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CELLULAR SOLUTIONS FOR AUTOIMMUNE DISORDERS

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Around the world, there are between 80 to 100 identified autoimmune diseases that affect more than 583 million people.

These conditions cause the body's immune system to attack its own healthy tissue. Unfortunately, the reasons for the attack often can't be identified or explained.

Incidence of autoimmune diseases has been increasing in the western world over the last several decades for unknown reasons. Common conditions include type 1 diabetes, multiple sclerosis, rheumatoid arthritis, lupus

and celiac disease. Women are disproportionately affected, and make up three quarters of autoimmune patients.

Autoimmune patients can often experience chronic incapacitating symptoms such as, in patients with multiple sclerosis, debilitating fatigue and brain fog. Because there is no single definitive diagnostic test and a myriad of symptoms for most autoimmune disorders, diagnoses can be delayed. The American Autoimmune Related Diseases Association (AARDA) believes it may take as long as five years for a patient with an autoimmune disease to receive a correct diagnosis.

Cell therapy holds promise for many autoimmune conditions. Once the diagnosis is made, therapy is limited to minimizing the symptoms or progression of the disease, which often comes with significant side effects. The Northwestern University Feinberg School of Medicine in Chicago is one of the first institutions to study the impact of cell therapy on autoimmune conditions in the United States.

Professor Richard Burt at Northwestern paved the way in the application of stem cells for autoimmune conditions for over 20 years and led multiple clinical trials testing stem cell transplantation for autoimmune conditions such as myasthenia gravis, systemic sclerosis, systemic lupus erythematosus, chronic inflammatory demyelinating disease, and multiple sclerosis. Dr. Burt has numerous peer-reviewed publications in journals such as *The Lancet*, and *Journal of the American Medical Association* that focus on the efficacy of stem cells for autoimmune diseases.

The clinical trials use autologous hematopoietic transplantation where the patient's own peripheral blood stem cells are collected through apheresis and reintroduced back into the patient after a short course of immune ablative drugs. This procedure has the ability to create a new immune system that has no memory

the autoimmune condition and allow the patient to start his or her life anew.



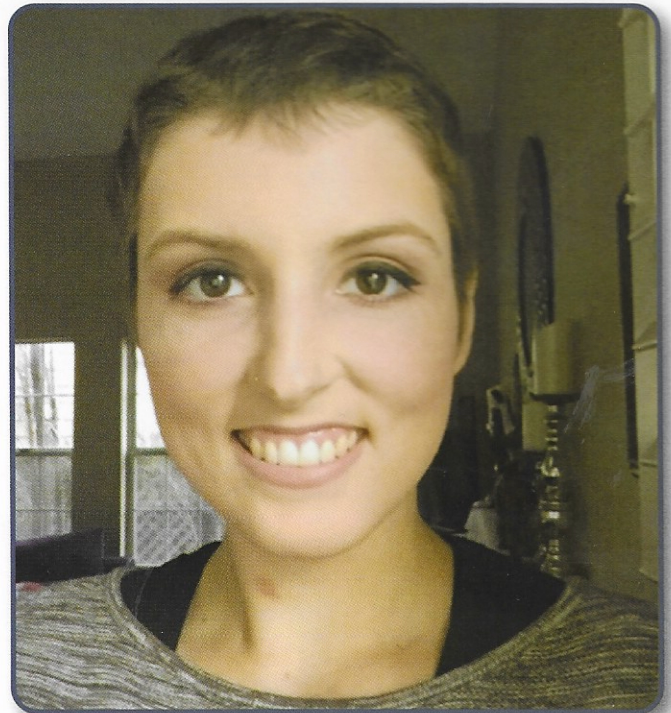
Below are two success stories of young women with debilitating autoimmune conditions who were treated by Dr. Burt's team.

ELIZABETH COUGENTAKIS'S STORY Elizabeth Cougentakis was healthy, athletic and an outstanding student until 2004, when at age 13, she was diagnosed with myasthenia gravis (MG). First, her vision and her ability to walk and feed herself were compromised. Then it became difficult to breathe and eventually Elizabeth was completely disabled. Six months later, she was intubated to breathe and fed through a feeding tube.

MG, a neuromuscular autoimmune disorder, leads to muscle weakness and fatigue and can sometimes be managed with medications. Unfortunately, for Elizabeth, nothing worked and she continued to deteriorate. She was evaluated by several neurologists, had her thyroids removed and underwent 17 sessions of IVIg and numerous plasmapheresis treatments. Desperate to save her life, her parents took her to Venezuela for an evaluation from another neurologist. Again, the treatment was ineffective and the doctors told her she would be bedridden for the rest of her life.

In 2006, after nearly two years of hospitalizations and being dependent on ventilators and feeding tubes, Elizabeth joined the stem cell study at the Feinberg School of Medicine at Northwestern University in Chicago. As with many other autoimmune conditions, autologous hematopoietic stem cell transplantation was being used to treat MG.

Elizabeth's own stem cells were harvested, she received a short course of chemotherapy and was then reinfused with the stem cells to regenerate the immune system. Elizabeth felt the results of the procedure almost immediately when she gained control of her eyes. She could chew her food and progressively all of her symptoms disappeared. Within a year after the procedure, Elizabeth recovered and has been healthy requiring no medication for the last eight years.



GRACE MEIHAUS'S STORY

When she was 17, Grace Meihaus noticed patches of her skin had suddenly become tight and her fingers swelled up and turned blue whenever she was cold. An active teenager who enjoyed playing sports and hiking, Grace suddenly fatigued easily and started losing focus in school. Depression and anxiety soon followed. First misdiagnosed with lupus, it was soon determined that Grace had scleroderma, or systemic sclerosis (SSc).

SSc is a rare autoimmune rheumatic disease that affects the skin and other organs of the body, especially the lungs and heart. Primary symptoms include Raynaud's phenomenon, which is an exaggerated response to cold temperatures, a thickening and tightening of the skin and inflammation and scarring of many body parts, leading to problems in the lungs, kidneys, heart, intestinal system and other areas. Typically, a disease of young women, SSc affects upwards of 100,000 people in the United States. Systemic sclerosis is a lethal disease and has a mortality of 6% per year, i.e. a 30% and 60% mortality in 5 and 10 years, respectively.

By 2015, Grace's symptoms worsened and she left college to take care of her SSc. Through a scleroderma support group, she learned about the experimental scleroderma treatment at the Feinberg School of Medicine at Northwestern University. Several months later Grace received an autologous hematopoietic stem cell transplant. Within months, her skin loosened, her internal inflammation stopped and her immune system improved significantly. Her shortness of breath also vanished completely and she was again able to enjoy sports. Grace, who is now 22 and lives in Santa Rosa, California, with her family, returned to college in the fall of 2015 and intends to pursue a degree in communications media.



Dr. Richard Burt (right), Elizabeth Cougentakis (middle)
and Grace Meihaus (left)