

Testimony of
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SLIDE 1

Destruction of specific cells results in many chronic disease states such as Type 1 Diabetes, Parkinson's Disease, and Spinal Cord Injury. Replacement of these tissues, with replacement of their specific function, would provide an effective cure for the disease state.

SLIDE 2

All cells within an individual contain the same DNA sequence. The DNA located on the chromosomes in the cells' nucleus selectively codes for different signals. Which signals are expressed depends on the cells environment, and determines the function of the cells. A differentiated heart cell has the same DNA template as a differentiated skin cell or brain cell. The cells differ only in which part of the DNA template is expressed, and this is determined by the microenvironment of the developing tissue.

Two recent theories to replace damaged tissue involve the use of transplanted human embryonic tissues, or tissues derived from cloned individuals. Neither of these sources of embryonic transplantation material has successfully resulted in recovery of clinical function in large animal studies, largely because appropriate communication with host tissues is not made.

SLIDE 3

Since cellular transplant material obtained from developing embryos, either foreign or cloned, 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.

I would like to share with the committee the preliminary results of a product I developed while with my first biotechnology company. This product was designed to induce regeneration of a specific kind of tissue in animal and human patients. My hypothesis was that exposing cells 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.

The scaffolding I invented was made from modified naturally occurring compounds, synthetically polymerized to give the desired structure. This product contained no cells, only structures for the patient's cells to bind to upon injection at the damaged site. If the hypothesis were correct, after exposing the patient's damaged tissue to this synthetic biopolymer, the patient's tissues would 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 to a peer-reviewed journal.

SLIDE 4

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.

SLIDE 5

This photomicrograph shows the result of injecting the synthetic biopolymer into an 8 year old dog's liver. After three weeks, the section of the liver was removed, and showed the apparent regeneration of embryonic tissue development within the mature dog liver cells.

Shown are cells that have the appearance of undifferentiated mesenchymal cells, apparently associated with differentiating fibroblasts and endothelial cells (the cells making up blood vessel walls). Finally, nucleated red blood cells, found in large quantities only during early fetogenesis, are found in the newly formed blood vessels, apparently differentiating from the endothelial cell lining of the blood vessel wall. This process only occurs during early fetogenesis, as red blood cells, without nuclei, are made in the bone marrow later in development. The interpretation of this slide was done by Dr. Ron Dudek, a medical embryologist.

SLIDE 6

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.

SLIDES 7-13

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.

SLIDE 14

Transplantation strategies, whether derived from foreign donors or cloned cells from the patient themselves, are clearly not the only approach to replace damaged tissues. Such transplantation strategies require destruction of the newly formed individual DNA template. 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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