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INTRODUCTION

Stem cell research holds great promise for the treatment of the more than 128 million Americans with debilitating and possibly fatal diseases such as Parkinson's disease, Alzheimer's disease, diabetes, spinal cord injury, stroke, muscular dystrophy, Lou Gehrig's disease, heart disease, lung disease, kidney disease, liver disease, AIDS, arthritis, and anemias. No research in recent history has offered as much hope in treating these diseases as stem cell research.

BACKGROUND

Stem cells have two important characteristics that distinguish them from other types of cells. First, they are unspecialized cells that renew themselves for long periods through cell division. The second is that under certain physiologic or experimental conditions, they can be induced to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.

Scientists primarily work with two kinds of stem cells from animals and humans—embryonic stem cells and adult stem cells, which have different functions and characteristics. 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. These are called human embryonic stem cells. 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 that purpose were then donated for research with the informed consent of the donors.

Stem cells are important for living organisms for many reasons. In the three- to five-day-old embryo, called a blastocyst, stem cells in developing tissues give rise to the multiple specialized cell types that make up the heart, lung, skin, and other tissues. In some adult tissues, such as bone marrow, muscle, and brain, discrete populations of adult stem cells generate replacements for cells that are lost through normal wear and tear, injury, or disease.

Scientists want to study stem cells in the laboratory so they can learn about their essential properties and what makes them different from specialized cell types. As scientists learn more about stem cells, it may become possible to use the cells not just in cell-based therapies, but also for screening new drugs and toxins and understanding birth defects and genetic disorders.¹

CONSIDERATIONS

President Bush imposed federal funding restrictions on stem cell research in 2001. In the three years since the restrictions on for stem cell research were announced, more than 4 million Americans have died from diseases that embryonic stem cells have the potential to treat.

In 2003, NIH provided only \$24.8 million in funding for human embryonic stem cell research and \$190.7 million for human non-embryonic stem cells (adult stem cells, including those from cord blood, placenta, and bone marrow). NIH grants far exceeded those from state and local governments, universities, and private foundations—the next-largest spenders on basic research. With federal funding for embryonic stem cell research now restricted, the nation's top academic researchers at universities, medical schools and teaching hospitals cannot join in the search for cures, which means much slower progress. Scientists are reporting that it is increasingly difficult to attract new scientists to this area of research due to concerns that funding restrictions will keep this research from being successful.

Originally, it appeared that 78 embryonic stem cell lines were available for research under the federal policy. Today, estimates from the NIH show the number of available stem cell lines at only 19, well short of what the policy intended.

¹ "The Official National Institutes of Health Resource for Stem Cell Research", *Stem Cell Information*, NIH web site: www.nih.gov. Accessed on October 18, 2004.

CONSIDERATIONS (CONT.)

Furthermore, the remaining stem cell lines are contaminated with non-human cells which preclude their use in clinical studies, and make them not viable for research. In response to this information, the U.S. Department of Health and Human Services claims that the involvement of non-human cells in many lines of embryonic stem cells will not affect the scientific value of the stem cells. However, Society members remain concerned that if these lines are compromised, there will be no stem cell lines on which to conduct valuable scientific research.

Adding to this concern is the fact that the federal government is still banned from supporting the development of disease-specific stem cell lines as well as from granting scientists access to new lines that would add to the genetic diversity of stem cells available for research.

POSITIONS

The Endocrine Society enthusiastically supports NIH funding for stem cell research. 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 for many specialized cells that may become dysfunctional, such as brain cells, which are lost in patients with Parkinson's disease, there has been no source of tissue for transplant, until now. Funding of stem cell research is vital to this progression in medical technology.

The Endocrine Society also supports the American Society for Reproductive Medicine (ASRM) 1997 guidelines on the use of gametes and embryos for research², which recommends a carefully specified procedure for obtaining informed consent for the ethical implementation of studies involving human gametes and embryos, including active IRB involvement and confidentiality.

Like most of the scientific community and NIH, The Endocrine Society agrees that for the full potential of

embryonic stem cell research to be reached, the number of stem cell lines readily available to scientists must increase. The Society therefore encourages expansion of the scope of current federal policy on human embryonic stem cell research, beginning with an increase of stem cell lines available to researchers. NIH Director Elias Zerhouni, MD, has stated his support for more stem cell lines in a May, 2004, letter to members of Congress: "...more cell lines may well speed some areas of hESC research."

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 embryonic stem cells, must adhere to the highest ethical and scientific standards. The Endocrine Society therefore supports appropriate public oversight of embryonic stem cell 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 stem cell lines for research;
- Adherence to the highest ethical and scientific research standards;
- Oversight of embryonic stem cell research to assure ethical standards are always met.

² *Informed Consent and the Use of Gametes and Embryos for Research*, American Society for Reproductive Medicine. *Fertil Steril* 1997;68:780-1.