A Recommendation for the Funding of Embryonic Stem Cell Research

A report by Jack Zhou

December 4, 2008

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SUMMARY

Stem cell research is at the forefront of medicine, with the potential to treat over 100 million Americans. The purpose of stem cells is to create a multitude of different cells that the body needs to repair itself. When a stem cell divides, it can either create another copy of itself, or it can create a completely different, specialized cell. The two types of stem cells are embryonic stem cells, and adult stem cells. Embryonic stem cells are able to differentiate into any type of cell, whereas adult stem cells can only differentiate into a narrow range of cells.

The main focus of research on stem cell treatments is cell replacement therapy, where specialized cells grown from stem cells are implanted into the body to repair or replace damaged tissues.

There are some disadvantages to using adult stem cells for these kinds of treatments. They require a matching donor and are hard to extract. Embryonic stem cells can divide infinitely, so large tissues can be grown without a donor. Adult stem cells cause an immune reaction, which must be controlled with harmful immunosuppressant medication. Embryonic stem cells can be modified so they won't cause an immune response. Lastly, there are some cells that do not come from any type of adult stem cell, whereas embryonic stem cells can make every type of cell. Embryonic stem cells can be used to grow human tissues to be used in drug toxicity screening, saving drug companies and consumers money and time. They can also be used to closely study the development of an embryo, which is otherwise impossible to do.

The harvesting of embryonic stem cells requires the destruction of the embryo, a very controversial subject. Some think that the benefit to society justifies this, while others think that the destruction of human life can never be justified. To address this issue, President Bush signed a law declaring that federal funds may only be used for embryonic stem cells derived before August 9th, 2001. This means that only 19 cell lines are available, many of which are unusable or unobtainable. Any researcher wanting to conduct privately funded research on new embryonic stem cell lines must not use any federal funds in any way, which is difficult to do considering the ubiquity of federal money in scientific research.

I believe that the great benefits of embryonic stem cell research outweigh its ethical issues. The current law on federal funding is too restrictive. Other countries, such as the United Kingdom, are fully funding their research, and are finding it hard to work with American scientists and their outdated stem cells. The United States government should fully support all embryonic stem cell research, as long as it is carried out with respect for the embryo, and has a clear societal benefit.

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INTRODUCTION

Background

One of the most exciting fields of medical science right now is stem cell therapy. Stem cells have the potential to treat many diseases that are currently incurable, by replacing diseased or damaged tissue (Monroe 1). In fact, it is estimated that at least 100 million people in the United States alone can benefit from stem cell therapies. This includes 79.4 million people with cardiovascular disease, 14.7 to 23.5 million with autoimmune diseases such as multiple sclerosis, 20.8 million with diabetes, 10.5 million with various cancers, and 10 million with osteoporosis (Bryant 37).

Stem cells are undifferentiated cells found in both embryos and adults. They are able to self renew, as well as differentiate and become a particular cell type. Many scientists agree that research into embryonic stem cells is as important, if not more important, than research into adult stem cells (Bryant 10).

The Problem

However, since extracting embryonic stem cells involves destroying the embryo, there are many controversies regarding its research. Opponents of embryonic stem cell research say that the use of adult stem cells is a promising alterative. Supporters say that embryonic stem cells can offer more and better treatments, and that its research should be vigorously pursued. The current laws regarding stem cell research restrict federal funding to only a few lines of embryonic stem cells. Other countries around the world are far more supportive of embryonic stem cell research.

This report explains why embryonic stem cells are superior to adult stem cells, why models of ethical decision making allow for their use in research, and why the current federal funding policy should be revised to provide full support towards research of all embryonic stem cells.

First, I will discuss the types of treatments possible with stem cells, and explain why embryonic stem cells are considered to be superior. Second, I will detail the ethical controversies surrounding embryonic stem cell research. Third, I will analyze the government's response to it, and how that affects stem cell research. Finally, I will make a conclusion about what needs to be done.

STEM CELLS

Stem cells are undifferentiated cells that are found in embryos and adults. They can either divide for self renewal purposes, or divide into differentiated cells that contribute to the repair or renewal of tissues. There are two types of stem cells: embryonic stem cells and adult stem cells (Bryant 10).

Embryonic Stem Cells

Human embryonic stem cells (abbreviated hES), are *pluripotent*, which means that they can form every type of cell present in an adult human with the only exception being placental cells. They are also *immortal*, meaning they are able to continuously divide without losing their genetic structure. Lines of hES cells have been isolated and grown in culture for well over two years without losing their ability to self-renew or to differentiate. Lastly, they are *malleable*, meaning they can be manipulated and even moved into a different organism without losing their function (Okarma 5).

Embryonic stem cells are typically derived from the blastocysts of embryos created for in vitro fertilization. A blastocyst is simply a hollow ball of cells formed from the egg shortly after it is fertilized (Monroe 13). The inner cell mass of the blastocyst, which contains the stem cells, is removed from the embryo. Removing the stem cells destroys the embryo, which is why embryonic stem cell research is so controversial. The cells need to be plated onto a layer of feeder cells, typically derived from mice, which sustain the stem cells. This is important because the FDA does not allow cells that have been in contact with animal cells to be used in human therapy (Bryant 50).

Adult Stem Cells

As mammals develop from embryos, their cells become more and more specialized, and less able to repair and renew themselves. However, there are still populations of localized stem cells in adults that can differentiate into certain types of cells. They are *multipotent*, meaning they have the ability to generate many, but not all, of the body's cell types (Bryant 19). They are not immortal like the embryonic stem cells, but instead lose their ability to divide or differentiate after a certain number of divisions (Okarma 5).

Scientists have known about adult stem cells for a while, and they are even being used in therapies today. Hematopoietic stem cells, derived from bone marrow, give rise to different types of blood cells and are being used to help treat leukemia. Mesenchymal cells give rise to cartilage, bone, and fat cells. Skin and neural stem cells are other types of stem cells found in an adult human.

STEM CELL THERAPIES

Both adult and embryonic stem cells offer the potential to greatly advance the field of medicine and to provide treatments for millions of Americans with currently untreatable diseases. One may wonder why scientists are making such a big deal over

embryonic stem cells, when stem cells can be derived from an adult without controversy. The difference is that embryonic stem cells have far more untapped potential than adult stem cells. Many medical scientists and organizations agree that embryonic stem cells have a greater potential for curing diseases and injuries than adult stem cells. In this section I will discuss the various treatments that are possible with embryonic stem cell research and adult stem cell research.

Current Treatments

Most of the current and experimental treatments are types of stem cell replacement therapies. Stem cells are induced to create specialized cells, which are then injected into the body to repair the damaged tissue that is causing disease.

Adult stem cells are already being used in stem cell replacement therapies. Hematopoietic stem cells are found in the blood marrow and are able to generate all the blood and immune cells found in the blood. The transplantation of bone marrow is a treatment for severe immune deficiency and leukemia (Bryant 38). Since hematopoietic stem cells generate all the immune cells in the blood, replacing the bone marrow will solve the problem of either too few (immune deficiency), or too many (leukemia) immune cells. However, this treatment requires the availability of a donor, which leads to long waits as the number of donors is always less than the number of people on the waiting list.

Bone marrow transplants, along with treatments for lysosomal storage disorders are the extent of the current treatments involving stem cells. Other treatments are being explored for conditions such as Parkinson's disease, spinal cord injury, retinal degeneration, cardiovascular disease, various types of cancers and type 1 diabetes. All of these treatments are being explored with both adult and embryonic stem cells, each with their own successes.

Experimental Treatments

One of those experimental treatments in an advanced state of research is for type 1 diabetes. Type 1 diabetes, or juvenile diabetes, is caused when the insulin producing cells in the pancreas do not exist or are malfunctioning (Bryant 43). Someone with this condition must inject themselves daily with insulin, and will run into complications such as blindness, kidney damage, and cardiovascular disease later in life. An experimental treatment for this is a pancreas transplant to restore function back to the insulin producing cells. In these cases, the symptoms disappear when the cells took hold. However, two to three pancreases are needed for each transplant, and there is a severe shortage of donors. Since the transplant is foreign, the patient's body will begin to reject it and attack it. Therefore, the patient must also take immune suppressants for the rest of his or her life. Immune suppressant drugs cannot be given to children, and will damage the body over time (Solo 24).

While these treatments with adult stem cells are definitely extremely promising, there are three problems that they run into. The first is the availability of these stem cells. Adult stem cells are hard to harvest, and treatments usually require at least one

donor, which are hard to come by. The second is the issue of an immune response to the foreign cells, which require strong medication to manage. The third is that some cell types, such as heart muscle cells, do not have adult stem cells.

Embryonic stem cells can solve all these problems. Embryonic stem cells are immortal, so large cultures of tissues can be grown from them. This is useful, for example, when replacing the insulin creating cells of the pancreas, which otherwise would require the cells from 2-3 donors. Using a process called somatic cell nuclear transfer (abbreviated SCNT), scientists can make stem cells that have the same DNA as the patient, eliminating the need for immune suppression medication (Miller 154). Because embryonic stem cells are pluripotent, they can differentiate into all cells, including those that do not have adult stem cells (Thomson 22).

Other Research Opportunities

All the experimental treatments listed involve replacement of dying or dysfunctional cells. However, stem cell research has far more uses than just cell replacement therapy. Since human life comes from a ball of embryonic stem cells, scientists can use them to increase their understanding of normal human development. This information provides scientists with a foundation for understanding fetal developmental abnormalities and eventually producing some sort of cure. This could not be done before, as there was simply no ethical or practical way to study an embryo's natural development in the woman's womb (Okarma 5-6).

Embryonic stem cells can also be used to develop human tissues and organs, which can be used in drug toxicity testing. Pharmaceutical companies spend millions of dollars testing their new drugs on animals and then carefully testing on humans to make sure they are safe. Even then, many drugs are withdrawn from the market due to toxic effects that were not detected (Okarma 7). If these companies could simply grow a human liver and directly test it, then not only would drugs cost less and arrive to market faster, but the likelihood of unforeseen harmful side effects will be reduced (Thomson 21).

ETHICAL CONTROVERSY

The controversy surrounding embryonic stem cells was first brought up by researchers. The issue is that the extraction of stem cells from the embryo destroys the embryo. The scientists concluded that the best way to harvest stem cells was to use frozen eggs derived from in vitro fertilization. In vitro fertilization creates many embryos, as many as 12, only a few of which are actually implanted in the womb. The rest just sit in frozen storage or are just discarded. The scientists thought that research was the best use of the embryos (Solo 9).

Against Embryonic Stem Cell Research

Even though the stem cells are taken from unused embryos, many argue that the life contained in the embryo is sacred and cannot be sacrificed for research. (Nickel 65-

71). An organization called Do No Harm: The Coalition of Americans of Research Ethics lobbies against federally funded research. They state that

> "That some individuals would be destroyed in the name of medical science constitutes a threat to us all… Human embryos are… the tiniest of human beings. Thus, we have a moral responsibility to not deliberately harm them" (Peters 129).

They suggest that we cannot practice crass utilitarianism, where the rights of a few are sacrificed for the supposed benefit of many. If we do, we risk repeating similar situations from the past, such as slavery and the Holocaust (Peters 129).

For Embryonic Stem Cell Research

I disagree with this view. To explain my view, I will take a step by step approach, reasoning through each step with well defined arguments to reach my conclusion about the ethical status of embryonic stem cell research.

There are two main beliefs about embryonic stem cells that have general societal agreement. First, it is universally acknowledged that embryonic stem cells will greatly advance medical science and is a boon to mankind. Second, it is believed that the blastocyst is human, and should be treated with respect. This does not, however, necessarily mean that the blastocyst is a human being or a person (Miller 152-3). The degree of respect for the embryo is a point of great debate, and that is the point I will explore next.

At the center of the ethics debate is the question of whether an embryo has moral status, and to what degree. For something to have moral status is for it to be deserving of consideration. Most agree that embryos do have moral status. However, the degree is of great importance in this discussion (Young 164). For example, we can say that mice have some sort of moral status. Some people have them as pets, and medical researchers using them in experiments are still obliged to treat them with respect. However, society generally accepts that the use of mice in medical research yields such great benefits to mankind that medical experiments conducted on them, which can cause suffering and death, are justified. Does the same thing apply to embryos?

To analyze this, I am using the criteria for moral status developed by philosopher Mary Anne Warren. I will paraphrase her seven criteria here:

1. *Respect for life. Living organisms are not to be harmed or killed without good reasons that do not violate principles 2-7.* The embryo is a living organism, and so we cannot extract its stem cells, and thus kill it, without good reason. The good reason is that the research done on these stem cells will greatly benefit society. We must analyze the rest of the principles to make sure that we are not violating them.

2. *Anticruelty principle. Sentient beings are not to be subjected to pain or suffering unless there is no other way to further goals that are consistent with principles 3-7 and are important to humans or other beings that have a stronger moral status.* To be sentient is to be aware of oneself. Only a few animals, such as dolphins, are sentient, and a ball of cells without any nervous

system or sensory organs certainly cannot be considered sentient. Therefore, this rule does not apply to the embryo.

3. *The agent's rights principle. Moral agents, or something that is capable of making moral decisions, have full equal and basic rights, including the rights to life and liberty*. Embryos do not have the capacity to think, and thus cannot be moral agent.

4. *Human rights principle. Humans who are capable of sentience but not of moral agency have the same moral rights as do moral agents*. Since embryos are not capable of sentience in and of themselves, but only have the potential to develop into beings that are capable of sentience, this rule does not apply to them.

5. *Ecologic principle. Living things that are important to their ecosystems may have a stronger moral status than their intrinsic properties would suggest.* Embryos are not a necessary part of any ecosystem, so this rule doesn't apply.

6. *Interspecific principle. Non human members of mixed social communities have a strong morals status than based on their intrinsic properties alone.* Embryos are not part of a social community, so this rule doesn't apply.

7. *The transitivity of respect principle. Moral agents should respect one another's attributions of moral status*. This rule states that we should show respect for beliefs of people who are morally opposed to the destruction of embryos for research. However, this also means that they must respect the beliefs of people who think that the research is so important and the moral standing of the embryo so slight that it should be allowed to continue. (Young 169-73)

Through this analysis, one can see that the destruction of human embryos do not explicitly violate principles 2-7. Therefore, we can conclude that if it is done in a respectful way, then the destruction of the embryo for research that will benefit mankind is justified. In this case, respectful means that only the minimum number of embryos be used for research, that the research is scientifically sound and beneficial to society, and that informed consent from the embryo donor be obtained prior to stem cell extraction (Young 173). In fact, one could argue that the most respectful way to treat embryos is to not let them stay stored indefinitely in a freezer, or be meaninglessly destroyed, but to use them in a way that benefits society.

Of course, this analysis can be subject to criticism. I have based my argument on only one person's model of conferring moral standing. However, I believe that this model covers all the possible reasons for the attribution of moral standing. I also believe that my reasoning is sound, and based on rational arguments and not on subjective opinions.

GOVERNMENTAL POLICY

Federal Policy

Not everyone agrees with me that embryonic stem cell research is morally justified. To address these concerns, President Bush decided to do his own review of the issue, and declared this policy, which is as follows:

On August 9th, 2001, President George W. Bush announced that federal funds may be awarded for research using human embryonic stem cells if the following criteria are met:

- The derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 P.M. EDT on August 9, 2001.
- The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed.
- Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements.

(Federal Policy 2006)

This policy intended for 71 stem cell lines from around the world to be available for federally funded research. However, only 19 of those stem cells lines are actually available for use, as many of the others have been destroyed or lost. Some of those 19 cells lines have accumulated genetic abnormalities, and others are unable to differentiate. The availability of those 19 lines is questionable, because some of the lines are held by private companies that may not want to sell them to the public.

All of the federally available cells lines were grown on mouse feeder cells, so they eventually take on the characteristics of rodent cells instead of human cells. If these cells were ever to be implanted in a human body, they would destroyed by the immune system. Other types of feeder cells are currently being used that would make the stem cells compatible with the human body. However, the research on those stem cells grown on this medium cannot be federally funded because the cell lines were derived after August 9th, 2001 (Biever 2004).

What does federally funded research really mean? It means that the research cannot be performed in laboratories that have a lot of federal funding put into them. In order to carry out research on new stem cell lines derived after August 9th, 2001, the principle investigator must make sure that not a single penny of federal funds goes to it. This makes privately funded embryonic stem cell research extremely difficult to set up, as most labs have some sort of federal funding in them For example, Harvard receives a great deal of money for research from the government in some way or another. Douglas Melton, a professor in charge of the Harvard Stem Cell Institute, which is privately financed, built a completely separate lab than the one Harvard currently has, and has "an accountant who makes sure that not a penny of federal funds goes to embryonic stem cell research. We have to separate everything - light bulbs, computers, centrifuges." If there is a graduate student who is receiving a federally funded fellowship, then he or she cannot "participate in thinking about this research or even

look at the data," (Parker 2006). Under this policy, scientists either have to work with difficult to obtain, outdated cells, or build a new lab with all private money in order to work with new embryonic stem cells.

State Policies

Majorities in every demographic group have favored federal funding for embryonic stem cell research (Solo 5). In response to this, many states have adopted their own embryonic stem cell funding policies. In 2004, New Jersey became the first state to publicly fund both adult and embryonic stem cell research. In California, three billion dollars have been raised to support adult and embryonic stem cell research, to be distributed over several years. In Illinois, the governor created the Illinois Regenerative Medicine Institute, to hand out grants for research on stem cells, regardless of the source. Several other states, including Massachusetts, Connecticut, Maryland, Iowa, and New York all encourage and fund embryonic stem cell research (Nation Conference of State Legislatures 2008).

Global Impact

Countries such as the United Kingdom, Iran, China, Israel, and Singapore are actively funding their embryonic stem cell research efforts. Their scientists are producing a comparatively large amount of research papers in this area. Science is an internationally collaborative process, and the U.S. has the most and best facilities. However, it is frustrating for scientists around the world to work with U.S. scientists. They are using the newest stem cells lines to advance their research, while U.S. researchers are falling behind with their use of outdated, federally funded stem cells. In fact, scientists from the United Kingdom have bypassed federal labs, and are collaborating with state funded scientists in California, who are using the latest stem cell lines. In effect, the U.S. is losing ground as an important global research hub (Moreno 2006).

CONCLUSION

In this report, I have described the differences in adult and embryonic stem cells. I have addressed the ethical issues, and used several criteria to form my own opinions. Finally, I discussed the governmental regulations and their effect on stem cell research nationally and globally.

In stem cell replacement therapy, embryonic stem cells are clearly superior to adult stem cells. They can be grown in large numbers, do not elicit an immune response, and can create every cell in the body. They can also be used to accelerate drug trials, and to understand the normal development of embryos.

The ethical issues surrounding embryonic stem cell research are complicated. There are a multitude of viewpoints taken. However, using a structured system of

determining the moral status of something, I conclude that the moral status of embryos is slight enough that their destruction for the purposes of research is justified by the benefits for mankind.

The federal government has a policy dictating the use of federal funds in embryonic stem cell research. This policy is extremely restrictive on the types of cells that scientists can use with federal funding, and makes it difficult for scientists to conduct privately funded research on newer cells. This policy is restrictive and unpopular enough that several states have instated their own stem cell funding policies that include state support for embryonic stem cell research. Many countries fully support their stem cell programs, regardless of the source of the stem cells. The United States is falling behind as a leader in science and innovation.

RECOMMENDATION

With all this evidence, I think that it is obvious why embryonic stem cell research should be supported with the full funding of the U.S. government. The policy should allow funding for research of all types of stem cells, regardless of their source or time of derivation, as long as they follow these rules: only the minimum number of embryos be used for research, the research is scientifically sound and beneficial to society, and that informed consent from the embryo donor be obtained prior to stem cell extraction.

"Federal funding is the highest form of blessing and approbation that a scientist can get for his work," (Maguire 2008). Our government should give our scientists its full support in exploring this exciting new field of medicine, and continue establishing ourselves as a leader in science and innovation. We owe it to the 100 million Americans who could potentially benefit from this, and we owe it to the world to benefit mankind in any way possible.

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