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Chronic disease states such as Type 1 Diabetes, Parkinson's Disease, and Spinal Cord Injury result from the destruction of specific cells. Replacement of these tissues may provide immense relief, and possibly cure, of the disease.

One approach to replace these tissues is to find acceptable transplantation sources and implant donor cells into a patient. If these cells are derived from a source other than the patient, there will be problems with rejecting the "foreign" transplant material. Cloned patient cells (cells that are induced to replicate with the same DNA template as the patient) do not have many of foreign markers and theoretically would not be rejected. However, cloning by the transfer of somatic nuclei into unfertilized eggs requires a dramatic remodeling of chromosomal architecture. Many proteins are specifically lost from nuclei and others are taken up from the egg cytoplasm. These proteins determine which DNA genes are promoted and expressed, and which DNA genes are repressed.

The specialization of cells for specific function occurs during embryogenesis, fetal development, and continues throughout adult life. The microenvironment that developing cells are exposed to plays a major role in determining which factors of the DNA are expressed, and which factors are not expressed. We all have met identical twins, which have the same DNA template, but have quite different personalities and even different physical appearances. These differences are largely determined by differences in environment that the differentiating cells are exposed .

Since cellular transplant material obtained from developing embryos must overcome the problem of appropriate integration into the transplant site in order to replace the function of the destroyed tissue, scientifically it may make more sense to induce the patient's own tissues to replicate at the desired site. If the patient's own tissue could be induced to regenerate at the desired site of injury, the communication and integration networks are mostly in place. Embryonic stem cell transplantation has repeatedly been shown to be ineffective in large animal models largely because they are not capable of integrating into mature host structures. Even if the stem cells are obtained from cloned embryos, and subsequently are not rejected on the basis of major immunologic compatibility, the transplanted stem cells are still not capable of forming the complex integrative network that many structures require.

The developing embryo is surrounded by unique proteins and environmental factors. Once the embryo reaches a more mature fetal stage, the cells are surrounded by more mature proteins and growth factors, leading to more highly differentiated cell functions. Throughout this process, the DNA template that codes for the expression of all cell functions remains the same. One hypothesis states that if the correct embryonic environment could be duplicated, a patient's cells may be able to be induced to regenerate in a given site, as they rapidly did earlier in the patient's life during embryogenesis. This would result in totally compatible, integrated, replacement tissue for the disease being treated.

I would like to share with the committee the preliminary results of a product I developed to induce regeneration of a specific kind of tissue in animal and human patients. My hypothesis was that exposing cells derived from a specific embryonic germ layer (the mesoderm) to an environmental structure similar to that present during natural embryogenesis, might induce the patient cells to behave as they did during embryogenesis, and induce explosive generation of tissue. Mesodermally derived cells give rise to such differentiated structures as blood vessels, deep skin structures, bone and cartilage. The artificial embryonic scaffolding I invented was made from modified long chain, naturally occurring coumpounds that were synthetically polymerized to give the desired structure. This embryonic scaffolding contained no cells, only structures for the patient's cells to bind to. If the hypothesis were correct, after exposing the patient's damaged tissue to this synthetic biopolymer, the patient's tissues should be induced to rapidly regenerate according to the direction of the patient's own DNA template.

The results I am about to show have been presented at several scientific meetings, and have recently been submitted for review in a peer reviewed journal. Shown is an example of the rapid wound healing induced in a dog that had naturally occurring diabetes and developed multiple full thickness skin ulcers. The dog had undergone multiple courses of antibiotics and surgical closure procedures, but the ulcers would not heal because of the chronic destruction of blood vessels commonly seen with long standing diabetes. After a one-time injection of the artificial embryonic scaffolding, the dog's wound's healed with regenerated tissue. The new tissue resulting from exposure to the embryonic like matrix was determined to be structurally identical to non-wounded areas, without the usual scarring that is normally seen with healing lesions. Further large and small animal studies confirmed our finding, and a six patient feasibility study was reviewed by the Food and Drug Administration to examine the effect of a one-time injection in patients with chronic diabetic foot ulcers refractory to conventional therapy.

Within days of a one-time injection, all the patients experienced rapid diminution of ulcer size, with apparent regeneration of skin, blood vessels, and surrounding structures. Since the new tissue derived from the patients' own tissue, there was seamless integration with no evidence of rejection. Further study is required to determine if this particular product is safe and effective, but clearly the large animal and human patient studies suggest cellular transplantation is not necessarily required to replace damaged tissue.

Destroying a human embryo to obtain cellular material does in fact destroy a human life, not a potential human life. Shortly after conception, a human being has a DNA template from which ALL other cells are generated. The process by which cells become specialized is called differentiation. A differentiated heart cell has the same DNA template as a differentiated skin cell, and they both have the same DNA template as the undifferentiated cells early in embryogenesis.

The mass of cells that begins this replication and differentiation, either shortly after conception or induction through nuclear transfer, defines the beginning of any mammal's life. This differentiation process continues until death. The continuum of human life thus starts at the beginning of the complex, explosive process of cellular DNA differentiation during embryogenesis and ends at death. One cannot stop the continuum at any one point and say it is not human life because it lacks the ability to do certain functions. When the mass of cells has feelings or reason is subject to debate. When it begins as human life is a biologic fact.

All laws are based on precedent. The difference between a just and an unjust society is the precedent the society accepts to base its jurisprudence upon. In my view, the United States is a uniquely just society because it is the first government in the history of humankind in which the right of the individual supersedes the perceived right of the state, thus defining the individual as society's most valued entity. The first ten amendments to our constitution explicitly prevents government, even if so desired by the majority, from violating these individual rights. As a developing embryo, whether cloned or naturally created, is scientifically a human being, the United States must not set the precedent of allowing individuals to be sacrificed for the illusion of a greater good.

Transplantation strategies, whether derived from foreign donors or cloned cells from the patient themselves, are clearly not the only approach to replace damaged tissues. Other avenues are further along in clinical trials, and should be considered as a first approach for study. Indeed, the patient's existing cells provide the most rationale source for fully integrating replacement tissues, as occurred during embryogenesis.

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