to a failed procedure or horrifying side effects. Figure-2 is a photograph of a generation of mice that have been treated with the highly controversial embryonic stem cells (Potten, 1997).

Figure 8: The photograph above is of a family of mice all used in experimental embryonic stem cell research. Though these mice appear to be physical healthy, not all applications have turned out successful. Image provided by www.utmb.edu.

Another issue that has raised great concern among researchers is the fact that stem cells are currently cultured in a non-human serum (usually fetal bovine serum with a feeder layer of mouse cells). This has led to a fear of a potential health risks and the spread of non-human disease to individuals treated with stem cells. The feeder cells used in the culturing phase are usually obtained from mice or cows (National Research Council, 2003). In the case that stem cell therapies are legalized in the United States, a human based or synthetic serum would have to be utilized, ensuring the public that there is no chance of rodent or bovine disease crossing over to humans. Geron, a stem cell research company based out of California, has made claims that they have created such a serum; possibly deleting one concern on this highly debatable topic. In addition, several labs have recently learned how to culture ES cells without the feeder layer cells (International Stem Cell Meeting, San Francisco, Summer 2005), so these new ES cell lines would not be contaminated by animal products. But to use these new ES cell lines in federally funded research would necessitate a reversal of the Bush 2001 legislation

banning the generation of new ES lines. Figure-3 shows adult neuronal stem cells which were cultured in a rodent derived serum (Weiss, 2005).

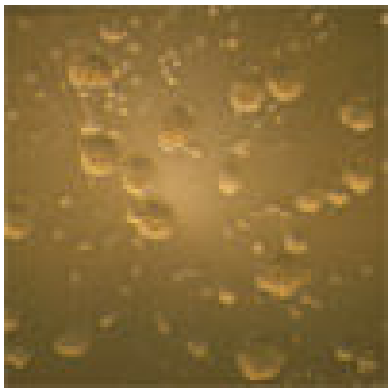

Figure 9: The image above displays adult neuronal stem cells successfully cultured in a rodent derived serum. Image provided by www.neuronnova.com.

The applications of stem cells to regenerative medicine would largely encompass the insertions of new tissue into a patient with damaged or diseased organs. Stem cell derived tissues have been grown effectively in the laboratory, but there has been no such case where the tissue was proven to be fully functional and normal. Until the implementation of human clinical trials, there will be no way to guarantee that the grown tissue will survive in the human body. Though many researches believe that these processes will be very successful because the tissue is stem cell derived, and can be matched easily with a patient; there is still an underlying fear of immune-mediated rejection. This has raised ethical issues over whether or not it would be worth it to spend the time and money on a procedure that may fail. There is a possibility that the patient may have to spend the rest of their life ingesting immunosuppressive drugs, which are often life threatening and bring new side effects (National Research Council, 2003).

Stem cell research is not the first scientific and medical topic to raise great ethical opposition. When DNA recombinant techniques initially came into the public eye,

opposition of all sorts came from social groups throughout the world. These issues were eventually resolved when committees were developed to set guidelines and standards which ensured that the research was conducted to the highest of medical and ethical standards. If the United States government chooses to fund stem cell research, similar assemblies could be formed to monitor and regulate the procedures. This would allow research to progress and for the true practicality of stem cells to be understood (McClean, 1997).

Religious Views on Stem Cells

Ethical opposition from various religious groups has caused a major setback for stem cell research, especially related to ES cell harvesting. Surprisingly, the views of different religious groups vary significantly; and even the thoughts of individuals within the same religion can show a drastic discrepancy.

The roots of most of the debates come from the fact that when harvesting an ESC, a human embryo is destroyed. ES cells are derived from the inner cell mass of the blastocyst at day-5 post-fertilization. The blastocyst is about the size of the period at the end of this sentence, and has no brain, eyes, nerves, etc. There has been much argument as to when life actually starts for an embryo, and the various religions all have a different view on it. The Jewish people believe that an embryo has no moral status until 40 days after conception. They also believe that the life of embryo does no begin until after the birth of the baby, before that the embryo is just a part of the mother's body. The Jewish faith has stated that if the embryo was conceived outside of the body (in vitro), the embryo is of no moral or legal status; sperm and egg mixed outside of the body is not a conception. Thus, while it seems that the Jewish faith is not strongly opposed to ES cell

research, they have made it public that they feel ESC harvesting denies the embryo a future to evolve into a life, so some are against ESC research (Eisenberg, 2001). However others in the Jewish faith see no problem with it so long as it supports the common good (saves lives).

The Muslim's view on when life begins is similar to the Jewish people in that they do not believe life begins immediately upon conception; Muslim law sates that life begins for the embryo four months into the pregnancy, which is well after blastocyst formation. As for specific laws applying to stem cells and abortions, the Muslim faith does not have a central authority to state a specific position. Generally, Muslims are very conservative and deeply religious, yet most are not opposed to stem cell research because they do not believe that the embryo possesses a soul until the later stages of the pregnancy. Of course there are Muslims who are deeply against ESC research because of the destruction of an early embryo. As with all of the religious groups, Muslims seem to be split as to what shall be allowed in stem cell research. Figure-4 is of photographs taken at a stem cell research laboratory located in Cairo, Egypt (Dabu, 2005).

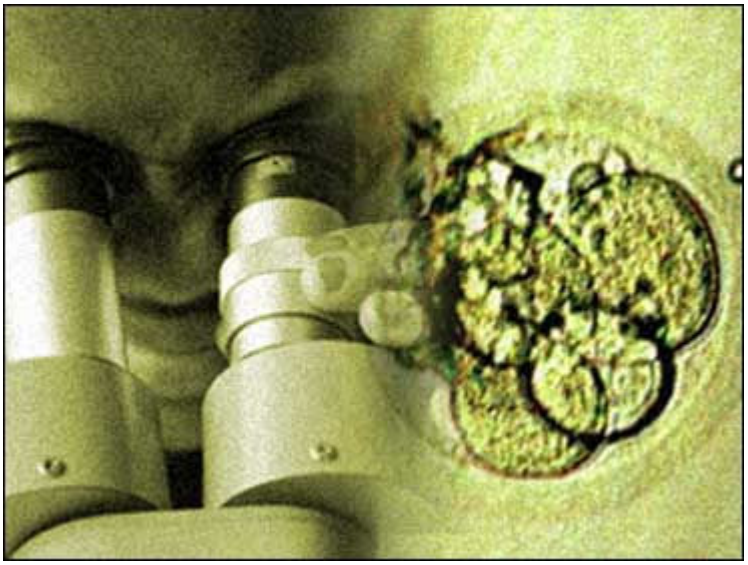

Figure 10: The images above were taken at a stem cell research laboratory located in Egypt. Facilities of this nature are new to this area which is heavily populated by Muslims. Image provided by www.cbsnews.com.

The scientist that first successfully cloned the world's first stem cell line in 2003, was a professor by the name of Hwang Woo-suk. Professor Woo-suk is a practicing Buddhist, and gives his faith the credit for his success. Woo-suk says that in every aspect of his research he makes sure it follows in the spirit of Buddha. If he ever had a doubt about the ethics behind his research, he would cease immediately. Woo-suk claims that the compassion of the Buddhist faith, and it's long history of practicing medicine to alleviate suffering has allowed the Buddhist people to embrace stem cell research and biotechnology as a whole. The Buddhist do not view an early-embryo as life, the embryo must be inside of a uterus for life to begin (Tae-gyu, 2005). Though the Buddhist faith is seemingly open to the idea and practice of stem cell research, there are still practicing Buddhists that do not approve of ESC research because of the deliberate destruction of life (Buddhism and Stem Cells…2005).

Professor Woo-suk not only admitted that his faith allows him to carry out research with stem cells, but he knows that if he were a Roman Catholic, he would have never been allowed to do what he has done (Tae-gyu, 2005).

The Roman Catholic Church has extremely strong moral and ethical qualms with ESC research. The Pope, the head of the Church, publicly denounces all forms of ESC research and claims that it is the same as abortion; a crime. The Vatican has even been so bold as to claim that scientists and researchers are committing murderous acts when conducting ECS research (Weiss, 2005). In the past Catholics used to follow the same views as the Jewish people, that an embryo is not considered "living" until 40 days after conception. In 1869, the church adopted the idea that human life begins at the time of conception, because there is no way to positively determine when life actually begins. Therefore, the Catholic faith is completely against any type of research in which an embryo is destroyed (National Research Council, 2003). Their defense is that the only difference between an embryo and a baby is time, and both deserve equal protection. Not all Roman Catholics believe that ESC research is as erroneous as the church is claiming, and feel that the research must go on in order to fully comprehend how stem cells could benefit the world. Christians as a whole are generally not in support of ESC research, but most denominations are not as severely in opposition as the Roman Catholics. In fact, a large majority of Protestants are in strong support of ESC research, and confident that it will do far more good than harm for the human race (Weiss, 2005).

A Global View on Stem Cells

The research allowed within a country is determined by governmental laws and determined by officials. People throughout the world have drastically different views on

ESC research, which are not always in accordance with local laws. In the United States it is not uncommon to view protesters outside of facilities which deal with stem cell research. Not only will you often find protestors, but these establishments are usually forced to maintain tight security because of the pressure of those opposed to ESC research. On the other hand at the Human Fertilization and Embryology Authority in downtown London, there are never protestors or a need for strict security. Generally, the people of Europe are much more open to the idea of ESC research, and the laws of these nations (as discussed in our chapter-4) seem to reflect that (Holland, 2005).

The peoples of Asian countries appear to have a similar acceptance of ESC research as the Europeans. This region of the world believes strongly in not only the future of ESC research to help the ill, but also realizes that a great economic gain could be achieved by embracing this research. In fact, many in Asia argue it is unethical not to try to save lives with ES cells. Singapore is rapidly becoming the stem cell Mecca of the world, welcoming the biotechnological community. The government of Singapore has even constructed official and public committees to come together and devise a plan for creating ethical guidelines for stem cell research. Though ESC research is welcome in this city, it is not supported by everyone. A common bumper stick often seen on vehicles traveling the streets of Singapore reads, "Embryos- Let them live, you were once an embryo too" (Weiss, 2005).

In the United States, the public seems to be ethically and morally divided. As mentioned earlier, protesting and rallies denouncing stem cell research are an everyday occurrence. Some opponents of ESC research are in favor of furthering the knowledge of adult stem cells, and believe that they may be just as useful as ESC; but without the

destruction of embryos. Others believe that embryos left over from in vitro fertilization should be used in ESC research. Some mothers with "excess" embryos would rather donate them to ESC research where they will be useful in helping others. The alternative would be that the embryos were destroyed. In the United States there are over 400,000 excess embryos in storage, and of that only three percent will be saved for ESC research, the rest will be destroyed. A mother who donated her excess embryos stated, "If they had a heartbeat it would make a big difference, but embryos are bunches of cells and I couldn't throw them down the drain when they could further science" (Holland, 2005).

Ethics of Parthenotes

Parthenotes are chemically treated eggs that divide to the blastocyst stage without fertilization. Such embryos can not mature into adults, but can be used to derive ES cell lines, so parthenotes are perhaps one way to avoid the ethical pitfalls of deriving ES cells from fertilized embryos. To date, ES cell lines have been derived from monkeys but not humans (Cibelli et al, 2002). If this technology can be adapted to humans, most religions would support its use instead of using embryos, so long as the eggs are used to save lives.

Ethics of Therapeutic Cloning

Somatic cell nuclear transfer is a form of therapeutic cloning in which a line of identical stem cells can be created by isolating the nucleus of an adult patient's fibroblast cell obtained from the skin, and injecting the nucleus into an enucleated egg to eventually derive an ES line specific for that patient. The goal is to create an ES cell line specific for that patient to avoid their immunorejection when placed back into the patient. This

topic raises ethical and moral issues in which almost all religions and communities worldwide are against. Therapeutic cloning is not only highly controversial, but also is illegal in a large portion of the world (National Research Council, 2003). This procedure of creating stem cells creates upheaval because the cells are cloned, and not created naturally. Ethical issues are also raised for a fear of biological mutations and abnormalities that may occur during the cloning process. Scientists believe that with further research much of these concerns will be determined as unreasonable (Weiss, 2005).

ESC research has caused ethical and moral opposition globally. Though some communities may be more accepting than others, government officials and laws hinder the further progression of researching therapeutic medicine and stem cells applications. Until researchers are allowed to explore the possibilities of ESC in great detail, the true practicality of ESC applications will remain unknown.

CHAPTER-4: STEM CELL LEGALITIES

The purpose of this chapter is to examine current laws relating to stem cell use, both in the U.S. and abroad.

Roe v. Wade

U.S. legislature regarding the development and use of stem cells began with a very important landmark Supreme Court case, Roe v. Wade. This case questioned the constitutionality of abortion, which in turn questioned the legal status of an embryo, and laws regulating the extraction of stem cells.

"Roe v. Wade, 410 U.S. 113 (1973) was a landmark United States Supreme Court case establishing that most laws against abortion violate a constitutional right to privacy, overturning all state laws outlawing or restricting abortion. It is one of the most controversial decisions in Supreme Court history"(wikipedia.com, 2005)

This case settled the argument of whether abortion is legal, and opened the doors for stem cell research.

National Bioethics Advisory Commission (NBAC)

The real debate about stem cells did not transpire until the Clinton Administration (nih.gov, 2005). The National Bioethics Advisory Commission (NBAC) was asked by President Clinton to prepare a report on stem cells. In September of 1999 the report was finished and handed over to the Clinton Administration. The guidelines were published in the Federal Registrar on August 23, 2000 (MIT, 2005).

The report consisted of thirteen guidelines on the ethical uses of stem cells with federally funded research (MIT, 2005), and gave restrictions on the sources of stem cells. hES cells and embryonic germ cells (EG cells) were now only to be harvested from embryos from in vitro fertility clinics or cadaver fetuses. ES cells could not be obtained by somatic cell nuclear transfer (SCNT) or from embryos created specifically for research by means of *in vitro* fertilization.

When President Bush took office, he delayed the revision of this report so his incoming administration had time to review its the information. In his revised report he stated that federal funding would be acceptable only if it was used on ES cell lines derived previous to the release of his report on August 9, 2001 (stemcells.nih.gov, 2005). Also stated was that federal funding would be available if certain requirements were met:

> 1) there must have been informed consent of the donors, 2) the embryos must have been created for reproductive purposes and in excess of clinical need, 3) there must not have been any financial inducements to the donors, and 4) the embryos must not have been created for research purposes. During fiscal year (FY) 2002, the National Institutes of Health (NIH) funded the first grants to conduct human embryonic stem cell research, including both new grants and supplements to existing grants. (stemcells.nih.gov, 2005)

National Institute of Health Report

The National Institute of Health (NIH) also came out with a report regarding the use of federal money on stem cells. "…only (regarding) research involving the derivation of ES cells from human embryos, but not to research involving the use of ES cells (MIT, 2005)." This quote in a January of 1999 NIH report pushes for a federal ban on the derivation of new ES cell lines. "NIH through the Department of Health and Human Services permits funding for research on embryos that were not derived by NIH-funded

scientists, which, as NBAC points out, might solve the legal problems… (MIT, 2005)." During the 2002 fiscal year, at the end of the Clinton Administration, 180 million dollars was put into stem cell research (ss.ca.gov, 2005).

107th Congress

During the two years of the 107th Congress eight different pieces of stem cell legislation were passed in both the House of Representatives and Senate. Aside from legislation that went though Congress, the Senate Sub Committee on Labor, Health and Human Services (HHS) held four separate hearings regarding stem cell research.

The July 18 hearing focused on the release of a comprehensive report prepared by NIH that described the current state of the science on stem cells derived from human embryos, fetal tissue, and adult tissue. In addition, several Senators holding pro-life views testified in support of stem cell research. The August 1 hearing focused on intellectual property issues and ethical issues. The October 31 hearing focused on testimony from the various derivers of the existing stem cell lines. The September 25 hearing was held to provide the new Director of NIH with an opportunity to update the Subcommittee on the implementation of the President's stem cell decision by NIH, and to hear from researchers on their efforts to obtain the eligible stem cell lines listed in the NIH Stem Cell Registry. The Senate Health, Education, Labor and Pensions Committee (Senator Edward M. Kennedy [D-MA], Chairman) held one hearing on this topic on September 5, 2001. The hearing focused on the quality and viability of the existing stem cell lines. The Secretary of HHS, Tommy G. Thompson, testified (stemcells.nih.gov, 2005)

The House of Rep. also held hearings on the topic of stem cells during the 107th Congress. The House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources had people testify whom, "adopted frozen embryos from *in vitro* clinics (stemcells.nih.gov, 2005)."

The first pieces of legislation to go through the 107th Congress were the bills H.R. 2059 and S. 723. 2059, introduced into the House by Rep. Jim McDermott (D-WA)

(stemcells.nih.gov, 2005). Labeled as the Stem Cell Research Act of 2001, this bill amends the Public Health Services Act, allowing hES cell generation and research (stemcells.nih.gov, 2005). Bill number S. 723 was brought to the Senate by Sen. Arlon Specter (R-PA) (stemcells.nih.gov, 2005). Truly a bi-partisan effort, the Senate passed the bill. After the bill was passed certain provisions were made to make sure the bill served its purpose. The provisions for all bills are found at stemcells.nih.gov.

- Notwithstanding any other provision of law, "the Secretary of Health and Human Services (HHS) may only conduct, support, or fund research on, or utilizing, human embryos for the purpose of generating embryonic stem cells and utilizing stem cells that have been derived from embryos in accordance with this section" (Section 489C).
- The only embryos that may be used for such activities are "those embryos that otherwise would be discarded that have been donated from in-vitro fertilization clinics with the written informed consent of the progenitors."
- The research involved shall not result in the creation of human embryos.
- The research involved shall not result in the reproductive cloning of a human being.
- Any person receiving Federal funds would be prohibited from knowingly acquiring or transferring embryos for "valuable consideration." Valuable consideration would not include reasonable payments associated with transportation, transplantation, processing, preservation, quality control, or storage.
- The Secretary of HHS would be required to develop guidelines that would "expand on the rules governing human embryonic stem cell research to include rules that govern the derivation of stem cells from donated embryos under this section."

The Responsible Stem Cell Research Act of 2001 was the next piece of legislature to go through congress. S. 1349 was brought into the Senate by Sen. John Ensign (R-NV) (stemcells.nih.gov, 2005). This bill was not written to protect private interests of the citizens, but rather to ensure that a good supply of stem cells could be readily available to researchers and scientists. "… and to require the Secretary of HHS to maintain a stem cell donor bank containing stem cells derived from adult tissue, placentas, and umbilical cord

blood (stemcells.nih.gov, 2005)." H.R. 2096 was introduced by Rep. Christopher Smith (R-NJ) (stemcells.nih.gov, 2005) with the following provisions:

- The Secretary of HHS would have been required to establish and maintain by contract a National Stem Cell Donor Bank for the purpose of seeking and preserving donations of "qualifying human stem cells" and shall make such donated cells available for biomedical research and therapeutic purposes
- "Qualifying stem cells" were defined as human cells obtained from human placentas, umbilical cord blood, organs or tissues of a living or deceased human being who has been born, or organs or tissues of unborn human offspring who died of natural causes (such as spontaneous abortion).
- The bills would have authorized appropriations of $30 million for FY 2002 and such sums as may be necessary for each of the FYs 2003 through 2006 for NIH to conduct and support research using qualifying human stem cells.

H.R. 2838 could possibly be the most important piece of legislation to go through Congress regarding stem cell use. Brought to the House by Juanita Millender- McDonald (D-CA), the New Century Health Advantage Act serves many purposes (stemcells.nih.gov, 2005). Most importantly this bill nullified the Human Embryo research Ban that was passed through the Labor, HHS and Education Appropriations Act (stemcells.nih.gov, 2005). This bill also requires that the NIH conduct hES research and report all findings and innovations to congress (stemcells.nih.gov, 2005). Provisions:

- The Director of NIH would have been required to conduct or support research using human pluripotent stem cells derived from excess embryos created for purposes of fertility treatment and in excess of clinical need.
- Section 510 of the FY 2001 Labor, HHS, and Education Appropriations Act, which prohibits certain research involving human embryos, would have been repealed.

Rep. McDermott was also responsible for H.R. 2863, the Cell Development Research Act of 2001. This act did not directly affect the research on stem cells, rather it

aided in the overseeing of the research"…requiring the establishment of an additional Food and Drug Administration (FDA) Advisory Committee to make recommendations on the field of cell development, including human embryonic stem cell research and therapeutic cloning (stemcells.nih.gov, 2005)." The 2863 provisions included:

> A Cell Development Advisory Panel would have been created to provide recommendations to the FDA regarding the field of cell development, including human embryonic stem cell research and therapeutic cloning.

In connection to this bill H.R. 4011, the Science of Stem Cell Research Act was also written. Brought to the house by Rep. Carolyn Maloney (D- NY), this act created a panel to review and evaluate the outcome of Bush's 2001 stem cell report (stemcells.nih.gov, 2005). The 4011 provisions included:

- A bipartisan commission to be known as the Stem Cell Research Board would have been established in the legislative branch.
- The Board would have been required to conduct research on the effects of the President's August 9 stem cell policy, including the progress in advances in curing certain diseases, and all aspects of the NIH funding process for both embryonic and adult stem cell research.
- The Board would have been required to make recommendations to Congress regarding any changes in legislation that may be warranted to reduce any inefficiencies in Federal funding of human embryonic stem cell research.
- The Board would have included members appointed by the President, Speaker of the House, minority leader of the House, and majority and minority leaders of the Senate. There was no specification in the bill that any of the members be individuals with scientific expertise.

108th Congress

On February 27, 2003, the first piece of stem cell legislature passed through the House of Representatives (stemcells.nih.gov). The Human Cloning Prohibition Act of 2003 (H.R.534) was written to outlaw both reproductive and therapeutic cloning, as well

as to establish a criminal penalty if the laws the bill established were broken (stemcells.nih.gov, 2005). Although cloning and stem cell research are very much different there are some strong connections, and in particular 'the phrase "human cloning" was defined to include somatic cell nuclear transfer technology for the purpose of deriving stem cells (stemcells.nih.gov)." While conducting stem cell research, a process was discovered that may allow human cells to be extracted and copied. The process of cloning was ethically argued and lawfully prohibited.

Soon after H.R. 534 passed, H.R. 801 was introduced by Rep. Jim Greenwood (R-Pa) (stemcells.nih.gov, 2005). Human cloning would still be prohibited by this act, but only reproductive cloning, the bill would allow therapeutic cloning. The bill was recommended to the House Committee on Energy and Commerce.

After the cloning and stem cell debate within the 107th congress the discussion on the matter took a back seat. "Rather than passing new legislation, most members of Congress appeared willing to accept the President's policy and await the results of its implementation before determining whether any specific legislative remedies were needed (stemcells.nih.gov, 2005)." The 108th congress does expect to see changes to Bush's policy. "It is possible, however, that if the 108th Congress considers the Labor, HHS, Education, and Related Agencies Appropriations bill this spring, rather than one omnibus spending bill, stem cell amendments may be added. It is also possible that members of Congress who have been active on this issue, such as Senator Specter and Senator Sam Brownback (R-KS), will introduce legislation to either expand or limit the President's policy (stemcells.nih.gov, 2005)."

State Laws

In addition to the national debate on ES cell research, individual states have also taken up the debate. Both the state and federal government have control over the issue of stem cells, unless Congress deems it illegal, which is not very likely. Currently 26 states have legislation on the books regarding the regulation of stem cell research (bioethics.gov, 2005). Below is part of an interview by Dr. Lori Andrews a science and technology law expert:

Now, the states as well as the Federal Government have a role in setting policy in this area, and 26 states have laws that govern research on fetuses and embryos. They are enormously different, and they vary widely on things such as whether they only apply in situations where there's been an abortion. For example, 12 of the states only apply if the research subject was the subject of a planned abortion.

So there's more leeway in those states to do research on a miscarried fetus, but there are medical reasons to think that might be less than optimal, since most stem cell research will not take place on miscarried conceptuses but on *in vitro* embryos.

In that situation, we currently have nine states that banned research on IVF embryos altogether. And what that means, though, is that it doesn't really get to the heart of the activity. For example, if Dr. Gearhart found that a certain type of destructive embryo research produced a safe and effective therapy, once it passed the experimental stage it could be done in those states. It only applies when the activity is at the research stage.

Some states have bans on the destruction of a human embryo or fetus for any purpose, making stem cell research and abortion completely illegal (bioethics.gov, 2005). Some states have also started to create advisory boards. Biotechnology companies would have to go in front of these boards to explain the purpose of their research. The panel would hold the ability to grant research rights, or to say no.

While some states are creating panels, other states have created a system of consent (bioethics.gov, 2005). In California it is legal to perform all types of stem cell research from all sources, but with one stipulation: the researchers must have written and documented consent from the donor of the fetus or embryo. This has raised the question, why consent from women is needed, but not men. California was also the first state to float a bond establishing a stem cell research center, with bond money funding research in the center. Other states soon worried about a possible brain drain of stem cell scientists to that state, so others soon followed, including New Jersey, then Massachusetts. Likely this trend of states overriding federal stem cell laws will continue.

Although much progress has been made in the area of stem cell research law, the variation from state to state law needs improvement. Some states do not allow early stage research such as Massachusetts, but Connecticut does. A biotechnology company in Conn. could do the research and then send the cells to Mass. for clinical study. These laws will most likely change with time, as will the ability to derive and regenerate stem cells. With time will come improvements in research, ethics, law and application.

CONCLUSIONS

Stem cell therapies have a promising future which will certainly change the world of science and medicine. ES cells are the only types of cells capable of forming many different types of tissues, a property that will benefit mankind greatly in the years to come. Such cells will be used to repair and replace damaged tissue and organs, and also will play a vital role in curing many degenerative diseases. Adult stem cells are already currently used in everyday therapeutic procedures, and as time goes on more types of these will be discovered.

Ethical and moral issues are severely impeding the advancement of ES cell research. With further investigation, the public may realize IVF embryos are already routinely being disposed of, so why not allow ES cells to be isolated from them to save lives? Similarly the current legislation in the U.S. is severely impeding the forward progress of regenerative medicine. The authors of this IQP support the trend of states and the private sector funding research to override current federal laws. Our hope is that the congress and President design looser guidelines for federal funding of this research, and in coordination with less strict state laws allowing research, the United States may retain its status at the forefront of the race to commercialize stem cell use.

Stem cells represent the future of biotechnology. The sooner the U.S. drops its semi-conservative views the closer we will be to curing Parkinson's, stopping birth defects, eradicating Alzheimer's, and possibly even growing new body parts. This process may take decades, but slow improvements are better than no improvements at all.

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