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STEM CELLS

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STEM CELLS

An Interactive Qualifying Project Report

Submitted to the Faculty of

WORCESTER POLYTECHNIC INSTITUTE

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ABSTRACT

Stem cell research holds hope for saving human lives, but the effect of this controversial technology on society has profound ethical and legal implications. This IQP investigation shows the ability of these simple cells to possibly treat a number of human ailments, from stroke to diabetes to spinal cord injuries. While there is a general consensus among the five major world religions that the use of adult stem cells is ethically and morally just, embryonic stem (ES) cells generate significant debate due to the source of the derived cells and people's various views about when life begins. Laws governing stem cell funding vary widely in different U.S. states, and internationally. We support efforts to re-establish U.S. federal funding for ES cell research, but also support the development of alternative approaches, such as iES cells. A better public understanding of stem cells will help enact clear, consistent laws to guide future research in this area that holds so much promise.

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PROJECT OBJECTIVES

The objective of this IQP is to investigate the ever changing topic of stem cell research and to discuss the effects of this controversial new technology on our society. The intention of chapter-1 is to explain and delineate between the truly successful, productive stem cell experiments conducted thus far. The purpose of chapter-2 is to examine the complex ethical debate surrounding this controversial topic, particularly for embryonic stem cells. The goal of chapter-3 is to delve into the widely varying state, federal and international laws governing stem cell research and its funding. Finally, based on information derived in this investigation, the authors provide conclusions and recommendations on stem cell legislations that best represent the authors viewpoints.

Chapter-1: Stem Cell Applications

Alex Demers

Introduction

Given the regenerative nature of stem cells, they have very numerous and diverse applications. Adult stem cells have already been used in the treatment of more than 73 medical conditions, and have also been used in over 1400 FDA approved clinical trials (Saunders et al., 2008). As one striking example, Dr. Rich James, a chiropractor who lives in New York City, suffered a stroke in 2006. In July of that year, he began receiving therapy from a private company, Stem Cell Therapy INTL. Within a few months, Dr. James was not only able to walk by himself, he had large improvements compared to when he previously received more traditional rehabilitation for strokes (Vega, 2006). In addition to strokes, many other conditions can be also treated with adult stem cells, including various autoimmune disorders, antiphospholipid syndrome, sclerodoma, and multiple sclerosis, genetic diseases, tissue regeneration, leukemia, and Parkinson's Disease (Saunders, 2008). To be highlighted in this chapter are specific ailments that can be treated with stem cells, specific examples of people who have received stem cell treatments, and current research being done to expand the use of stem cells.

Embryonic Stem Cells Versus Adult Stem Cells

Embryonic stem (ES) cells are the most versatile stem cells available, as they can develop into any type of cell in an organism (except the placenta). They represent the inner cell mass of a 5-day old blastula, and can develop into the three major types of tissues, ectoderm, mesoderm,

and endoderm (Thomson and Yu, 2006). Those tissues can change into every type of cell in the body. Ectodermal cells develop into neurons, hair, sensory nodes, and others. Mesoderm tissues becomes muscle, blood, and connective tissue. And endoderm, becomes liver, stomach, pancreas, germ cells, lungs, bladder, and other organs. An exciting branch of biology, developmental biology analyzes how a human develops from the beginning of fertilization, to division, specialization, and organogenesis.

Adult stem cells (ASCs) are isolated from various tissues in the body, and generally have less potential than ES cells. ASCs are also harder to isolate and grow in culture. Throughout this chapter, an attempt will be made to distinguish whether a particular experiment was performed using ES cells or ASCs, and whether the work was performed on animals or in human clinical trials.

Treatment of Stroke with Stem Cells

A stroke occurs when the flow of blood to the brain is obstructed, causing either death or disability. The two types of strokes are ischemic and hemorrhagic, each causing the blood flow to be compromised in a different way. Ischemic strokes are caused by an obstruction in blood vessels, such as clots, causing less blood to be able to transport itself into the brain. From this kind of stroke, the diminished blood loss can cause delayed damage to the brain cells well after the stroke occurs (Stroke Overview, 2007). Hemorrhagic strokes are caused by ruptured blood vessels in the brain. Strokes are the third leading cause of death in the United States as well as the leading cause of disabilities. Roughly one in four strokes are fatal.

Current treatments for stroke depend on which type of stroke happened. For ischemic strokes, drugs that break down clots are given within a few hours of the event (Stroke

Treatments, 2007). To prevent the stroke from happening again, patients are prescribed anticoagulants to prevent clots from reforming. Hemorrhagic strokes generally require surgery to reduce intracranial pressure caused by the bleeding. Blood flow can either be redirected to other blood vessels, supplying neighboring parts of the brain, or vessels can be repaired using stents.

Rehabilitation from a stroke, as with any major medical incident, is a long and arduous process. Physical rehabilitation helps patients regain motor control that may have been lost due to paralysis from having parts of their brains shut down. Other types of therapy, such as speech and occupational, allow stroke sufferers to regain use of speech and simple tasks such as buttoning shirts, respectively. The whole process of helping people restore mobility and functionality is a long process. Luckily, through the use of stem cells, advances are being made to help improve and speed up the process.

Using stem cells to help stroke patients has been one of the major focus points of regenerative research. The first success in humans came in 2004, at the Stanford University School of Medicine (Stem Cells Fill Gap, 2004). Using ES stem cells, they were able to close the gap of dead neural cells caused by a stroke. The study, however, was not able to show that the new neurons could replace the functionality of the dead cells. Since then, however, that ability has been shown by other investigators.

Since the Stanford study, there has been more research done in the area of treating strokes with adult stem cells in the form of animal models. Two studies, one by South Koreans and another by Canadians and Chinese, found that inserting stem cells into animals that had strokes caused dramatic improvements over the control animals. Specifically, in the South Korean study, human mesenchymal stem cells were transplanted into the animal models, all of which had been induced to an ischemic stroke. Within 10 weeks, magnetic resonance imaging showed that “the

majority of the cells were detected in the core of the infarcted area” (Stem Cells Useful in Animal Stroke Models, 2008). The Canadian-Chinese study injected bone marrow stromal cells into animals induced to stroke 24 hours previously. Within a week, there were great “reductions in scar size and cell death, and improvements in neurological function compared to controls receiving no BMSCs” (Stem Cells Useful..., 2008).

With more research being performed on strokes using stem cells, there will hopefully be a time when stroke rehabilitation will be much faster, and all brain activity can be restored. For now, advances that have already been obtained by the use of stem cells are of great hope to those who suffer from strokes.

Cardiac Tissue Regeneration

Heart failure is a large issue in the American medical world. According to the Center for Disease Control, around 5 million people suffer from heart failure (Heart Failure Fact, 2006), with 550,000 new cases documented each year. Of these people with heart failure, 287,000 perish annually. Heart failure is most likely to be caused by coronary artery disease, high blood pressure, or diabetes. The lack of blood flow to the heart tissue itself causes the cells in the organ to die, decreasing the power with which the heart can pump blood throughout the body. There are several ways that the organ tries to combat the decrease in efficiency. The heart will try to enlarge the chambers (Learning about, 2008), so that the chambers stretch more and have more compression power. The heart can also try to develop more muscle mass, also increasing the compression strength. The heart will also beat faster. Unfortunately, over an extended period of time, the heart and body cannot keep up with all of the extra demand, and the problems

associated with heart failure resurface. It is because of this that people can have heart failure for several years before symptoms are visible.

In February of 2003, Dimitri Bonnville suffered a large heart trauma, including being shot in the organ by a nail gun, open heart surgery, and a heart attack. The sixteen year old needed a heart transplant, but the doctors had another option. Bonnville could be “the first human to receive experimental stem cell therapy to revive his damaged heart tissue (Philipkoski, 2003).” The procedure, performed by doctors at William Beaumont Hospital in Michigan, used drug therapy to stimulate hematopoietic stem cell (HSC) production in Bonnville’s blood. The newly produced HSCs were isolated, and transplanted into the artery that supplies blood to the front of the heart (Philipkoski, 2003)”. From this point, the stem cells began to help heal the dead region of tissue. To put how monumental this procedure was into perspective, patients who had this type of damage to their hearts with no therapy rarely had improvements. Normally, when dealing with procedures of this nature, rejection of the new cells or tissue could be a problem. Since the cells were taken from the same patient, the rejection of the cells was not an issue.

There are three major types of cell within the heart. Cardiomyocytes are the heart muscles that contract. Endothelial cells help form the inner lining of new blood vessels. The third type, smooth muscle cells, form blood vessel walls. The latter two cell types help form new networks of blood vessels to deliver blood to damaged cardiomyocytes (Report on Stem Cells, Chapter 9, 2007). Recently, researchers at the Harvard Stem Cell Institute found a type of ‘master cell,’ a type of stem cell that can develop into any of the three types of heart cell (Cromie, 2006). This breakthrough could help lead to new ways to regenerate new hearts for people, no matter the age or condition of the heart.

Bone Mending Using Stem Cells

Imagine playing a friendly game of softball, chasing down a fly ball one of your feet gets caught in the dirt and you begin to fall, with all of your body weight landing on your shoulder, suffering a double fracture. That is exactly what happened to Monique Biggins in 2002 (Chang and Sherwood, 2008). After she had undergone several surgeries on her shoulder in a two year period, including having a plate and multiple pins put in, nothing had worked. But using stem cells taken from her own body, the bone was able to be mended, and Biggins was able to play softball, as well as the piano, once again. The group at the Cleveland Clinic who performed the procedure is now looking to expand the technique to be able to treat veterans coming back from combat zones.

Further research has been done in the area of re-growing bone. In December of 2007, scientists at John Hopkins University were able to steer mouse mesenchymal precursor cells “into bone regeneration by using ‘scaffolds’ -- tiny, three-dimensional platforms made from biomaterials (Stem Cells Heal Massive Skull Injury, 2007).” The researchers were also able to show the ability to have these “scaffolds” develop into the smaller bones found in the jaw, and the longer bones found in the limbs.

Expanding upon the John Hopkins research are British scientists (British Scientists, 2008) who are currently working on developing a surgical technique to regenerate bone tissue. Hematopoietic stem cells would be taken from either the patient’s blood or bone marrow. The group is currently working with the Scottish National Blood Transfusion Service to induce bone forming HSCs to be released into peripheral blood, so surgery would not be needed to remove

the HSCs from the patient's bone marrow. This type of research is also currently looking into coating or inserting a drug into the HSCs that would allow them to engraft to the patient easier.

Not only can HSCs re-grow bones in patients, they can also regenerate skin tissue and blood vessels (Torma, 2008). For example, a 65 year old Finnish man had his upper jaw removed due to a tumor. Doctors were able to take stem cells from fat deposits from the man, and allowed them to grow attached to a calcium phosphate biomaterial scaffold for several months. When the material was ready, the scaffold was attached to the man, and when the procedure was all done, the man's new jaw was complete. Looking at it, you can not tell that the jaw is artificial. Doctors are currently developing a method to use a similar scaffold to treat arthritis and joint problems.

Treatment of Hemophilia Using Stem Cells

Hemophilia is a blood disease that causes problems with clotting. In the two types of hemophilia, specific proteins, called clotting factors, are missing in the blood (What is Hemophilia, 2007). In type A hemophilia, clotting factor VIII is either missing or in very low concentration. Type B hemophiliacs are missing clotting factor IX. Nine out of ten people with hemophilia suffer from Type A. These clotting factors work with platelets to help seal circulatory ruptures. The severity of the hemophilia depends on the concentration of clotting factors in the blood; it can be mild, moderate, or severe. The majority of people with type A suffer from a severe form of the disorder. Roughly 18,000 Americans are hemophiliacs, and 400 babies are born with the condition annually. Nearly all occurrences of the disease are in males.

People who suffer from hemophilia tend to bleed excessively and bruise easily. Excessive bleeding can occur externally or internally (What are the Signs and symptoms of

Hemophilia, 2007). External bleeding is signified by random nosebleeds, cuts bleeding again after initially stopping, or major bleeding from a minor cut. Internal bleeding can be either be seen in urine or stool. Bleeding can also occur in the joints, causing pain, swelling, immobility and even permanent damage to the joint if immediate care is not taken. Bleeding in the brain can also occur, even after a slight bump.

Fortunately, research is being done with stem cells to attempt to correct hemophilia. In 2005, scientists at the University of North Carolina at Chapel Hill (Embryonic Stem Cells Treated, 2005) have been working with mice genetically altered to be lacking a functional gene for factor IX for type B hemophilia. By growing murine ES cells and adding a fibroblast growth factor before implantation, they developed into cells similar to those found in the digestive and respiratory tracks. These cells also engrafted themselves in the liver, further developing to become hepatocytes and expressing the gene for the missing clotting factor IX. The researchers felt that this initial mouse study answered a lot of questions on the topic, and showed promising signs for the future, though there were still some questions that needed answering before moving to human therapy.

Diabetes Treatment Using Stem Cells

Diabetes is a condition affecting nearly 8% of the U.S. population (All About Diabetes, 2008). In type 1 diabetes, the body does not produce insulin, a hormone responsible for signaling the body to take up glucose from the blood and store it as glycogen for later energy use. In diabetics, β -cells that produce insulin in the pancreas are either damaged or destroyed by an autoimmune response, so this vital peptide hormone cannot be produced, and external insulin injections are required. Initially, insulin for these injections was taken from cow and pig livers,

but the current method for insulin production uses insulin produced from genetically altered bacteria. Animal insulin is no longer produced in the U.S, however, the FDA allows it to be imported for people to use for their diabetes. People with type 1 diabetes, if untreated, can suffer from any number of ailments, including heart disease, blindness, nerve damage, kidney damage, skin damage, and circulation problems, as well as others (Type 1 Diabetes Complications, 2008). At this point in time, there is no cure. The closest procedure to a cure is an organ transplant, but it can be rejected by the host.

The potential for treating type 1 diabetes with stem cells is high, as the only type of cell that needs to be made is the β -cell (Goldwaithe, 2008), however, before the β -cells can be inserted they need to be engineered so they will not be destroyed by the autoimmune response. The difficult part about generating only the β -cell is that the pancreas is a very diverse organ, consisting of many different cell types. In the adult stem cell method is taken, isolating the pancreatic stem cell is a challenge. After showing that new β -cells were only produced by preexisting ones, a precursor multipotent stem cell was found in the pancreas that can develop into a number of endocrine cells within the pancreas, including β -cells (Goldwaithe, 2008). Other research has shown that there may be cells within the liver, spleen, bone marrow, or other organs that can differentiate into insulin-producing cells. The validity of those reports, however, is being debated.

Israeli scientists have been working to develop insulin secreting cells in laboratory work (Assady et al., 2001). They have been able to produce β -cells, but they do not know the specific factor in the cascade that created them. Another item this team was looking at is the response to glucose of the cells, but the results were inconclusive, as they did not display responsiveness.

Overall, they feel confident that with further development, stem cells can be a feasible and effective treatment for diabetes.

Nervous System Regeneration

When diseases of the nervous system occur in people, such as Parkinson's, Alzheimer's, Lou Gehrig's Diseases of the central nervous system, or any number of disorders of the peripheral nervous system, they are often serious and potentially life threatening. In addition, there are several other types of nervous system diseases (Panchision, 2006), including congenital disorders resulting from improperly developed brains or spinal cords, cancers resulting from aberrant cells growing uncontrollably, and degenerative diseases resulting from neural cells breaking down and not functioning properly. Most of the focus of stem cell research for nervous system disorders is on the degenerative diseases, as those are the result of failing cells that can be identified and then hopefully replaced with the use of neural stem cells. One of the common myths people are brought up with are that once a brain cell dies, new ones are never made. There has been evidence from as early as the 1960's that show that is just a myth. There are packs of slowly reproducing cells within the brain that are believed to be leftover from development (Panchision, 2006). These cells are referred to as adult neural stem cells (NSCs).

Parkinson's disease is one of the diseases that researchers have targeted with their studies. Parkinson's develops when neurons that produce dopamine, a chemical that helps with the body's physical movement, die off (Parkinson's Disease: An Overview). Results of this process are tremors within the hands and feet, stiffness, bradykinesia, and lack of motor control and coordination. One current treatment for Parkinson's include drugs containing a compound (L-dopa) that is converted into dopamine by an enzyme found within neural cells (Medication's

and Treatments). Another treatment is a drug that stimulates the parts of the brain that respond to dopamine, fooling the cells to act as though they had received the hormone.

Researchers in Israel have been working on animal models (Ryan, 2004) to see what effect stem cells can have on Parkinson's. Using rats suffering from Parkinson's-like symptoms, i.e. a lack of dopamine producing cells in the brain, after inserting NSCs the animals showed remarkable improvement. After not being able to move laterally while being dragged, the mice were able to do this post-implantation. Post mortem analysis showed that the new stem cells had developed into dopamine producing cells in the brain, and that no cancerous tumors had developed as a result of the insertion, which was one of the doctors fears.

Other neural applications of stem cells include the repair of the spinal cord. Doctors at the University of California at Irvine were implanting ES stem cells into rats that had suffered from spinal cord injuries (Stem Cell Treatment Improves Mobility, 2005). The group found that when the cells were inserted within 7 days of the injury, the animals were able to heal and regain motor skills. However, in the group of mice where the injury was suffered several months beforehand, the same treatment was not effective, and little if any motor skills were recovered. In the early therapy, these cells were able reform myelin, which is the biological insulation for the cells that allows them to function properly. In the mice receiving the late therapy, however, the oligodendrocytes were able to survive, but were unable to produce myelin because of the formation of scar tissue in the area around the spinal cord. The animal findings, however, are promising for the future in the translation into humans.

Chapter-2 Conclusions

Stem cells are a very diverse, exciting, and extremely beneficial method for treatment of many types of medical problems. As is typical for most areas of medicine, most of the human data are based on previously performed animal studies, but individual human success stories have been achieved, and were discussed here. Some of the approaches with adult stem cells have moved into clinical trials, but new legislation would have to be put into place to allow ES human therapies. The ability of these simple cells that we produce in our own bodies to fix a number of ailments, from stroke to diabetes to spinal cord injuries, is an amazing new tool that has led to the field of regenerative medicine. With more research, the possibilities from stem cells are limitless in the medical field, as well as helping to expand our developmental understanding of how humans develop from fertilization to the adult.

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Chapter-2: Stem Cell Ethics

Alex Demers

Introduction

In 2001, President Bush approved legislation that would allow for federally funded stem cell research, as long as the tests were done using already established ES cell lines, taken from embryos that had already been terminated before that time. From that point to a public statement concerning the stem cell policy in July of 2006, more than \$90 million federal dollars were allotted to stem cells research (Bush, 2006). This federal policy shows both sides of a dangerous sword. On one side, there lies the desire to expand stem cell research to allow for the development of new and more effective treatments for medical problems, but on the other hand we have the desire to preserve human life, to allow all living beings to at least have a chance at life. Ethics will help us decide between the benefit to society versus the detriment to an embryo.

One of the biggest problems with stem cells is the ethical dilemmas they present. Embryonic stem (ES) cells, taken from 5-6 day old blastocyst embryos, are seen by some to be human life in its earliest stages. Much of the debate stems from this point: what defines a human life? When does human life begin? Opponents of stem cell research see this as disrespectful to human life, as a life is being taken. Those in favor of stem cell research see these embryos not as human life, but as *potential* human life, as they are not developed enough. Some do consider them to be living beings, but with less value than that of an independent human. The worlds five major religions each has their own views of this controversial topic.

Religion and Stem Cells

Religious factions are some of the most outspoken groups about stem cell research. Based on deep beliefs, some of which have been sculpted over thousands of years, some people find stem cell research immoral, as it lessens the value of human life in some state of its being. Some religions are opposed to this type of research, while others support the research based on circumstances.

Catholicism

In 2001, when President Bush decided to allow continuing ES cell research with limited federal funding, the Catholic Church was quick to voice their dismay of the decision (American Catholic, 2006). The way the church saw the decision was that the federal government is supporting the “research that relies on the destruction of some defenseless human beings for possible benefit to others.” They were hoping the President would change his mind, and bring back respect for the human life. Bishops were outspoken about the decision before the legislation was passed. They also mentioned that no matter how insignificant stem cells are, they still are the basis of human life, as *eventually* they could have developed into complete human beings.

At a conference in Orlando, Florida, American bishops voted overwhelmingly against ES cell research. They referred to the practice as “gravely immoral and unnecessary (Filteau, 2007).” There was even an overwhelming vote of 191 to 1 in favor of releasing a document deploring ES cell research. The document was the first one released by the church that focused exclusively on this issue. These bishops are also one of the largest voices in the debate, according to Archbishop Joseph F. Naumann. However, with respect to working with *adult stem cells*, the document did say “There is no moral objection to research and therapy of this kind,

when it involves no harm to human beings at any stage of development and is conducted with appropriate informed consent." Those sentiments are backed by Pope Benedict, who endorsed adult stem cell use on September 16th, 2006 (Pope Benedict, 2007). He sees using adult stem cells as respecting human life, as they are taken from donors in a relatively painless process. In other words, the church approves of the use of adult stem cells, as long as they are taken with consent of the patient. Embryonic stem cells, however, are out of the question in their opinion.

Judaism

The Jewish faith believes that our bodies, as human beings, essentially are on a loan from God, as he still owns them (Dorff, 2001). Following this, they believe that it is our responsibility to do what we must in preserving these bodies by developing new remedies for ailments that can cause damage to them, while preserving all forms of human life. Jewish people say that in the first 40 days of gestation, the fetus is "as if it were simply water." From the 41st day on, they believe that the fetus is "like the thigh of its mother." Since they believe we must preserve our bodies, abortions cannot be performed because it is an act of self mutilation. However, if the pregnancy poses a risk to the mother, an abortion may occur, as the fetus is only a part of the being and not its own individual. If the fetus is aborted, the Jewish faith says that it can be used for stem cell research, as it is no longer a person, and harvesting the stem cells is developing new remedies for medical ailments.

The Jewish view on the first 40 days of gestation is a curious one. Since they view the fetus as little more than water, and not a human being, working with a 5-6 day old blastocyst to obtain ES cells poses no problem. Also performing an abortion within that period of time is not

a problem with Jewish law (Eisenberg, 2006). However, there is some contention between Rabbis about this situation. Some view that an abortion within this period of time is the equivalent of wasting the male seed, which is prohibited even before conception. Other Rabbi's views are that since there is no limb to be harmed within the early days of gestation, there is no problem with the abortion within that time frame. Those rules are only for Torah Jews; anyone else does not have to follow them. Because of that, there is no restriction on abortion for non-Jews. Jewish doctors can also aid in performing the abortion within the first 40 days.

Islam

In the views of the Muslims, the embryo does not develop into a human until after the fourth month of pregnancy (Weckerly, 2002). Before that point in time, the embryo is not considered human life, and is thus allowed to be used for stem cell research. Thus working with a blastocyst to obtain ES cells is allowed. But under Islamic Law is the disallowance of surrogate parenting, adoption, and adoption of human embryos. Those stipulations allow for an added influx of embryos for ES cell research. Muslims possess similar views to the people of Jewish faith in that they see our bodies as extensions of God, and any research done to help keep the bodies healthy is beneficial to us as a people.

Hinduism

The Hindu people, located mostly in the eastern hemisphere, have a slightly different view for their stance on abortion. Although there is no single spokesperson for the Hindu faith,

in a series of questions asked to several prominent swamis (Hindu leaders) in India, they all had very similar answers (Saraswati, 2003). The general answer was that stem cell research, along with most other scientific advances, will go a long way in corrupting the human race. They believe that we must respect nature, and most of our new advances help distort the natural balance of the world. Another common thread from their responses pertained to the motives of the research. If the desire to develop new technologies occurred from the desire to help people, then that would be acceptable; if it was purely for a commercial gain, then they are against it.

Buddhism

Buddhism is one of the unique religions in that it has no central authority to speak out on topics that cause controversy among members, making generalizing the religion's stance on the topic of stem cell research difficult. However, there are some aspects on which comments can be made. Most followers of Buddhism, which believes in a reincarnation of the soul, believe that the transfer of the soul takes place at conception (Keown, 2004). From that point on, the embryo contains the karmic being of a recently deceased person, meaning that it is entitled to the same rights as humans and should not be terminated. The religion, however, has no qualms with adult stem cell use and research.

Women's Groups and Stem Cells

The Concerned Women For America group has a similar point of view to stem cell research as some religious groups in that adult stem cell research is a fantastic opportunity to

cure diseases previously believed as incurable (Elliot, 2005). They feel embryonic stem cell research, however, puts the value of scientific breakthroughs over the sanctity of human life. They feel, along with several doctors, including the chairman of the Mayo Clinic and a professor at the Harvard School of Medicine, that human life begins at conception, so at any point, termination of the embryo is the killing of a human being. One of the major concerns had is the rejection of the foreign tissue into the body. This occurred once, when a man who received embryonic stem cells to treat Parkinson's Disease died after skin, hair, and bone began to develop in his brain. Another problem cited with embryonic stem cell treatment is the creation of tumors at the point of injection. These tumors have occurred at a rate of approximately one in five animal test subjects (Adult Stem Cell Breakthrough, 2005).

Parthenogenesis as an Alternative to Fertilized Embryos

Parthenogenesis is the process by which eggs undergo development into living organisms without undergoing fertilization (Parthenogenesis). Using the chromosomes already present within the egg, development and cell division begin after chemical stimulation. These embryos are then cultured to the blastocyst stage, and are used to harvest ES cells.

The eggs are can be coerced into beginning development *in vitro* by changing the surrounding environment, such as temperature changes, in unison with chemical agents such as strontium chloride. Although parthenote embryos can not develop into adults, and some argue have less moral status than fertilized embryos, the Family Research Council sees these organisms as living beings, and that the "clone and kill (Cloning and Parthogenesis Ban, 2006)" method used to harvest these stem cells discards "human dignity to satisfy human curiosity."

Some positive aspects of parthenogenesis are that for this method, if the eggs used are those of the patient, a perfect compatibility match with no worries of rejection is created. They also say that since gestation cannot be completed, due to a lack of required genetic components, the organism is not a living human being. Opponents of parthenogenesis have a different view, saying that medical evidence does not show that the organism cannot develop into a human being. Dr. William Cheshire states that labeling the organism as not a human being does not justify exploiting it for the sake of research.

Chapter Conclusions

There is a general consensus among the five major world religions and other women's groups that the use of adult stem cells is ethically and morally just; since the tissue is being taken by a donor with consent, and is used (often in the same person) to try to save lives. I agree with this view. Since adult stem cells can be taken from several places in the body, including the brain, bone marrow, peripheral blood, blood vessels, skeletal muscle, skin and liver (Stem Cell Basics), as well as from umbilical cords, there are a plethora of suitable uses for these cells. With future research on these applications, there can be an outstanding benefit to mankind.

Embryonic stem cells are the area where people begin to differentiate in their feelings. As was seen earlier, 2 of the five major world religious groups allow ES research, while 3 are either totally against it, or would allow it only under very special circumstances. Part of this distinction comes from the view of when human life begins. If your view of when human life begins is at conception, then you are opposed to any type of ES stem cell research. Two religions say you

attain the same rights as humans only after a certain period of time in the womb, thus so as long as the cells were obtained before that point, it is not a problem.

There is obviously contention as to when human life begins, as well as to when abortions can occur, which is a related problem often discussed simultaneously with stem cell research. But we must be clear to distinguish the difference between a 5-6 day old blastocyst from which ES cells are obtained (and which has no brain, nervous system, eyes, or arms, etc) versus aborted fetuses which are obtained at far older developmental stages. The views of this author are that there is no problem working with IVF embryos the age of blastocysts to obtain ES cells. And with respect to older fetuses, if up until the third trimester a termination is desired, by all means, go ahead and allow fetal tissue to be harvested for research. If doing so can allow for cures to the numerous diseases and debilitating occurrences that continue to cripple the population, make it happen. There is some validity to the statement that everyone should get a chance at life, however, why not allow for one who has never even developed a brain or had a thought, to be used to save the lives of those who have already established their niches in this world.

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Chapter-3: Stem Cell Legality

Tim D'Souza

Overview

The unique regenerative properties of stem cells generate significant scientific interest as a possible means to treat many challenging diseases, including Parkinson's disease, Diabetes, and Heart Disease (Stem Cell Basics-NIH, 2006). Due to ethical debates associated with certain types of stem cell lines discussed in Chapter 3, in particular those derived from human embryos, this has become a controversial legal topic at the State, Federal and international levels. Additionally, recent advances that allow the creation of embryonic stem (ES) cells through means such as Altered Nuclear Transfer (ANT) or Pre-implantation Genetic Diagnosis (PGD) continue to cloud the research. Should this research be legal, and should public tax revenue go to funding it? It is the contention of many scientists that core biomedical research in regenerative medicine can not flourish without this key federal funding (Dunn, 2005). Additionally, the number and quality of researchers available with the required expertise to conduct the research is impacted by the legality and funding availability for stem cell research (Agnew, 2003). In this Chapter, the legal landscape of stem cell research in the United States, at the federal and State level, and also internationally will be discussed.

United States Federal Stance on Stem Cell Research

Many of the legal issues surrounding stem cell research focus on the use of human ES cells and the different forms and nuances of this research. The backdrop to the current legal situation begins in 1993. Then US President Bill Clinton, and congress, passed the National

Institutes of Health Revitalization Act. This bill gave the National Institutes of Health the ability to fund research on human embryos (Dunn, 2005). In 1995, however, Congress passed the Dickey-Wicker Amendment banning federal funding of research that either created or harmed human embryos (Johnson and Williams, 2006). The political and legal battle came to the limelight however, in 1998 when researchers at the University of Wisconsin derived the first human embryonic stem cell lines. In 1999 the Clinton administration responded by reinterpreting the meaning of the Dickey-Wicker Amendment. In January 1999, Harriet Rabb (Health and Human Services General Council) rendered an opinion that the Dickey-Wicker Amendment did not apply to human stem cell research, as they are not technically human embryos (Johnson and Williams, 2006). Following this opinion, the Clinton administration then asserted that the federal funding prohibition did not apply to research on cells derived from human embryos, even though the cells could be derived only by destroying the embryos (Stem Cell Research, 2007). On August 25, 2000, the National Institutes of Health (NIH) published funding guidelines for research using ES cells, and began receiving applications for grants of stem cell research.

Things changed precipitously however in 2001, when President Bush took office. On August 9th 2001, he declared that scientists who receive federal research funds could work only on human ES lines that were in existence before that day (Wade, 2006). Since that time, there have been several pieces of legislation proposed to widen the available cell lines and techniques for deriving new cell lines, to loosen the 2001 mandate by President Bush. In July 2006, a bill passed the senate that allowed scientists to spend federal money in a much broader manner of research (Pollack, 2006). But President Bush, as promised, vetoed the bill preserving his 2001 mandate. President Bush said "I'm a strong supporter of adult stem cell research, of course"

(Baker, 2005). President Bush offered some signs that Cord Blood banks may offer an acceptable alternative as well.

It is currently illegal to use federal funds for any experiment that creates or destroys a human embryo. Creating new embryos through cloning and destroying an embryo to create stem cells is covered under this law as well. It is, however, legal to both clone and create human embryonic stem cells with private funds (Dunn, 2005). This means that research tools funded with federal appropriations can not be used for embryonic stem cell research of any kind. Much of the recent research that has been done has been funded through private means. This includes much of the pioneering work at University of Wisconsin, Johns Hopkins, Harvard/Children's Hospital, MIT and companies such as Advanced Cell Technology.

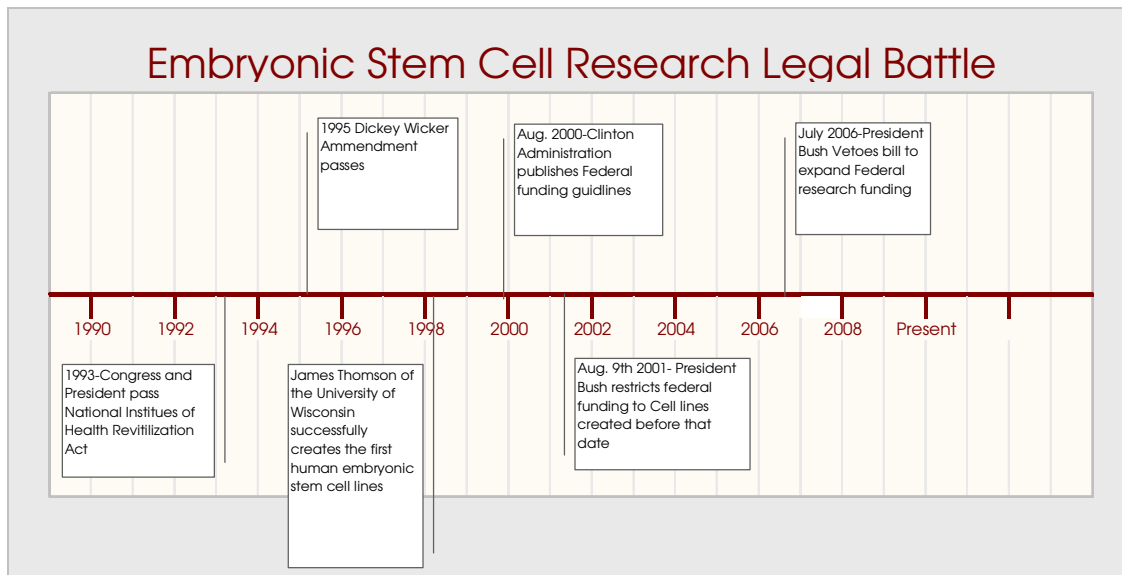


Figure 4.1 Federal Legal Battle on Stem Cell Research. Timeline reflects an overview of information based on “CRS Report for congress on Stem Cell Research” by Judith A. Johnson and Erin D Williams along with information from “Stem Cell News Could Intensify Political Debate” by Nicholas Wade, and the Stem Cell Bill Seen as a Qualified Boon for Research by Andrew Pollack. Figure 4.1 graph created by the IQP author.

An additional legal consideration at the federal level is that the Food and Drug Administration (FDA) is responsible for the regulation of all food, drugs, medical devices and

cosmetics. As such, 2 key areas of bio-related oversight have come up. First is xenotransplantation (the transplant of animal organs into humans), which some current ES cell therapies would fall under if they use animal-derived ES cells. This technique has to be proven safe and effective under the Public Health Service Act, and the Federal Food, Drug and Cosmetic Act. Due to the concern of viruses in animal tissues, many scientists feel that developing sterile cell lines, not ones co-cultured with animal feeder cells, is a safer path forward (Johnson and Williams, 2006). This ES transplant technique can not currently be done on humans using Federal money, since all current stem cell lines that fall under President Bush's mandate were co-cultured with mouse fibroblast cells. The FDA has also claimed authority over the regulation of human cloning technology (which would apply to SCNT derived ES Cells) as an investigational new drug (IND) (Johnson, 2005).

US States Legal Stance

Individual states have the ability to over-ride the ES cell federal funding block by passing legislation to allow private stem cell institutes, or allow state bonds to fund state stem cell institutes. The state legal stance on stem cell research varies widely across the United States. Again, the use of human embryonic stem cells is at the center of the debate. Some states have embraced legislation to promote stem cell research, while others have banned all forms of cloning and human embryonic stem cell research (Dunn, 2005). This has essentially created 3 groups of state positions on the legality of stem cell research: those actively encouraging all forms of stem cell research, those outwardly banning it, and those with middle, sometimes ambiguous, ground that allow specific types of human ES cell research.

Individual states must also discuss issues such as whether women may be paid for donating their eggs, patent eligibility, and sharing of funds and knowledge with researchers in other states and countries (Weiss, 2007). In states where ES research is legal, there may or may not be state level funding available. In some states there is funding available, but only for adult stem cell research.

Pioneering the state level research and funding was California. In 2002, California became the first state to officially endorse human ES cell research. This actively included experiments on cloned embryos. They followed this with an endorsement in 2004, by voting to approve proposition 71 to create the California Institute for Regenerative Medicine (CIRM). This also approved a bond measure that provided \$3 billion dollars in state funding over 10 years to support a wide variety of stem cell research, including human ES cell research. California has not been without its difficulties however, several lawsuits have arisen as a result of the stem cell research proposition. These range from right to life and other ethical challenges, to intellectual property debates.

In 2004, New Jersey created the nation's first state funded embryonic stem cell research facility. The initial \$350 million in funding that was requested has gone through several iterations in the state's legislative branch, and the debate still rages over issues that include a bond measure that will fund a large portion of the research over multiple years (Ralston, 2008). The New Jersey bond measure has still yet to come to fruition.

Even some of the states that encourage stem cell research, had internal legal/legislative battles that reflect the complexity of the legal situation on stem cell research. Wisconsin, home to the scientific team that originally derived embryonic stem cell lines, is providing \$750 million

of public and private funding for biotechnology and health care research that would include stem cell research. In 2005, the Wisconsin Governor vetoed a bill that would ban both reproductive and therapeutic cloning (Johnson and Williams, 2006). Similarly, in Ohio in mid 2005, Governor Bob Taft had to veto legislation that would prevent state funds from being used for any kind of ES cell research. Massachusetts faced a similar political stand-off to Ohio and Wisconsin, when then Governor Mitt Romney vetoed a bill on Stem Cell research because of opposition to therapeutic cloning. Romney's veto was ultimately overridden by the Governor Deval Patrick (Romney's successor) led legislature, making Massachusetts currently as one of the friendliest states for ES research.

Currently there are statutes in California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, New Jersey, and New York, which encourage ES cell research (Johnson, 2005). Along with New Jersey and California, over the past few years Connecticut, Illinois, Indiana, Massachusetts, Virginia, Ohio, and New York established funds for stem cell research. Indiana, Washington, and Virginia have provided funds only for the research of adult stem cells. As of January 2008, 9 states currently permit research on human fetus/embryos (State Embryonic, 2008).

On the conservative side of the legal spectrum, South Dakota forbids any research on embryos. Louisiana specifically prevents any research on In-Vitro Fertilization (IVF) embryos. As indicated in Figure 2 below, many states restrict embryonic stem cell research significantly, either through legal means or funding a combination of the two.

No less complicating to the legal landscape of stem cell research are the links that have been created to 2 of the most controversial issues around: abortion and cloning. Due to the source of certain embryonic stem cell lines, this has sparked the need for some states to create

very specific legislation and a variety of consent laws for use of embryos and aborted fetuses. The use of SCNT or cloning technology specifically has become a hot topic because of the ethical implications. Several states including Arkansas, Indiana, Iowa, Michigan, North Dakota, and South Dakota prohibit research on embryos derived from cloning. Arizona, while not outwardly banning cloning, prohibits state funds to be used for either reproductive or therapeutic cloning. Many other states, including those that outwardly encourage ES research such as California, New Jersey and Massachusetts, prohibit cloning for purposes of reproduction but allow some level of cloning for research (Johnson, 2005).

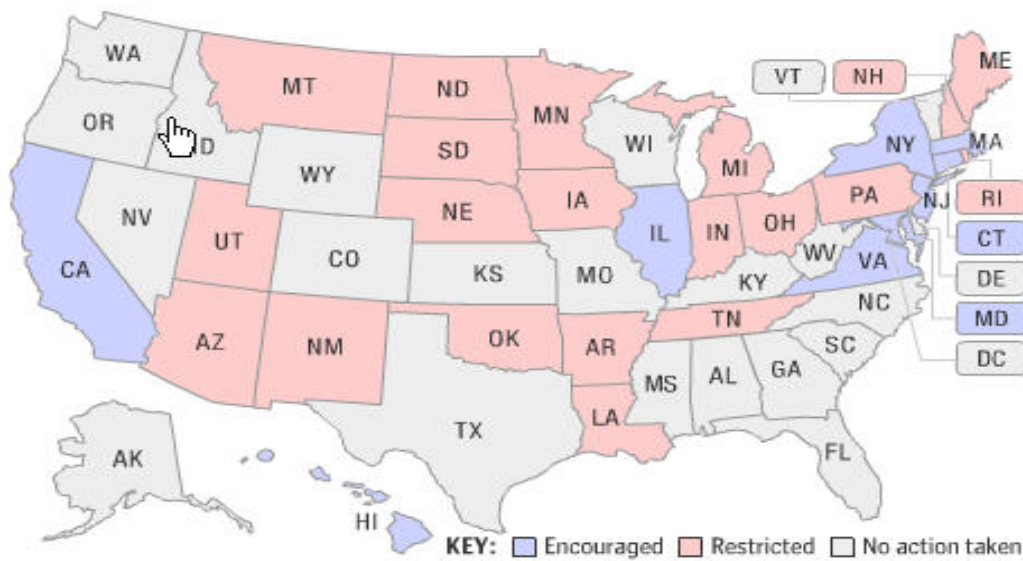


Figure 4.2 Stem Cell Legislation in the U.S. by State. (Stem Cell Legislation, 2005)

International Legal Stance on Stem Cell Research

The international legalities of stem cell research are no less varied or complex than in the United States (Figure-4.3). Europe and Asia have several countries that are encouraging or restrictive of stem cell research. In Europe, the cultural and religious differences provide for the same, if not a greater breadth of laws than seen among the individual states of the US.

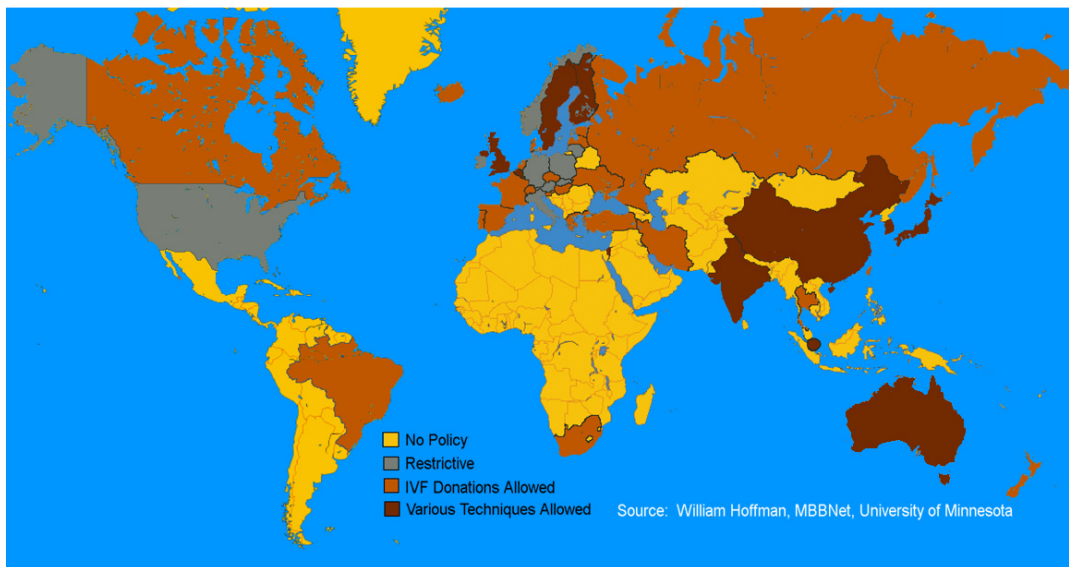


Figure 4.3 World Stem Cell Policy Map. Yellow denotes non stem cell policies in place. Gray denotes generally restrictive federal stem cell policies. Light brown denotes more liberal countries that allow IVF embryo donations for ES research. Dark brown denote the most liberal stem cell policies.

The United Kingdom (UK) has been very progressive and is one of the clear world leaders in biomedical research. Their originally limited human embryonic research was legalized in 1990. Embryonic stem cell research and guidelines were then approved by the British Parliament in 2001. The United Kingdom, with \$4.5 million dollars in government funds, created the UK Stem Cell Bank in 2002. This is a clearing house for all stem cell lines

that is required by law prior to shipment outside the UK (Rosenthal, 2004). In 2005, the British government gave an additional \$18 Million in continued funding through 2010 to expand the Bank. Because of such infrastructure and funding, some key researchers have even relocated to the UK because of the opportunities. Roger Pederson of the University of California, San Francisco, decided to move his laboratory to Cambridge University in England for “the possibility of carrying out my research with human embryonic stem cells with public support” (Zittner, 2001). The UK has not been without its own legal battles however. In April of 2008, a bill dealing with ES cell research spilled over into the abortion issue. The contention is that the legislation could be amended to change the current abortion law that has been in place since 1990 (Stinson, 2008). Great Britain continues to push the envelope. In May of 2008 Parliament voted to allow experiments on animal-human hybrid embryos.

Along with the UK, Sweden, Belgium, and more recently Spain, allow all forms of ES cell studies including cloning for therapeutic purposes. But Sweden, Belgium and Spain all forbid reproductive cloning. Sweden and Spain also used national funds to create stem cell banks (StemGen, 2008).

Similar to the United States, Europe has its conservative constituents too. Austria, Ireland, Poland, and Lithuania prohibit all forms of stem cell research. Germany and Italy banned the extraction of stem cells from human embryos, but research is permitted on stem cell lines from other sources, created prior to certain dates and imported. Germany, with a controversial past of medical research conducted by the Nazis during World Word II, has been purposely conservative in their approach. In June of 2008, the Bundestag (German Parliament) upheld a general ban on ES cell research, but approved moving the date that imported stem cell lines were created from January 1st 2002 to May 1st 2007. The approved act also removes the

criminalization of German scientists working abroad on international projects involving ES cell research (Herman et al., 2008). Denmark, Finland, France, Greece, Spain and the Netherlands restrict scientists to stem cell lines from surplus embryos generated through IVF that are scheduled for destruction (Vestal, 2008). The European Union (EU), as a whole, allows ES cell research where it is permitted by local law. In 2006, the EU ministers voted to fund research on ES cells, but not the procurement of the cells (EU to Fund, 2006).

In Asia, several countries have laws allowing ES cell research. Japan, China, India, Singapore and South Korea all banned cloning for reproductive purposes, but do permit cloning for therapeutic purposes. In Japan, stem cell lines are not allowed to be shipped to laboratories in other countries. Singapore has been very encouraging of stem cell research, using Federal funds and laws to try to lure top researchers from around the world. This has included establishing 40 stem cell research groups across the country. China actually conducts clinical trials of stem cell therapies with critically or terminally ill patients, but has received significant external pressure for the lack of oversight (Ralston, 2008).

Chapter-3 Conclusions

The promise of stem cell research offers society great hope to treat a variety of previously incurable diseases. This hope also brings with it significant ethical concerns, thus most countries enact laws to control the technology. The possibility of developing cell based regenerative therapies to combat a wide variety of disease and injury generates new hopes for many people. It is important to temper that excitement with knowing that “significant technical hurdles remain that will only be overcome through years of intensive research” (Stem Cell Basics-NIH, 2006). Like many scientific endeavors, there is no guarantee that stem cell research will lead to any

usable therapies or cures for the diseases that we desperately seek to conquer. Many people, rightfully, have a problem with their tax money going to fund research they may not understand and also have ethical reservations about. Due to the heterogeneous nature of Europe and the US, no one set of guidelines will satisfy all people.

It is important to establish clear, consistent guidelines for stem cell research, particularly at the state/local level. Having knowledgeable, representative oversight bodies to ensure strict adherence to the guidelines is just as important. Creation of centralized Stem Cell Banks in various states is an excellent starting place, as they would allow a more focused location for compliance. As demonstrated in some European countries, this would help with oversight, and ensure researchers have access to high quality, consistent, legal stem cell lines. This would require some upfront state/local government funding, but this may find surprising support if it were to help ensure certain ethics standards were followed. This would also serve the peripheral functions of making stem cell researchers feel comfortable in their line of work while very possibly attracting additional top researchers. This, in conjunction with possible tax benefits to businesses could in turn generate private funding for stem cell research.

To balance this action, a slightly conservative but open legal stance may be required to start. The more separate cell research becomes from the highly inflammatory topics of abortion and cloning, the less of a legal quagmire it will become. Governments should encourage and openly approve less controversial research. For example by supporting technologies that use induced ES cells derived from adult fibroblast cells, or ES cells derived from parthenotes, or adult stem cells, which may have more plasticity and potential, than originally thought. Continuing to fund research that offers fewer immediate hurdles may offer the best path forward for developing the stem cell technology. Advances using less controversial stem cell lines can

only benefit the research as a whole, both by validating its potential and increasing general education and awareness. The challenge is educating the people to better understand the science that underlies the laws. In time, it will be better understood, like most new technologies, and the guidelines and laws can then be honed for those fully aware people.

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Figures

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CONCLUSIONS

Stem cell research has the potential to be one of the most helpful medical breakthroughs of recent times. Through the use of stem cells, medical problems have been remedied for some diseases previously thought difficult or impossible to treat, including stroke, diabetes, spinal cord injuries, and heart trauma. Using animal models, great leaps have been taken in the area of regenerative medicine, and some of these findings have been extended into humans.

One of the major problems facing the advancement of stem cell research lies in the ethics of the way embryonic stem (ES) cells are obtained, the destruction of a blastocyst embryo. The dilemma focuses on when human life begins; individuals who argue life begins at conception are usually against using 5 day old blastocysts to derive ES cells, while individuals who believe life begins later usually support ES research. Three of the five major world religions morally object to using ES cells for research, however all five major religions have no problem using adult stem cells, provided they were obtained with permission from the donor. We conclude that if the ES cells can be obtained from the excess IVF clinics with donor consent, then by all means do what you can for medical research.

Another problem facing the advancement of stem cell research is legal issues. Major legal issues in the U.S. and abroad include whether federal funding can be used to derive new ES cell lines. We support the use of federal funds to derive alternative sources of pluripotent stem cells without the use of embryos. In general, as stem cell research is expanded and people become more knowledgeable of this new technology, people may become more comfortable with the concept of supporting this outstanding medical practice.