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Applied BioLogics and MS at Stowe BioTherapy

This report reviews the basic process and costs for using Applied BioLogics (comprehensive immune therapy), energy medicine and adult stem cells for tissue engineering, to reverse the PITTS Syndrome when the client has Multiple Sclerosis (MS). The combination of Applied BioLogics, energy medicine, and adult stem cell therapy is known as Regenerative Medicine. The PITTS Syndrome is considered by the Stowe Foundation to be the source of the chronic inflammation that destroys the myelin sheath and creates the diagnosis of MS. Applied BioLogics is not a cure or treatment for MS or any other disease or illness. The client should seek professional medical care for the treatment of MS. Applied BioLogics is the Foundation's key concept to eliminate chronic inflammation and to restore the body's natural ability to heal itself through the immune system.

The first step in the physical rehabilitation of the MS client is to eliminate the chronic inflammation that is attacking the myelin sheath. Therefore, Applied BioLogics is simply an adjunctive therapy in the fight against MS. The physical rehabilitation program for MS patients at Stowe BioTherapy is divided into five segments:

- Immune Modulation to control chronic inflammation
- Immune Vaccinations to eliminate infectious micro-organisms and regulate cytokines
- Anabolic Metabolism to internally repair vital tissue, glands and organs
- Adult Stem Cells to grow new tissue, glands and organs
- Physical Rehab to restore function to the muscles and nerves

Immune Modulation

The first protocol, Immune Modulation, which can be started "At Home", is to initiate a program to reverse poor nutrition, control opportunistic infections and decontaminate the body from a variety of environmental toxins. These are the first three letters of the PITTS Syndrome and the therapy can be carried out in the convenience of the home. The "At Home Program" involves three basic steps.

1. The Stowe Foundation's program starts with Nutritional BioTherapy to rebuild the immune response. The products required and the dosing instructions are described in the Immune Modulation package. The professional staff at Stowe BioTherapy can discuss the effect each supplement and biological agent will have on the body. The Nutritional BioTherapy program insures that the client is getting a full compliment of the essential proteins, fats, carbohydrates, sugars and trace minerals required to have a healthy and vibrant immune system. Nutritional BioTherapy is used to reverse the "P" of the PITTS Syndrome, which is poor nutrition.



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2. The “At Home Program” also uses Biological Response Modifiers such as broad spectrum transfer factors to activate the Natural Killer Cells and T-cells of the immune system. Natural Killer cells and T-cells are the part of the immune system that can destroy infections and abnormal cells that are foreign to the body. Transfer factors help protect the client from opportunistic infections and simultaneously strengthen the immune response to the infectious micro-organisms like the nanobacteria that Dr Lindner has discovered in human blood to be associated with the etiology of MS. Transfer factors are the communication molecules of the immune system. Proper communication between the different cells of the immune system is vital to regulating the inflammatory response of the immune system. Transfer factors help address the “I” of the PITTS Syndrome, which is the trigger mechanism to chronic inflammation.

3. The Stowe Foundation’s molecular biology lab provides a personalized and custom compounded decontamination program to eliminate toxins from the body tissue. Toxins are the fuel to the fire of chronic inflammation. The detox program purifies the blood, organs and glands of heavy metals, industrial chemicals, environmental toxins plus assorted neurotoxins. Elimination of toxins will substantially reduce the free radical pathology or oxidative stress that destroys the cell membrane walls of the myelin sheath. MS patients often show elevated heavy metals (mercury, lead, cadmium and arsenic) in tissue samples, such as the hair, blood and urine and often need a strong decontamination program of the bone marrow to restore immune function. The bone marrow is the source of the blood’s red and white blood cells. When the bone marrow is toxic, MS patients are often anemic, immune compromised and extremely fatigued. Toxins are the first “T” of the PITTS Syndrome. Using clathration agents instead of chelation agents allows Stowe BioTherapy to produce a detoxification program that can be safely administered “At Home”.

Each cycle of the three steps “At Home Program” will last 90 days and the estimated cost is \$6,000. The 90 day cycle of the program is repeated multiple times until the MS process has been resolved. It can not be predicted in advance how many cycles will be required.

The “At Home Program” can be optimized through a series of blood tests, stool sample analysis and hair analysis. The tests are used to determine how well the intestinal tract is performing. The test results help to establish the proper diet to eliminate food toxins, to detect specific nutritional deficiencies and to resolve chronic inflammation triggered by inflammatory cytokines released from gut associated lymphatic tissue. The tests cost \$1,500 to \$3,000 and are repeated every 120 days. Several of the tests require a doctor’s prescription. All of the tests are available at the Stowe BioTherapy clinic in San Diego, CA.



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Vaccination Program

The second segment of Applied BioLogics for MS patients is to target the immune response directly on the specific pathogens behind the chronic illness and to regulate the production of inflammatory cytokines and the abnormal antibodies that trigger the inflammatory response of the immune system. There are two active steps required to properly regulate the immune system. Step I is an injectable vaccine for MS and Step II is an oral vaccine made from patient specific transfer factors created in the Stowe Foundation's molecular biology lab. The vaccination program can only be ordered by physicians associated with Stowe BioTherapy. All clients on the vaccination program must schedule an office visit to Stowe BioTherapy.

I. Client's of Stowe BioTherapy use the Stowe Foundation's immune modulation vaccine for MS to control chronic inflammation and slow if not halt the progression of the MS. Chronic inflammation in MS patients is related to the MS antibodies that keep the immune system up-regulated and the subsequent chronic inflammation distracts from the ability of the immune system to focus on the repair of the myelin sheath. In the presence of chronic inflammation the immune system destroys tissue, which is the exact opposite of the desired response. The MS vaccine greatly improves the performance of the entire rehabilitation program by calming down the immune system in areas where the immune system is attacking otherwise healthy tissue. The MS vaccine dose can often be reduced as the program continues; hence subsequent rounds of the MS vaccine can be less expensive. The MS vaccine is an easy to administer injection much like an injection of insulin. The estimated cost for the initial MS vaccine and for all maximum dose regimens is \$45,000 for a 90 day supply.

II. Blood samples are drawn at the clinic to create the patient specific transfer factors that are the active ingredient in the oral vaccine for MS patients. The patient specific transfer factors are utilized to target the immune system directly on the specific pathogens which are the trigger behind the chronic inflammation associated with MS. Pathogens have a tendency to mutate within the human body and therefore the oral vaccine created by using patient specific transfer factors is a major technology breakthrough. In simple terms, The Stowe Foundation uses patient specific transfer factors to destroy the specific form of the pathogen that triggers the chronic inflammation associated with each individual case of MS and may also be the cause of the MS. This targets the immune system on the "I" of the PITTS Syndrome. The patient specific transfer factors can take up to 3 months to process, which means the patient will introduce them into the Applied BioLogics program after two rounds of the "At Home Program", depending on the timing of the office visit. The entire program uses broad spectrum transfer factors to control



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opportunistic infections. The supply of patient specific transfer factors will last approximately 9 months. The estimated cost for patient specific transfer factors is \$12,500.

Stowe BioTherapy Clinic Visit

The effectiveness of the Applied BioLogics program and chances for success can be greatly enhanced by a four week visit to Stowe BioTherapy to see our energy medicine team. The clinic provides a wide range of energy medicine that is unique and proprietary to The Stowe Foundation. Balancing the electrical potential of the cell membrane walls with micro-current therapy is perhaps the most dramatic way to resolve pain. Bio-oxidative and photodynamic therapy is provided to purify the blood and maximize oxygen delivery to the tissue beds, oxygen being the enemy of anaerobic cancer cells and many viral infections. Energy medicine is used at Stowe BioTherapy to adjust the bioactive energy fields of the body, to accelerate the immune system response, to enhance tissue repair, to reset the autonomic nervous system, to move the body into a healing response and to improve the body's anabolic metabolism.

The two main forms of metabolism are catabolic metabolism and anabolic metabolism. Catabolic metabolism is the process which is used to break down nutrients in foods and supplements so that these can be more easily absorbed and then used by the body as necessary. The Stowe Foundation's Nutritional BioTherapy program greatly supports the catabolic functions associated with digestion.

Anabolic metabolism is the exact opposite of this and instead uses enzymes to structure larger molecules from smaller ones. If toxins or adverse energy fields have clogged the anabolic pathways, tissues and organs simply cannot heal. The fact is that anabolic metabolism is a necessary factor of living a healthy life and maintaining a solid anabolic metabolism is extremely important. The opposite of anabolic metabolism within the human body is the wasting syndrome. Anabolic metabolism is crucial to physical activities, assisting growth and repair, and maintaining life itself. The biologically active energy fields that exist in a diseased body can totally suppress anabolic metabolism and thereby negate the Nutritional BioTherapy program.

Several factors contribute to the body not being able to heal. Disruption of the autonomic nervous system (ANS) is a common thread. The ANS controls whether the body is sympathetic dominant (fight or flee) or parasympathetic dominant (rest and relax). The body can only heal when it can move into a rest and relaxed state. The body heals at night from the physical activity of the day. Convalescence (bed rest) is still important after surgery, but not prolonged inactivity. The ANS controls the ebb and flow of human performance.



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Severe physical and emotional trauma can lead to a medical condition called Seyles' alarm response. In this condition, the ANS is pushed to the extreme limits of sympathetic dominance. The endocrine system moves completely into producing hormones and steroids that support the fight or flee activities of the adrenal glands. The immune system is severely suppressed. An imbalance in the ANS shows up as depression, anxiety, fear, anger and sleep deprivation. Many shades of grey exist between Seyles' alarm response and stress induced physical ailments. Trauma, both emotional and physical is the second "T" of the PITTS Syndrome. Stowe BioTherapy can provide sound and light therapy that can bring balance to the ANS. Being sympathetic dominant is part of nearly all chronic illnesses. Balancing the ANS is critical to recovery.

Stress, especially psychological distress, can suppress the body's defenses to the point of inducing physical illness. A college student suffers from a strep throat infection while studying for final exams. A corporate executive loses her voice prior to an important presentation to stockholders. A high school senior wakes up with a horrible headache on the morning of the prom. After several sleepless nights with their sick child, both parents come down with the flu. Living paycheck to paycheck causes a happy marriage to disintegrate into divorce. Mounting debt forces the husband or wife to take a second job leading to physical exhaustion. Virtually everyone has experienced similar reactions. Day to day stress leads to a suppressed immune system. Stress is the "S" of the PITTS Syndrome.

Clinic expenses for MS patients will average \$12,000 per 4 week stay. Travel and living expenses are extra for out of town clients. The clinic will also interact and help guide the patient's physical rehab program. Physical rehab is a very unique experience for each patient and should be carefully monitored and adjusted by the patient's personal medical team. The clinic's professional staff will be happy to provide guidelines to the rehab process.

Regenerative Medicine

The Stowe Foundation has created an entirely different approach to Regenerative Medicine. Regenerative Medicine is the ability to generate healthy new tissue, organs and glands in locations where traumatic injury or the disease process has caused severe damage. For example, a functional heart can be restored following a heart attack or the lesions of an MS patient repaired to restore function to the nerves. At Stowe Biotherapy, we have established a system of Regenerative Medicine based on adult stem cells. The FDA has recently cleared the source of the adult stem cells to be an autologous blood product. Hence, we offer the only point of care service for stem cell therapy.



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First we recognize that adult bone marrow produces a truly pluripotent adult stem cell. We call it the UPS cell, the Universal Pluripotent Stem Cell. It is not the CD34 cell or any of the progenitor cells used by the competitors to Stowe BioTherapy. The pluripotent adult stem cell is the precursor to the progenitor cells. The UPS cell has been ignored in stem cell research because conventional wisdom ruled that only the embryonic stem cell could be pluripotent. That is a false conclusion.

However, much like the progenitor cells currently used in human cell therapy, the UPS cell requires a whole host of co-factors to efficiently repair or regenerate tissue. The co-factors along with the UPS cell and a wide variety of progenitor cells can be found in the bone marrow. These cells can be recovered in a concentrated form called bone marrow concentrate (BMC).

The FDA has approved the equipment utilized by The Stowe Foundation to produce an autologous blood product for cell therapy. The bone marrow concentrate (BMC) can be used in any application where human cell therapy is approved for therapeutic use. In the US, the BMC is restricted to orthopedics. Outside the US, human cell therapy is being studied for the treatment and regeneration of the heart, pancreas, lungs, liver, spine and neurological conditions. All of these are areas of the body where tissue can be regenerated once the disease process has been stopped.

To harvest the BMC, the first step is to aspirate 60 cc of bone marrow, 10cc at a time. You place the bone marrow aspirate into the Harvest Technology equipment and centrifuge for 20 minutes. The bone marrow aspirate will separate into three phases. One of the phases is the bone marrow concentrate. It is a true autologous blood product. It will in fact contain a large population of CD34 cells and other progenitor cells and it will contain all of the co-factors for differentiation. It also contains the UPS cell.

The Stowe Foundation did all of the large animal studies to demonstrate that the BMC can be safely injected into a wide variety of organs. Hence we are prepared to move into the human clinical studies on the therapeutic applications of the BMC. Harvest Technology simply provides the BMC device. We are already legal for orthopedics in the US and will be legal in Mexico for a wide variety of applications upon completion of the clinical trials. US patients facing an urgent need can enroll in the clinical studies on a patient funded basis.

The FDA has ruled the BMC to be an autologous blood product suitable for clinical applications. However, we still must demonstrate the therapeutic benefits of the BMC to gain regulatory approval in the US to market the technique. Fortunately, orthopedics is already approved by the FDA for human cell therapy.



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Many organizations have gotten good preliminary results with purified progenitor cells with heart patients. But they do not address the underlying chronic inflammation associated with heart disease. The Stowe Foundation believes that the stem cells, used as a stand alone therapy for heart problems, will be a temporary band-aid. Just like many by-pass operations have to be repeated, the stem cell transplant procedures being used today in Europe and Asia will need to be repeated. Again it is because the medical community has not been trained to reverse chronic inflammation and stop the disease process. Stowe BioTherapy uses Applied BioLogics to eliminate chronic inflammation and to restore the body's natural ability to heal. It is not a hard concept to appreciate, but it defies the pharmaceutical and bio-tech model of medicine. The next step is to conduct the outcome based studies on Regenerative Medicine that will demonstrate the therapeutic benefits. That will take the manpower of a major US medical school.

The protocols will be optimized as our knowledge and experience grows with each individual protocol. For example one protocol will be required for acute myocardial infarctions and one for chronic heart failure patients. For chronic heart failure patients there will probably need to be distinct protocols for treating patients who had by-pass surgery and one protocol for those who had stents to treat the myocardial infarction. The FDA recognizes the novel nature of the procedures by requiring first laboratory studies to identify and characterize the biological blood product, followed by large animal studies to demonstrate the safety and efficacy prior to human clinical studies and then a round of phase I clinical trials on humans to proof safety, progressing to phase II studies for efficacy and then multi center phase III studies for proof that the results can be duplicated.

Treating knees and joints will require distinctly separate procedures from the cardiac care protocols. Treating cirrhosis of the liver induced by alcohol will be different then treating cirrhosis induced by Hepatitis C. Treating emphysema of the lungs from tobacco smoke will be a distinct protocol. The FDA will require the entire round of laboratory studies on the biological agents, the animal studies and the human clinical studies. The Stowe Foundation technology platform will guide those studies.

The cost of adult stem cell therapy available today by traveling outside the US is very dependent on the surgical procedure required to transplant the stem cells to the area to be restored. Transplanting adult stem cells to the heart is more expensive then treating the knee. Outside of the US, umbilical cord stem cells can be administered in coordination with the adult bone marrow stem cells. The cost of the stem cell transplant is relative to the surgical procedure required to transplant the stem cells and the country selected for the therapy.

Report prepared by
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