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Ethical Decision Making

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Second Chances: The Necessity for the Legality and Federal Funding of Embryonic Stem Cell Research

I Introduction

Around the world today, millions upon millions of people are suffering. But what if they could be helped, even temporarily, and possibly permanently? Research into embryonic stem cells is creating breakthrough methods to aid people around the globe. As laboratories have the ability to share priceless knowledge that can save lives, it is absolutely necessary to legally allow, federally fund, and morally uphold research into embryonic stem cells in order to help so many. Scientists, doctors, and activists are trying to discover new ways to solve debilitating health issues; some of this knowledge is already available, and it is vital that we use it, share it, and continue to explore it.

II Background and History

In order to understand the technicalities of stem cell research, it is necessary to define several key terms. Embryonic stem cell research uses the stem cells of embryos, which are new organisms from four days until nine weeks (after which point they are termed fetuses). Yet the question remains, what exactly are stem cells and why are they so important? Stem cells, or pluripotent (very powerful) cells, have the incredible ability to develop into various cell types in the body during early life and growth. As unspecialized cells, they function as a kind of maintenance system which can be used to replenish the body's cells. When a stem cell divides, it may either continue as a stem cell or become a more specialized cell, such a brain cell, nerve cell, or a heart muscle cell. This is the main reason they are so important, because they can be manipulated, or differentiated, by scientists into particular cells in order to help the body renew itself. In research, stem cell lines are used; these are groups of cultured stem cells which may divide continuously without differentiating; they may be separated and replated, where they may continue growing. In this way, fewer stem cell lines need to be started.

Stem cell research has much potential, only a minute fraction of which has been realized. Nevertheless, there is quite a bit of controversy surrounding it. Since the 1970's, there have been questions regarding embryonic pluripotent cell research. In 1978, the United States government banned the use of federal funds for embryonic stem cell research. Eighteen years later, in 1996, the Dickey-Wicker Act was passed, prohibiting further federal funding for embryonic stem cell research. In addition, it did not allow the use of federal funds for the creation of stem cells for the purpose of research. In 1998, a team at the University of Wisconsin at Madison isolated the first embryonic stem cells. In 2000, the National Institute of Health (NIH) interpreted the Dickey-Wicker Act with the following guidelines for embryonic stem cells: they must be derived

with independent funding from frozen embryos taken from fertility centers; they must be formed strictly for fertility treatment purposes; they must be obtained with the donor's consent; and they must be in excess of the clinical needs of the donor. The government maintained a fairly laissez-faire attitude throughout the 1990's - no federal funding, but also little regulation.

However, in August of 2001, President George W. Bush banned federal funding of research using embryonic stem cells, but this did not affect private research or state-funded research; he announced that federal funds would only be used for existing stem cell lines. In 2005, the Stem Cell Research Enhancement Act (H.R. 810) was vetoed by President Bush. It extended federal funding for stem cell research to include stem cells taken from embryos that were created for in vitro fertilization purposes, but were not used for it. In 2007, another bill for stem cell research was vetoed by President Bush. However, in March of 2009, President Obama reversed the 2001 ban. July of the same year, the noteworthy case of *Sherley v. Sebelius* was brought forward. In this case, two stem cell researchers sued Kathleen Sebelius, U.S. Secretary of Health and Human Services of the time, arguing that the NIH misinterpreted the Dickey-Wicker Act and was illegally using federal funding for stem cell research. In 2011, the court ruled in favor of embryonic stem cell research; this was a landmark moment for science. In 2013, the US Supreme Court dismissed the appeal from the *Sherley v. Sebelius* case. Under President Obama, research using new stem cell lines became federally funded. In 2016, President Obama signed the 21st Century Cures Act, which ensured regulatory review of regenerative therapies, including those using stem cells.

III Embryonic Stem Cell Research is Important

There are many medical needs for further research into how stem cells work and how such processes may be replicated and manipulated. Based on studies of stem cells, scientists are able to learn about vital properties of cells and what in particular makes them different from non-pluripotent cells. Labs are already using stem cells to replicate living systems to analyze normal biological development and to study the origins of various birth defects. In addition, scientists are studying abnormal cell division and differentiation as well as how pluripotent cells become differentiated; these are processes that include the turning on and off of genes, occurrences that are known to trigger terrible medical conditions, including various cancers and birth defects. In 2013, researchers were able to use a method known as somatic cell nuclear transfer (SCNT), in which an egg's DNA was replaced with skin cell DNA. This is just one example of the types of regenerative procedures that may be done using pluripotent cells. In 2014, several successful operations were completed using stem cells to improve poor (legally-blind) eyesight. Research is advancing knowledge about how organisms develop, so that stem cells can improve both duration and quality of life.

By comprehending the genetics and chemistry of these biological processes, scientists will be able to make apply this new knowledge and create new methods for therapy. In fact, researchers are already using stem cells to test new medications. In order to adequately screen drugs, however, the conditions must be identical when comparing different drugs. For this to be the case, scientists must be able to accurately regulate the specialization of stem cells into the particular type which will be used in testing. Finally, researchers will be able to use stem cell in cell therapy, using pluripotent stem cells to regenerate various muscles and tissues, from the brain to the heart.

In addition, according to the Centers for Disease Control and Prevention (CDC), chronic diseases are extremely prevalent in the United States. As of 2012, one in two adults suffer from debilitating diseases and one in four from two or more chronic diseases. In 2014, seven of the top ten sources of death were protracted illnesses, and 46% of all deaths were attributed to heart disease and cancer. Thus far, heart illness and cancers have no “cure,” but by using stem cells, scientists can regenerate tissue to heal the heart, as well as other tissues and organs in the body. Furthermore, by understanding how cell differentiation and duplication functions, scientists will have better tools with which to combat cancer and other cellular disorders. Moreover, it is the government’s responsibility to allow, aid, and fund research for its suffering populace. For instance, veterans come home with war wounds and terrible injuries - lost limbs, burns, etc. after fighting for their country; these are people who have offered the ultimate sacrifice. With modern medicine and stem cell research, they have the potential to be restored to normal physical abilities.

IV The Controversy

As mentioned earlier in this paper, using the stem cells of embryos is controversial. While it is true that in order for the stem cells to be extracted from the embryo, the embryo has to be killed, it is also correct that stem cells may be used from aborted or miscarried fetuses, given the mother’s consent. This brings many ethics questions into play, such as is the fetus already a living human being? Critics of the research state that it is unethical to kill an unborn human with the potential of becoming a person. However, most of the embryos used for the research are formed from leftover eggs that have been fertilized in vitro, some for the specific purposes of research; a large portion of the embryos are frozen from lab-assisted fertility treatments, which would often be discarded otherwise. Thus, the question becomes, is it ethical to allow the useless destruction of embryos or is it far more moral to use them to help others who are suffering needlessly? Another side to the controversy is how the research should be funded: with federal, state, and/or private funding. Yet, surely, in light of the occurring and potential medical progress with stem cells, it cannot be said that depriving ailing, hurting, and dying patients of help, from young children to the elderly, is ethical in any way, shape, or form.

One concern expressed over the research is that immune systems may reject the injection of foreign cells. However, this issue may be solved through the use of cloning of cells, using somatic cell nuclear transfer. This form of cloning would take an egg and replace its DNA with the patient's DNA so that cells may be grown and then used. Scientists are particularly enthusiastic about this method. Jeff Karp, associate professor at Harvard Medical School and co-director of the Center for Regenerative Therapeutics at the Brigham and Women's Hospital in Boston, believes cloning stem cells is a brilliant way to regenerate body tissue, "It is an incredibly powerful approach with potential to generate almost any tissue in the body, genetically identical to the patient." (Landau, par 3)

Yet, the question remains, why use embryonic pluripotent cells rather than adult? To a large degree, embryonic stem cells are taken from embryos that were developed from in vitro fertilized eggs, which are then donated for research with consent from the donor. Less information is known about adult stem cells, or somatic stem cells (SSC), as they are sometimes called, but more research is being done about them. However, thus far, they are not as easily manipulatable as embryonic stem cells and so it is more difficult to use them. Induced pluripotent stem cells (iPSCs) are adult stem cells that have been genetically reformed to an embryonic stem cell-like state by expressing genes and factors critical to the defining properties of embryonic stem cells. While they do meet the characteristic definition for unspecialized stem cells, it is as yet unknown if in practice iPSCs significantly differ from embryonic stem cells.

In 2015, an undercover video was released recording a Planned Parenthood official discussing abortion of fetuses in order to save organs as well as the costs of selling the tissue. Interviews of employees discussed how consent for the organs was demanded and refusals sometimes were ignored, although federal law dictates that consent must be completely voluntary. Planned Parenthood and its partners then used FedEx to ship the body parts to labs for research. This way of obtaining stem cells must be condemned as it is absolutely terrible and unethical. Nonetheless, there are humane and principled ways to obtain stem cells ethically, and this is important to note. The Planned Parenthood expose should only reflect on the companies, businesses, and people involved, not the dedicated researchers who are racing against time to find cures for the individuals who may be saved by embryonic pluripotent cell research.

There have been cases where physicians illegitimately advertise stem cell "cures" to help treat illnesses such as Parkinson's, Alzheimer's, strokes, and cancer, diseases which have no known cure yet. They combine various unapproved substances together for unapproved procedures and inject these supposed stem cells into desperate patients for obscene amounts of money. These fraudulent clinics are so convincing, yet so dangerous because they are unregulated, that the International Society for Stem Cell Research (ISSCR), an independent non-profit, issued a warning that "rogue clinics around the world exploit patients' hopes by offering unproven stem cell therapies, typically for large sums of money and without credible

scientific rationale, sight or patient protection.” (Gornall 2-3) These clinics do not represent the legitimate laboratories and organizations dedicated to the scientific analysis of stem cells.

In addition, it is important to remember that stem cell research is a very young field of medicine. If properly done, it has incredible potential and through selective processes is already helping people. For example, according to the California Institute for Regenerative Science (CIRM) blog, young Evangelina Padilla-Vaccaro was diagnosed early on with severe combined immunodeficiency disorder (SCID), or “bubble baby” disease. Essentially, she was allergic to the world around her because her body didn’t create white blood cells; the most minor infection may be fatal and many children diagnosed with the disease die within several years. However, when Evangelina was just a few months old, her parents placed her in a UCLA study led by Dr. Don Kohn, who, working with a company named Orchard Therapeutics Ltd., developed a treatment called OTL-101. This therapy genetically modified the patient’s blood cells in order to create a new, healthy, blood supply before returning it to the patient. As of July of 2017, more than forty children have been cured using this method. While this example is not using embryonic stem cell research, it is just one example of how stem cells may be used. The cured children are now able to live healthy and normal lives; they can hug their families, go to the park, and get the mail without fear of a lethal infection.

Some Americans appreciate the need for embryonic stem cell research, but would understandably like to limit the creation of new stem cell lines, using fewer embryos and following President Bush’s protocol. This sounds like a wonderful way to continue research; the problem lies in the way the old stem cell lines were grown: in a petri dish on a layer of mouse cells, which produce molecules incompatible to the human system. Additionally, the cells may simply be too old. Scientists cannot use these cells, and so they need new ones for practical purposes. Fortunately, moving forward, scientists have discovered ways of growing the cells without the mouse feeder layer.

Opponents to embryonic stem cell research question the use of federal funding because some Americans disagree with the idea of using embryos in experimentation. While this is an understandable and reasonable concern, the principle may be flawed. For instance, what about the wars, such as the Vietnam War, with which some Americans disagreed? Some citizens are against public schools, others want lower taxes. The fact is, some people will always disagree. It is impossible to run a nation in a way that everyone will always concur. The government is not forcing people to donate embryos; rather, they are creating an option and an opportunity to save lives. Furthermore, religious groups have put great pressure on the government, abortion clinics, and biotechnology companies, feeling that the concept of embryonic stem cell research is morally bankrupt and “against G-d”; however, both sides of the issue believe the other is “playing G-d”, one claiming that this research promotes the unethical sourcing of stem cells, and the other asserting that it is immoral to prohibit chronically-ill individuals a viable solution to

their suffering. More than any other point, the main controversy surrounding embryonic stem cell research is the use of embryos, in which a potential human life is ended. However, in 1998, the US Department of Health and Human Service (DHHS) decided that “the congressional ban on human embryo research does not apply to research on human embryonic stem cells because the cells are not an embryo as defined by statute.” This is because “human embryonic stem cells do not have the capacity to develop into a human being.” In other words, extra embryos are made for fertility purposes, but the “extras” are discarded (trashed, flushed down the sink, etc.). Unless, that is, they are used for research. They cannot survive on their own, so they are not considered even potential human beings.

V Conclusion

While the United States does allow federal funding of embryonic stem cell research, the subject has remained very divisive. During the George W. Bush administration, bills were introduced to ban and severely limit research. In order to make sure that people have access to the responsible healthcare opportunities they need to live a normal, healthy life, it is so crucial that Americans as a group understand how life-changing research into stem cells is and support it.

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