ENDOCRINE SOCIETY
Hormone Science to Health

POSITION STATEMENT

STEM CELL RESEARCH

INTRODUCTION

Stem cell research holds great promise for the treatment of the millions of Americans with debilitating and possibly fatal diseases including diabetes, heart disease, Parkinson's disease, Alzheimer's disease, spinal cord injury, stroke, muscular dystrophy, Lou Gehrig's disease, lung disease, kidney disease, liver disease, AIDS, arthritis, and anemias. No research in recent history has offered as much hope in treating such a constellation of diseases as stem cell research.

BACKGROUND

Stem cells have three important characteristics that distinguish them from other types of cells. First, they can renew themselves for long periods through cell division. Second, they are unspecialized cells, meaning they are not capable of performing specialized functions like producing insulin. Third, they can be induced to become cells with special functions, such as the insulin-producing cells of the pancreas or the beating cells of the heart muscle.

Naturally occurring stem cells are sometimes defined by the developmental stage at which they are found. Embryonic stem cells (ESC) come from a blastocyst (a ball of cells formed about 4 days after an egg becomes fertilized). Many years of detailed study of the biology of mouse stem cells led to the discovery, in 1998, of how to isolate stem cells from human embryos and grow the cells in the laboratory, creating human ESC lines. The embryos used in these studies were generated by in vitro fertilization for infertile couples. Extra or non-viable embryos that were no longer needed for fertility purposes were then donated for research with the informed consent of the donors. Adult stem cells come from the tissue of adults or children.

Adult stem cells were discovered after extensive work on ESCs shed light on identifying characteristics of stem cells, allowing researchers to use these characteristics to find and isolate stem cells from adult tissue.

To understand the significance of the embryonic versus adult stem cells, it is important to consider the cells in the context of what they can do. To understand the potential implications of the different types of stem cells for research and public health, it is important to consider the cells' abundance and accessibility.

ESCs are pluripotent. That is, they are capable of giving rise to any type of cell present in the adult body. ESC are easy to isolate because they are relatively abundant in the blastocyst.

On the other hand, most naturally occurring adult stem cells are not pluripotent, though recent research has shown that some adult stem cells are more malleable than originally thought. Furthermore, adult stem cells are more difficult to isolate because they are rare, comprising only a very small percentage of cells in the adult tissue.

As scientists have learned more about pluripotent ESCs, several important advances have been made. Groups of scientists have generated pluripotent stem cells from adult non-stem cells by inserting factors that are critical for pluripotency. These cells are called induced pluripotent stem cells, or iPSCs. This promising direction in research is advancing rapidly and should be pursued. However, much is still unknown about iPSCs and it is still unclear whether they possess all the properties of ESCs. iPSCs are probably many years away from becoming a viable treatment option.

Another way to generate pluripotent ESCs is by injecting the nucleus of a non-stem cell into an unfertilized egg from which the nucleus has been removed. This process, called somatic cell nuclear transfer (SCNT), results in ESCs in which all the nuclear DNA and subsequently produced proteins are molecularly matched to those of the original non-stem cell. SCNT is often referred to as therapeutic cloning because of the potential it has for fighting disease in patients. SCNT is a potentially powerful tool in research as well. This technique allows for the generation of cells that have known disease-causing mutations that scientists can study for disease progression and cures. Furthermore, SCNT is the only method by which scientists can differentiate the influence of nuclear factors from that of non-nuclear factors in development.

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CONSIDERATIONS

In 2001, President Bush imposed federal funding restrictions limiting the use of human ESC lines. The policy limited federal funding to research performed on human ESC lines for which the derivation process was initiated prior to 9 p.m. EDT August 9, 2001; the embryo was created for reproductive purposes; the embryo was no longer needed for these purposes; informed consent was obtained for the donation of the embryo; and no financial inducements were provided for donation of the embryo. On March 9, 2009, President Obama signed Executive Order 13505 overturning the temporal restriction in the Bush policy, allowing for a greater number of cell lines derived from IVF embryos to be qualified for use in federally funded research. This step is absolutely required to advance scientific knowledge by US scientists in the field of stem cell research. However, the executive order does not address funding for research on cell lines derived from sources other than IVF embryos, such as SCNT. Furthermore, federal funding of the derivation of human ESC lines is still prohibited by the Dickey-Wicker Amendment, and this restriction limits US scientists from exploring and harvesting the full potential of pluripotent stem cells.

In light of the promise of SCNT and of the need for scientists to be able to generate disease-specific stem cells for research, the executive order alone is insufficient to take full therapeutic advantage of the technology at our fingertips. Therapeutic cloning has immense potential in treating injury and disease without creating a need for patients to commit to a lifetime of immunosuppressive therapy. Because SCNT would generate stem cells with a patient's precise genetic make-up, the patient's body would not recognize them as foreign and would not reject them. Furthermore, SCNT-derived ESC would be a self-renewing source of cells that could be used for replacement of diseased or damaged tissue or for research into the origin of disease.

When SCNT-derived blastocysts are created for research applications and therapeutic cloning, they are not implanted and are thus not allowed to develop beyond the blastocyst stage. In contrast, reproductive cloning takes the additional step of implanting the SCNT-derived blastocyst in the attempt to generate a new living organism identical in nuclear makeup to the parent organism. Therapeutic cloning and reproductive cloning are scientifically distinct processes and must be distinguished from one another in policy discussions.

POSITIONS

The Endocrine Society enthusiastically supports Executive Order 13505 and NIH funding for stem cell research. The Endocrine Society agrees that for the full potential of ESC research to be reached, the number of stem cell lines readily available to scientists must increase. As the Society's members have witnessed, transplantation of human tissues such as kidneys, hearts, and bone marrow cells has given years of quality life to many patients. But transplantation requires a lifetime of immunosuppressive therapy, reducing the quality of life for transplant patients. Furthermore, for many specialized cells that may become dysfunctional, such as brain cells, which are lost in patients with Parkinson's disease, stem cells represent the only potential source of tissue for transplant. Funding of stem cell research is vital to ensure the progression of medical technology and the health of US citizens.

The Endocrine Society also supports the guidelines established by NIH (ref. NIH guidelines) to ensure the ethical derivation of human ESC from donated IVF embryos, though the Society encourages the agency to broaden its stance to allow federal funding for research on cells from other sources such as SCNT.

The Endocrine Society members recognize the enormous potential of stem cell research in understanding the processes whereby cells differentiate to form new tissues and organs and the potential such work has for improving human health and well-being. At the same time, the Society recognizes that any research, in particular that involving human ESCs, must adhere to the highest ethical and scientific standards. The Endocrine Society therefore supports appropriate public oversight of ESC research to assure that such standards are always met.

In summary, the Society supports the following positions:

- An increase in NIH funding for stem cell research;
- An increase in the number of embryonic stem cell lines for NIH-funded research;
- A broadening of the scope of federally funded research to include cells generated through somatic cell nuclear transfer;
- Availability of federal funding for the derivation of embryonic stem cells from discarded IVF embryos and through somatic cell nuclear transfer;
- Adherence to the highest ethical and scientific research standards;
- Federal oversight of embryonic stem cell research to assure ethical standards are always met.