Utilization and Commercialization of Human Embryonic Stem Cells in the United States

As of March 2015, there were eight industrial nations along with 15 agencies and institutions dedicated to stem cell utilization and treatment, according to the National Institutes of Health and U.S. Department of Health and Human Services. Ironically, one of the world's most influential nations, the United States, does not participate in such activities. Human Embryonic Stem Cell (HESC) treatment possesses the capability to spur self-relief from diseases and physical impairments by retaining properties that allow the injection of embryonic stem cells to differentiate into multiple types of cells and regenerate into healthier ones. Why would the United States deny its medical institutions the right to utilize the potential associated with embryonic stem cell treatment? Because it is an unethical practice, the health risks are innumerable, and it is politically infeasible. For these reasons, it is crucial that the United States not utilize or conduct HESC treatment until further research has been conducted and the benefits outweigh the negative effects.

Before indulging into the many repercussions of stem cell treatment, it is important to establish a general understanding of what they are and how they work. Stem cells are undifferentiated biological cells that can differentiate into specialized cells, such as liver cells and brain cells, and can divide into other stem cells. This ability to adapt and morph into its surrounding region or intended function is described as being either pluripotent or multipotent; pluripotent stem cells, often called embryonic stem cells, have the ability to differentiate into any type of body cell, whereas multipotent stem cells, often called adult stem cells, have the ability to differentiate into a great, however limited, amount of body cells. After stem cells are injected into a patient at a site of

interest, they respond to the surrounding tissue's signaling molecules, triggering cell differentiation (specialization) and cell division, and thus the potential reconstruction and replacement of lost or deteriorating tissues.

Although HESC treatment does sustain incredible potential, it is regarded as highly unethical, both by the means of obtaining HESCs and the effects this gathering has on the mother. It is heavily debated as to when an embryo is considered to be "living": at fertilization or days after the embryo would be derived in vitro? Scientists in support of HESC treatment consistently argue that defined life does not start at the instant of conception and evidence to support this claim suggests that monozygotic twinning occurs 14-15 days after fertilization (Smith & Brogaard 2003). This exclaims that twin zygote cells do not split until two weeks after fertilization and after the embryo would have been derived, thus not technically qualifying as taking away life. However, the cells of the embryo *are* living. At fertilization when the sperm meets the egg, a zygote is formed and cells forming the embryo begin to replicate. The act of these cells replicating suggests that they are living. In Lawrence Nelson's essay published by Santa Clara University, "A Brief Case for the Moral Permissibility of Stem Cell Research", he states, "Embryos *are* morally considerable; they are not just bunches of cells having no link to the moral community. Specifically, embryos have a modest moral status because they are alive, because they have a special ontological, biological, and moral relationship with the persons whose gametes literally constitute them..." This references the role embryos play in both the moral (abstract) community and the literal community. The act of deriving and killing the embryos after fertilization is a morally injustice that should not be recognized nor practiced until other means for obtaining these cells are discovered.

Ethical considerations also arise when it comes to evaluating the health risk of donors associated with embryonic donations. This relates to how safe oocyte (the female germ cell involved in reproduction) retrieval procedures are and what medical troubles may be associated with the donation procedure. In a report submitted by the US National Library of Medicine National Institutes of Health, medical risks associated with oocyte retrieval include: "ovarian hyper-stimulation syndrome, bleeding, infection, and complications of anesthesia." The report also went on to mention that further surgeries may be necessary to treat serious cases of ovarian hyper-stimulation syndrome developed from the oocyte retrieval. Another report, published by Medline Plus, which is supported by the US National Library of Medicine National Institutes of Health, elaborated on ovarian hyper-stimulation syndrome by stating that the most severe cases of the syndrome included the following complications: "blood clots, kidney failure, severe electrolyte imbalance, and severe fluid build-up in the abdomen or chest." It is clear that the procedures involved with embryonic retrieval put the donor at a greater risk than is intended to be, a risk that has yet to be justified.

Doctors and scientists around the globe have attempted to justify this treatment through successful trials and commercial use of HESCs; however, successful cases of stem cell utilization in humans are still scarce. Although the United States does not permit the use of stem cell treatment commercially, other countries, such as Russia and China, have loose regulations neither sanctioning nor prohibiting the use of stem cell treatment on patients. This brings upon a myriad of problems for patients around the world who are often enticed by the words "stem cells" and the potential miraculous cures they entail. Arnold Kreigstein, a neurologist and Director of stem cell research at the

University of California at San Francisco, stated that "unregulated therapy in the absence of any evidence that these cells are going to help patients is reckless. The potential to do harm is [just as] enormous [as the potential to do well]." This potential harm turned reality in a 2001 case, in which a young, male patient with Ataxia Telangiectasia – a rare disorder characterized by the degeneration of the brain region that controls movement and speech, and its surrounding fluid – was treated with fetal neural stem cell injections to the brain, at a hospital in Moscow, Russia. Four years later, the patient was experiencing reoccurring headaches, so he was brought in to conduct a resonance scan. The scan found that two tumors had formed, one in his spinal cord and one in his cerebral region. After the removal of the spinal tumor, doctors were able to examine its genetic material, in which they discovered DNA from the original stem cell donors (Amariglio 2). This proves a direct relationship between the formation of the spinal tumor and the injection of embryonic stem cells into the patient's body, by directly linking the genetic material from the tumor to the donors. The division of the implemented stem cells was not regulated by the body or the stem cells themselves, thus allowing for the formation a tumor with the potential to metastasize and grow more serious. Embryonic stem cells also possess a property that causes them to clump together – agglutination – that can possibly led to the formation of the tumors in the patient as well (Tissot 33). Regardless of the exact cause, the tumors were formed as a direct result of the stem cell injection. Until scientists and research discover feasible ways of controlling these dangerous stem cell properties, we cannot tap into the perennial positive potential stem cells have to offer.

Another serious repercussion of stem cell utilization in humans is tissue rejection. The human immune system is designed to launch extracellular and specific attacks on

'invading' pathogens. Almost any non-self or foreign molecule acts as a trigger that stimulates an active immune response against that molecule. Stem cells injected into the body, when coming from unfamiliar donors, have the potential to trigger an immune response. Although "it has been suggested that embryonic stem cells may provoke less of an immune response than solid organ transplants, this may not be true of the differentiated tissue derived from the embryonic stem cells," (*Nature Immunology* 1085). In other words, it is less likely to see an immediate immune response to initial stem cell treatment than it is to see a delayed response after the stem cells have differentiated into tissues that incorporate themselves into your body. This turns into an increasingly dangerous reaction, known as an autoimmune response – an immune reaction to the body's own tissues that can result in a plethora of autoimmune disorders such as Dermatomyosis and Graves' Disease. This, again, proves that the current HESC research has not yet advanced to a point where the United States can commercialize the use of HESC treatment on humans.

Of the many countries that already have HESC treatment programs, the United States is the most restrictive – having not yet allowed commercial HESC treatment to the public. This restriction is, to a great extent, justified. The only feasible benefit of the United States commercializing HESC treatment is the potential economic boost it sustains through the generation tax revenue, creation jobs, and saving of millions of dollars in long-term healthcare costs.

HESC treatment, through proper legislation, has the potential to bring an enormous amount of tax revenue to the economy. America would get a huge boost to its economy. HESC treatment does this in a variety of ways. First and foremost, HESC

treatment facilities can pay taxes in the same way that other treatment facilities do. Utilizing advanced machinery and facilities means that the treatment centers will produce and subsequently return a large amount of money. One center in California that deals with stem-cells has a plethora of data on how that center alone has helped the economy. Representatives from this center, known as the California Institute for Regenerative Medicine (CIRM) have stated that "as of January 2015, CIRM has not cost the state's general fund any money. The bonds used to fund CIRM's activities were *forward capitalized*, so that the agency paid all its own interest costs for the first five years. Once the state begins paying interest, tax revenue generated by CIRM research grants should exceed interest costs for at least the next three to five years" (CIRM.ca.gov) Therefore, not only is the institute bringing money into the economy, but also it is costing the government little to nothing. There is another method by which these research centers generate tax revenue that often goes overlooked. These centers allow for patients with debilitating health complications go back to work and continue contributing to the economy via taxes sooner. These gains will only increase as research continues. If HESC treatment were to finally be commercialized, treatment centers could follow in the footsteps of research centers and generate tax revenue to support the United States' economy.

Although there are potential economic benefits to utilizing embryonic stem cells and commercializing treatments, there are still greater drawbacks present. With the ethical and medical drawbacks of HESC treatment, comes legislation and debate over the funding and regulation of commercial implementation said treatment and research. Much of the political debate over HESCs coincides with the financial means of support for the

research. Those that oppose HESC treatment in the United States are backed by the fact that although there is a restriction to the amount of public money spent on the technology, private research is legal and known to receive a large amount of funding with little to no restrictions. Medical officials pushing for the implementation of HESCs are not, in fact, in dire need for funds. Sigrid Fry-Revere, founder and president of the Center for Ethical Solutions, as well as former director of biotech studies at the Cato Institute, explains this in her article with Molly Elgin, graduate of Tulane with B.A. in political economy summa cum laude, "Public Stem Cell Research Funding." Revere exclaims, "Biotech companies, philanthropic organizations, and individuals have already invested billions of dollars in such research." California has already made strides in an effort to create legislation to provide public funding for HESC research. In 2004, Proposition 71 was brought to the forefront of California politics. This legislation proposed to "raise $3 billion over 10 years to fund such research" (Revere and Elgin n.pg.). An easy alternative to the problem of funding for research within this field is to simply ask for private donations or partnerships, rather than using taxpayers' money. Also, ever since embryonic stem cells were initially researched and discovered, there has been no major advancement in the utilization of such technology. In his article in Esquire, "Whatever Happened to Stem Cells," Tyler Cabot, journalist for Esquire, The Atlantic, The Washington Post, and Slate states "that in fifteen years, embryonic stem cells have yielded no major clinical advancements or treatments, let alone made-to-order organs." Until there is further research conducted, lawmakers have no reason to create legislation allowing the utilization of stem cells. The private sector can easily generate funds to

sponsor research until there is clear-cut evidence that such utilization guarantees positive benefits in all aspects, and very few negative side effects.

The political debate behind HESCs also stems from the ethics of the origin from which these cells are derived. "In the United Sates, laws prohibit the creation of embryos for research purposes" (Univ. of Utah n. pg.). Embryonic stem cells originate, or are created from, human embryos that can be as young as five days old. Due to this, many organizations and activists against the research have stepped in and caused lawmakers to change legislation in order to make it illegal in the United States to conduct research from a live embryo. "Scientists instead receive 'leftover' embryos from fertility clinics with consent from doctors" (Univ. of Utah n. pg.). Although legislation is in place to prevent the usage of live embryos, the question still arises; should legislation be created to allow embryonic stem cells to be utilized commercially and have a more widespread use? One of the major issues with current legislation is the confusion on what is allowed in terms of the sources of the stem cells, and what is prohibited. James Bobrow, from the Department of Ophthalmology and Visual Sciences at the Washington University School of Medicine, states in his paper, "The Ethics and Politics of Stem Cell Research," with reference to the legislation on stem cells, that "sources of HESCs that are permitted and forbidden need to be delineated and the uses to which they are put outlined to avoid ambiguity, suspicion, and legal challenge." An easy solution to the overall debate on the ethics behind HESC research and possible implementation of HESCs is to create universal legislation clearly defining the exact way in which they can be utilized for medical purposes.

Politically, stem cell research and further utilization of embryonic stem cells is a

complicated and easily explosive topic. If lawmakers go too far in their legislation to allow the usage of stem cells on a large scale, there is a high chance that many organizations and groups will act up against the reforms. However, they must consider the fact that the technology is capable of making tremendous leaps and bounds within the medical community. That being said, governments and lawmakers worldwide are highly vulnerable to dissent whether or not they allow for the widespread usage of stem cells, and must consider all benefits, as well as the drawbacks, of such legislation. With the current research that has been conducted, there is no need to further expand legislation and allow doctors to use HESCs in medical practice. There is simply too much disparity between the positive and negative effects the utilization of HESCs entails. Until there is a clear-cut use for embryonic stem cells, with little to no drawbacks financially, or even a different source from which they can be derived, there is no dire need for them to be utilized in the medical field.

There is no doubt that the controversial debate regarding human embryonic stem cell treatment has a lot to overcome. The scientific benefits and wonders of HESC treatment are considered to be "limitless" and may influence major medical breakthroughs within humanity. Although commercializing embryonic stem cell treatment can pose a substantial amount of positive benefits to society, it can be concluded from the information showcased in the essay that the United States is not ready to embrace the utilization of embryonic stem cells as other nations do, because current research has not advanced as far as eliminating the ethical, medical and political drawbacks human embryonic stem cell treatment entails. [2701].

Work Cited

International Stem Cell Research. In *Stem Cell Information* [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, Web. April 03, 2015.

Smith, B., and Brogaard, B., 2003, "Sixteen Days," *Journal of Medicine and Philosophy*, 28: 45–78. Web. April 01, 2015

Lo, Bernard, and Lindsay Parham. "Ethical Issues in Stem Cell Research." *National Center for Biotechnology Information*. U.S. National Library of Medicine, 14 Apr. 2009. Web. 5 Apr. 2015. Website

Nelson, Lawrence J. "A Brief Case for the Moral Permissibility of Stem Cell Research." *Markkulah Center for Applied Ethics.* Santa Clara University, n.d. Web. 05 Apr, 2015.

"Ovarian Hyperstimulation Syndrome: MedlinePlus Medical Encyclopedia." *U.S. National Library of Medicine.* US National Library of Medicine, n.d. Web. 10 Apr. 2015

"US court halts government funding of stem cell research." *Phys.org.* Science X Network, 23 Aug. 2010. Web. 07 Apr. 2015.

"The Stem Cell Debate: Is it Over?" *University of Utah Health Sciences*. University of Utah. Web. 30 March 2015.

Perry, Daniel. "Patients' Voices: The Powerful Sound in the Stem Cell Debate." *Stem Cell Research and Ethics* 287.25 (2000): 1423. Web. 30 March 2015.

Bobrow, James. "The Ethics and Politics of Stem Cell Research." *Transitions of the American Ophthalmological Society* 103 (2005): 138-142. Web. 30 March 2015.

Cabot, Tyler. "Whatever Happened to Stem Cells." *Esquire.* Esquire, 18 March 2013. 30 March 2015.

"Overview of FDA Perspective on the Ethics of Stem Cell Therapy." Presentation. U.S. Food and Drug Administration. 4 April 2010. PDF file. 31 March 2015.

Fry-Reverem, Sigrid. Elgin, Molly. "Public Stem Cell Research Funding ." *Competitive Enterprise Institute.* Competitive Enterprise Institute. 3 September 2008. Web. 31 March 2015.

"The Economics of HESC Research." Southern California Public Radio. N.p., 28 Nov. 2011. Web. 03 Apr. 2015.

"Regenerating Our Economy With HESCs." Metromode. N.p., n.d. Web. 03 Apr. 2015.

"Economic Impact." HESCs Are You Pro or Con ? N.p., n.d. Web. 03 Apr. 2015.

"Headlines." *Americans for Cures : HESC Facts.* N.p., n.d. Web. 03 Apr. 2015.

Dhar, Deepali, and John Hsi-en Ho. "HESC TreatmentPolicies around the World." The Yale Journal of Biology and Medicine. YJBM, n.d. Web. 03 Apr. 2015.

"New Harvesting Techniques." *New Harvesting Techniques.* N.p., n.d. Web. 03 Apr. 2015.

"California's HESC Agency." California: The Leader in HESC Research. N.p., n.d. Web. 03 Apr. 2015.

"The Stakes Are Very High for Future U.S. Medical Research." Southern California Public Radio. N.p., 29 Nov. 2011. Web. 03 Apr. 2015.

"San Diego Business Journal." Study Released on Economic Impact of Agency's HESC Research. N.p., n.d. Web. 03 Apr. 2015.

"HESC TreatmentCan Spur Economic Growth, Researcher Says." Crain's Detroit Business. N.p., 05 Oct. 2010. Web. 03 Apr. 2015.

"Stem Cell Research Around The World." *Pew Forum.* Pew Research Center. 17 July 2008. Web. 2015.

Obama, Barack. "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells." *Presidential Documents 74.46* (2009): 10667. Web. 2015.

Eunjung Cha, Ariana. "With U.S. Stem Cell Treatments Limited, Patients Try Other Countries." *The Washington Post.* Washington Post, 6 June 2010. Web. 2015.

Hollowell, Kelly. "Ten Problems With Embryonic Stem Cell Research." *The Institute for Creation Research.* The Institute for Creation Research, 2002. Web. 2015.

Amariglio, Ninette. "Donor-Derived Brain Tumor Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient." *PLOS Medicine.* PLOS, 17 February 2009. Web. 2015.

Tissot, Jean-Daniel. "Agglutination and Flocculation of Stem Cells Collected by Apheresis Due to Cryofibrinogen." *Bone Marrow Transplantation* 33 (2004): 765-767. Web. 2015.