

THE PROJECT

2007

A PUBLICATION OF THE MIAMI PROJECT TO CURE PARALYSIS AND THE BUONICONTI FUND TO CURE PARALYSIS



Clinical Trials Initiative

Targeting the Brain in
SCI Rehabilitation

Great Sports Legends Dinner

Destination Fashion

Alec Kassorla



MILLER
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI

OUR DEFINING MOMENT

Every person, organization, community, and cause has its defining moment – a time when everything they worked toward comes together and great progress, promise and success is made. The Miami Project to Cure Paralysis' defining moment is upon us. Years in the making filled with unprecedented scientific triumphs and now, we are embarking in a **HUMAN CLINICAL TRIALS INITIATIVE**. What a medical achievement this is.

For twenty-two years, The Miami Project, based at the Lois Pope LIFE Center, has been making incredible advances in cutting-edge research; improving the lives of those paralyzed by spinal cord injury. The Project is the largest, most comprehensive spinal cord injury research center in the world, employing over 200 top scientists and technicians with a budget of almost \$20 million a year.

It is a life defining moment for millions who have been confined to wheelchairs. A bittersweet moment for those of us whose loved ones have suffered for so long.

Our scientists hail from all over the world achieving expertise in the research and clinical rehabilitative laboratories in every facet of spinal cord injury research. Now their expertise and successful scientific strategies will be applied to humans with **ACUTE AND CHRONIC** spinal cord injuries. The lives and hopes of millions of people will change when this initiative commences. Medical history will be re-written and resonate around the world.

This is also **YOUR** defining moment – a moment when your hard work and dream for others' well-being becomes solidified. It is a life defining moment for millions paralyzed by spinal cord injury. A bittersweet moment for those of us whose loved ones have suffered for so long. A gratifying moment for University of Miami President Donna Shalala and Pascal F. Goldschmidt, M.D., University of Miami Dean of the Miller School of Medicine, whose standard of excellence and level of support has been nothing short of remarkable. A proud moment for renowned neurosurgeon Barth A. Green, M.D., Co-founder and President of The Miami Project to Cure Paralysis, and W. Dalton Dietrich, Ph.D., Miami Project Scientific Director, the exceptional Buoniconti Fund Board of Directors, the scientific researchers, valued donors, selfless volunteers and support staff who have worked effectively and tirelessly. It is our obsession to cure paralysis and help those in wheelchairs to stand again - **THIS WILL BE OUR DEFINING MOMENT**.

Nick Buoniconti
Co-founder

Marc Buoniconti
Ambassador



The Miami Project's major goal has always been to improve function and quality of life for people paralyzed by spinal cord disorders. Our small army of scientists and clinicians are focused on taking our laboratory research into the trauma centers and hospitals across the USA and around the world. We have entered the exciting phase of translational research – the phase where basic research findings are carefully transformed into clinical treatments that can be tested on humans in clinical trials.



Over the last 20 years, our research faculty has pioneered the development of various therapeutic interventions and cellular therapies that target acute and chronic spinal cord injury. Our track record can be seen in interventions such as the FDA-approved intra-operative monitoring of the spinal cord motor system, the use of functional electrical stimulation in outpatient rehabilitation centers, the way patients are surgically managed following delayed deterioration after injury or surgery, and the advances in treatments for infertility. The development of these interventions has been enhanced by Miami Project research contributions.

The Miami Project has also pioneered interventions that are now being prepared for clinical trial. We are conducting critical pre-clinical tests and are proceeding according to FDA guidelines to gain approval to conduct a Phase I clinical trial in individuals with spinal cord injury. We continue to develop clinically relevant outcome measures as well as rehabilitative strategies to assist in these early clinical trials. Because of our research findings, human studies have already been initiated to examine the use of modest hypothermia (mild body cooling) for neuroprotection during delicate spinal cord surgeries and in the treatment of acute spinal cord and brain injuries.

Our basic science research team has developed cutting-edge experimental technologies to screen large numbers of compounds to find those that might be critical for neuroprotection and repair of the nervous system. Their work is identifying exciting therapeutic targets that were previously unknown. Our clinical research laboratories have also made new discoveries about the ability of the brain and spinal cord to reorganize. New rehabilitation strategies are being tested to enhance this reorganization. Clinical protocols targeting children with spinal cord injury are also now being advanced. These basic and clinical investigations are positioning us in an ideal situation to initiate exciting clinical studies.

We sense the momentum. Our research team and their numerous collaborators across the U.S. and around the world are moving the field of neuroscience forward so we can speak realistically about clinical trials. We are proud of the accomplishments – accomplishments that offer optimism and hope, and we are truly convinced, as we often say, “it is not a matter of if, but a matter of when.”

Barth A. Green, M.D.
President

W. Dalton Dietrich, Ph.D.
Scientific Director



www.themiamiproject.org
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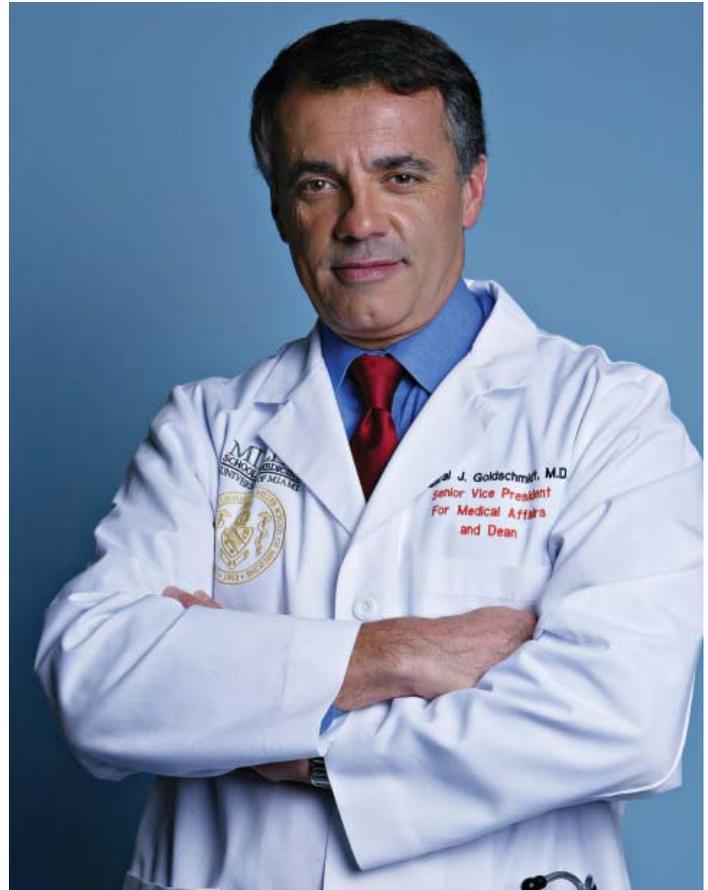
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Then he stood up. With steps that were slow and measured, a bit like when Neil Armstrong took his first walk on the moon in 1969, Marc was walking. In the video created for the Great Sports Legends Dinner in New York, his eyes were locked on the eyes of his father. It is difficult to express the intensity of the thoughts and emotions that must have traveled silently between these two men within the narrow space of their shared fields of vision. It was like a dream, more precisely like a dream within a dream. I wonder how many times Marc, Nick, Terry, sister Gina and brother Nick have wondered if this entire story of Marc's accident was just a bad dream from which they would wake up one day, and everything would be back the way it was before the Citadel football accident.

The brain as we understand it in the 21st Century is a sophisticated model of electronic biological wires organized in bundles that connect some pretty amazing processors within the brain structure – processors that are responsible for functions such as vision, hearing, smell, motion, memory, feeling, etc. As it relates to motion, the electronic bundles extend to the lower body through the cocoon of the spinal cord. Coming upstream within the spinal cord are other bundles of electronic wires that carry an amazing array of information, the “intelligence” that tells the body how it relates to its environment, intelligence that is essential for proper navigation of the human body through the environment.

Once traumatized beyond a certain limit, the electronic bundles of the spinal cord are destroyed and, consequently, intelligence information from the lower body does not reach the processing centers of the brain and, in turn, the orders from the brain about motion-related commands do not get distributed to the muscle fibers that execute motion within the lower body. Many other functions besides motion are disrupted concurrently with the locomotive system upon severe spinal injury. Downstream from the line of injury, nerve fibers, the biological electronic wires of the nervous system, are apparently irreversibly destroyed and vanish, unreplaced along their trajectory. Above the line of spinal injury, the nerve fibers are left traumatized, unable to re-elongate and often succumbing to the injury. At the level of the line of injury, scar tissue replaces the previously healthy spinal cord – scar tissue that is not so different from what forms on a knee after a bad excoriation. When the injury line is at the level of the neck as is the case for Marc Buoniconti, paralysis involves both the arms and the legs and has been named quadriplegia.

The Miami Project to Cure Paralysis is simply the greatest project on Earth to fight paralysis resulting from spinal injury. With Barth Green and Dalton Dietrich in the command seats, the army of doctors and scientists is our best hope – the only hope – to cure a situation which since the dawn of time has been irreversible, restoring a functional nervous system in a child or adult following severe spinal cord injury. It is certainly the most daunting task of all in the field of medicine. But with our scientists and doctors, with



their dedication and inspiration, there is a chance to succeed. With Marc and Nick Buoniconti, and Suzie Sayfie in charge of operations for the resourcing of the project, we have the best team to achieve our highest goal. But it takes all of you, our donors and supporters, those who have been faithful in providing us their support year after year and those of you who are new and will join our family. To all of you, we express our greatest gratitude for your contribution to this formidable project, The Miami Project to Cure Paralysis.

And then he stood up, took a few steps and kissed his Dad. Yes, we all felt it, the emotion that surrounded our neck and dried our throats. But behind the robot that simulated motion for Marc, there is the symbol of what makes America the greatest place on Earth. We are a bunch that never surrenders, never gives up, and will never let down those of us who have been injured. We can actually catch the moon with rockets or, when it comes to spinal injury, come up with a cure.

As the Dean of the Miller School of Medicine of the University of Miami, I am deeply grateful for your support and the hope that you bring to our patients.

Pascal J. Goldschmidt, M.D.
Senior Vice President for Medical Affairs and Dean

Promoting **Functional** Recovery In Children



Alec Kassoria ran all over by the age of ten months. As a toddler, he snow skied and water skied. He loved to go boating and he swam like a fish. At three and a half years of age, Alec was just playing under a table in the safety of his own home, when the table collapsed. Alec became a quadriplegic.

At 10 months old, Caroline Lanctot was just beginning to learn how to walk. One day, while strapped in a child restraint seat and heading home with her mother, the vehicle they were in was struck from the side. Caroline suffered severe injuries that left her paralyzed from the neck down.

Ashley Moore was on her way to school – a routine five-minute car ride from her home – when a minor accident activated the airbag. Instead of protecting her, it caused a cervical spine fracture and spinal cord injury. Since the accident at age seven, Ashley, now 16, has remained paralyzed and relies on a respirator to breathe.

Alec, Ashley, Caroline – they are just a few of the children living with spinal cord injury. One day they were playing ball, dancing, going to school – doing what children normally do. Then a car accident, a faulty piece of furniture, a rare disease changed all of that. Of the 11,000 new injuries in the United States each year, approximately 10 percent occur in children under the age of 15. That's at least 1,000 children per year whose world and that of their family is turned upside down by spinal cord injury.

"After Alec's accident, my life totally stopped," says Ronnie Kassoria. "I'm a single parent and unfortunately life for my daughter also changed. We focused on Alec, trying to help him and treat him."

As one can imagine, spinal cord injury is emotionally devastating, especially when it happens to a very young child. "You feel just so absolutely helpless," said Michael Lanctot. "It was about a month after her injury before I got to hold Caroline and when I held her, she fell asleep in my arms...I was so happy to at least have a chance to start over. It wasn't going to be our normal life that we knew before, but we would make the best of it."

Making the best of it – that's what studies in The Miami Project's rehabilitation laboratories are aimed to do. While basic scientists look for a cure, rehabilitation researchers are working on improving current rehabilitation care and quality of life. Among the rehabilitation studies now underway at The Miami Project are two that involve children.

Virtual Reality Exercise

To grow and develop normally, kids need to play and take part in physical activity. Having a spinal cord injury doesn't change that. But how can they reap the benefits of play when SCI limits their options?

A recent interest in the laboratory of Mark Nash, Ph.D., is how effectively "virtual reality" exercise can be used to improve fitness and wheelchair functions in children and adolescents with SCI. Typically, doctors and therapists will prescribe exercises after SCI that include upper extremity weight lifting and endurance training. These exercises are often performed with an arm cycle.

Alec was given a similar prescription. Unfortunately most kids, as well as adults, find these types of exercises boring which in turn makes it difficult for them to adopt or maintain good exercise habits. However, what if you could make the exercise more enjoyable? Dr. Nash is investigating new methods of putting some fun and game-play into fitness.



Caroline Lanctot, age 5

One of the methods uses the GameCycle®, an arm exercise device integrated with a Nintendo® GameCube video game system. What child doesn't like Nintendo? Instead of using hand controllers, the child uses arm crank handles to control a game-play scenario

such as a car race. Is this exercise? According to Nash's preliminary findings, the metabolic responses that result from this game-play activity actually exceed the intensity of work needed to improve fitness in persons with spinal cord injuries.

In addition to his studies of GameCycle®, Dr. Nash is investigating another new method of game-play exercise that involves the use of "green screen" technology. This technology captures real-time video images of the child and incorporates them into a variety of game-play settings. The child sees himself in a video monitor within a video game environment. Games such as blocking a soccer ball, juggling balloons or playing a variety of percussion instruments encourage the child to move their arms. While the child plays the video game, his arms are linked to weight lifting equipment and he performs resistance exercise as he moves during play.

The children who volunteer for this study are between the ages of 8 and 18 and have SCI levels between C7 and L1. They come to The Miami Project three times a week for 16 weeks and are helping Dr. Nash learn more about these two forms of exercise. "We expect the results of this study to show that the kids improve their endurance and strength, reduce their body fat, and improve their ability to propel their wheelchairs," says Dr. Nash. "They will also have fun doing it."

Walking Training

Alec Kassorla has learned to be quite self-sufficient in his wheelchair – he certainly can make it down the basketball court a lot



Alec Kassorla, age 9

quicker than some of his able-bodied friends. There's no stopping him, but even though Alec doesn't remember walking, he still has the desire to walk. And he should, especially for its potential health benefits.

Since children with SCI are still growing, they have the tendency to develop orthopedic complications such as scoliosis and instability in the hip joints especially if they were injured before the age of five. Taking part in a walking exercise program, however, has the potential to reverse some of the problems related to SCI. Walking is known to improve cardiovascular and pulmonary health, improve bone density, muscle mass, general wellness and quality of life. Alec does several types of exercise including leg exercises, standing, and assisted biking.

In addition to exercise training, Alec has taken part in a specialized walking training known as body weight support gait-training. He served as the first pediatric research volunteer in studies in California to evaluate the effect of this therapy in children with SCI. At The Miami Project, Edelle Field-Fote, Ph.D., P.T., director of the Neuromotor Rehabilitation Research



Ashley Moore, age 16 and her canine companion Fantom

Laboratory, has also initiated similar studies in children with incomplete SCI.

Body weight support gait-training uses a harness to suspend the child from an overhead lift and take some of the child's weight off of his legs. The child is assisted while practicing steps on a treadmill. Dr. Field-Fote's studies in adults with incomplete SCI have shown that body-weight supported treadmill training plus functional electrical stimulation can improve walking function and muscle strength.

"One of the basic things we hope to learn," explains Kathleen Manella, P.T., M.S., Research Physical Therapist, "is whether intensive practice of a pattern

Body weight support gait training and virtual reality exercise are expected to promote a more active lifestyle, improve general health and well-being as well as open opportunities for children to explore their environment, interact with their peers and improve their overall quality of life.

of walking helps the child to improve his walking. Because children are still growing, their nervous

system may be geared to accomplish more." It is thought that this therapy might help tap into and enhance a naturally occurring process within the nervous system and therefore promote functional recovery.

Presently, it is unknown whether children, because their nervous system is still developing, have more potential for recovery of walking function. Ms. Manella says the 4 to 15 years olds with incomplete injuries at or above T10 who take part in this study will help determine the therapy's effects on muscle strength, gait, balance, mobility, cardio-pulmonary function and quality of life. The 14-week schedule of gait training sessions may also help determine if this therapy can effectively retrain a child's nervous system.

Currently, body weight support gait training is not a part of traditional rehabilitation programs. Neither is virtual reality exercise. Alec, Caroline, Ashley and other children like them can only find these therapies at specialized research and clinical locations. However, if studies carried out at The Miami Project prove these non-traditional and innovative interventions to be of benefit, the therapies could become more widely available. Body weight support gait training and virtual reality exercise are expected to promote a more active lifestyle, improve general health and well-being as well as open opportunities for children to explore their environment, interact with their peers and improve their overall quality of life. Who wouldn't want to see the quality of life of a child with SCI improved?

For more information about the studies described, send a message regarding the virtual reality exercise study to Patricia Burns, Research Associate or about the gait training study to Kathleen Manella, Research Physical Therapist. They can be reached at MPINFO@med.miami.edu or by calling 305-243-7108. 

Switch for Axon Development

Anthony Oliva, Ph.D., an assistant scientist in the laboratory of Dr. Vance Lemmon, has discovered a new role for what he refers to as “junk.” In the world of biochemistry, when he says “junk”, he is talking about c-Jun N-terminal kinase (JNK), a protein in the nervous system that controls complex processes in cells.

Researchers are learning that JNK plays many different roles in the chemistry of the nervous system. In some instances, JNK is responsible for switching on cell death, while at others times it may signal regeneration. Dr. Oliva, his wife and fellow scientist Coleen Atkins, Ph.D., and his former advisor Gary Banker, Ph.D., were the first to show that when a neurite makes the commitment to become an axon, JNK plays a critical role in its formation.

Neurites are the tiny projections that a nerve cell body sends out during the early stages of its development. Neurites will eventually form the many dendrites and the single axon of the cell (see photo). Dendrites are the input structures of the nerve cell, while the axon is the output structure.

For decades, researchers have known the order in which these structures develop. “If you do live cell imaging,” explains Dr. Oliva, “the neurites grow

and retract, grow and retract. The neurites all have similar lengths until all of a sudden one undergoes a prolonged growth spurt. That’s the one that becomes the axon, and the others become the dendrites.” While this physical growth process has been easily observed under the microscope, the biochemical events that take place to control the formation of axons are only beginning to be known. A hallmark of

spinal cord injury is the degeneration of axons, the specialized output structures of nerve cells. “After SCI, we need to get neurons to put out new axons.” says Dr. Oliva. “If we can understand the biochemical events that determine how and why one neurite becomes the axon over another, then therapies for promoting axonal regeneration and sparing can be revealed.” The discovery that JNK somehow regulates axon growth is a promising finding.

During his stint as a postdoctoral fellow in Oregon, Dr. Oliva worked tediously on projects to identify specific proteins that might trigger axon development. He compared the activity of multiple proteins in both axons and dendrites. After much hard work, he discovered that developing axons contain high concentrations of an activated form of JNK. Dendrites



Drs. Coleen Atkins and Anthony Oliva review confocal microscopy images.

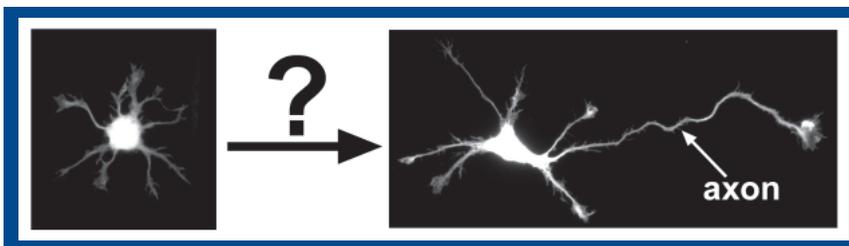
developing neuron did not form an axon – yet dendrites still appeared to form normally. When he released the block to allow JNK to be activated, an axon formed. His recent studies also revealed that JNK is not only found in the axons of developing neurons, but in the axons of mature nerve cells as well.

“In mammals in general, the older the axon the less it is able to regenerate. The intrinsic ability of a neuron to regenerate an axon diminishes rapidly after birth,” explains Dr. Oliva. “For a therapeutic intervention, we might need to reactivate the intrinsic switch.”

The discovery that JNK is a molecular switch that turns a neurite into an axon is an exciting new finding. It’s still not clear, however, exactly how JNK controls axon development.

“JNK comes in at least 10 different versions and we don’t

yet know which versions are key to axon formation,” explains Dr. Oliva. Some versions of JNK might be involved in axon growth, while others may signal cell death. Despite the need for further clarification, this new discovery opens up the possibility of developing new treatment strategies for spinal cord injury – ones that might flip an intrinsic switch in injured adult nerve cells and restart axon development. 



Neuron on left has neurites of similar length. On the right, one of the neurites undergoes a growth spurt to form the axon. Researchers are determining the biochemical events that control this.

contained little activated JNK. Thus, a possible connection between JNK and the formation of an axon had been identified.

To clarify JNK’s role in axon development, Dr. Oliva carried out further research that led him to conclude that JNK is definitely an important molecular switch for axon growth. In cell culture studies, when he blocked the activation of JNK, the

Making a Shift: Targeting the Brain in SCI Rehabilitation

IT IS WELL KNOWN THAT SPINAL CORD INJURY CAUSES DAMAGE TO THE NERVE PATHWAYS THAT CONTROL VOLUNTARY MOVEMENT. IN PEOPLE WITH TETRAPLEGIA, THIS DAMAGE RESULTS IN AN INABILITY TO CONTROL THE ARMS AND THE HANDS. NATURALLY FOR RECOVERY TO OCCUR, ONE WOULD THINK THAT YOU'D HAVE TO REPAIR THE DAMAGE AND THEN GET THE BRAIN TO USE THE RESTORED PATHWAY AGAIN.

BUT ARE LOST CONNECTIONS FROM THE BRAIN TO THE MUSCLES ALL THERE IS TO THE IMPAIRED ABILITY TO CONTROL MOVEMENT? EDELLE FIELD-FOTE, PH.D., P.T., DIRECTOR OF THE MIAMI PROJECT'S NEUROMOTOR REHABILITATION RESEARCH LABORATORY THINKS THERE IS SOMETHING MORE, SOMETHING THAT COULD BE AMENABLE TO REHABILITATION THERAPY.

Amazingly, the brain is capable of reorganizing throughout life. In just the last decade, new tools to "look inside" the brain have helped scientists learn that neurons and synapses can change, even after injury. This capacity to change and reorganize has been termed plasticity. Without plasticity, a baby might not learn to walk nor a musician learn a difficult part on their instrument.

It is now known that plasticity is why people with stroke and brain injury can often recover some motor functions. Researchers have proof that uninjured portions of the brain change to take up the function of an injured area. Does this type of reorganization also occur after SCI?

Dr. Field-Fote first became interested in what might be going on in the brain after SCI when she learned of a colleague's research that mapped changes in the cortex of people with SCI. The cortex is where the neurons that control voluntary movements are housed. Using electroencephalogram (EEG) recordings, these investigators found the area of the brain that controls finger function had shifted its location in people with tetraplegia. Normally, the area representing the hand is located in the anterior region of the cortex. In these people with SCI, this region was reduced in size and had shifted away from the anterior region.

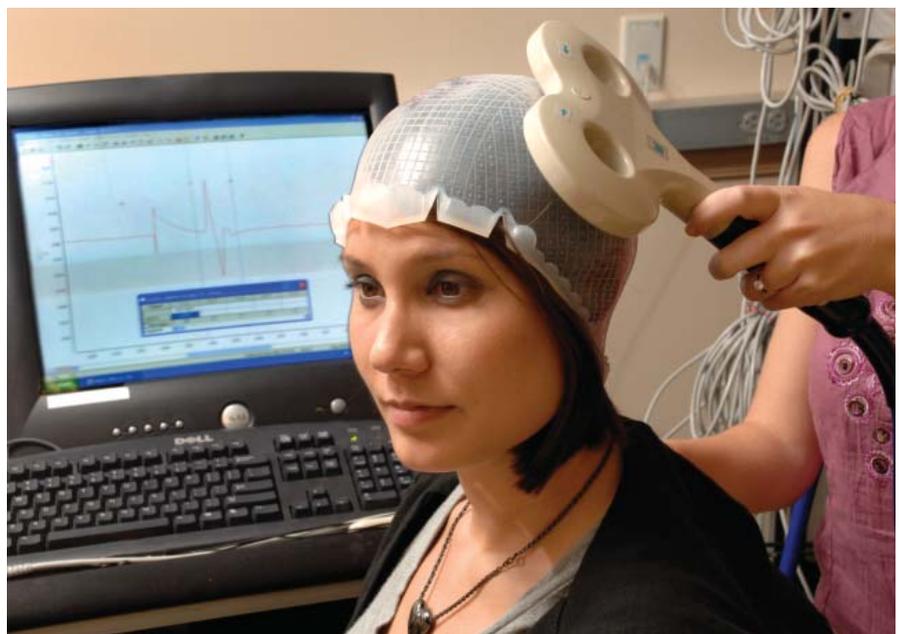
These researchers made another interesting observation. "One of the volunteers they examined experienced spontaneous recovery of hand function," explains Dr. Field-Fote, "and through the course of his recovery, the recordings from the EEG showed the region associated with hand function shifted back to the right place."

"These changes in the brain were really intriguing to me," continued Dr. Field-Fote. From her perspective as a physical therapist,

she was fascinated with the possibility of developing therapies for people with SCI that could induce useful changes in the brain. "I began to wonder how these changes occur. What causes the shift? Is it possible to make it move back? And if you can make it move back, is that shift associated with improvements in the ability to use the hand?"

Learning from stroke

Dr. Field-Fote already knew that therapeutic changes could occur in the brain after a stroke. Researchers had shown that a therapy, repetitive task-oriented practice (massed practice), could improve hand function in people who after their stroke had a smaller than normal area of their brain associated with hand function. The therapy increased the size of the region of the brain associated with hand function. In addition, sensory stimulation was shown in one small study to improve pinch grip force in individuals with stroke. Since her colleagues had shown that changes in the



Lanitia Gorman, a research volunteer undergoes testing with transcranial magnetic stimulation.



Larisa Hoffman helps Claude Gerstle as he practices pinching to remove paper clips from a magnet.

brain occur with SCI, Dr. Field-Fote hypothesized that some of the interventions that are effective in people with stroke might also be effective in those with SCI.

“We always think about how the input from the brain to the spinal cord is interrupted after SCI,” says Field-Fote, “but information going from the spinal cord to the brain is interrupted as well. We are now learning that sensory input is required to maintain the normal organization of the sensory portions of the brain. And normal sensory portions of the brain are required for normal excitation of the motor portion of the brain.”

After SCI, if people don’t use their arms or hands because of paralysis, the brain may not be getting the sensory input it needs to maintain its organization. Because there isn’t as much sensory information reaching the brain, the region normally associated with hand and arm function may change.

Armed with these findings, Dr. Field-Fote and Kristina Beekhuizen, then a Ph.D. student in her lab, set up a study to find out if repetitive training similar to that developed to treat patients with stroke could also be useful in people with SCI. They also investigated whether adding electrical stimulation to this training

regimen would result in added benefits. Sort of like “juicing” the system – providing sensory input to possibly prevent or influence changes taking place in the brain.

In the study, research volunteers practiced specific repetitive tasks, training 2 hours per day, 5 days a week for 3 weeks. Another group of volunteers did the same training except they also received trains of electrical stimulation to a nerve in the wrist. “The results,” Dr. Beekhuizen reported, “suggest that greater improvements in hand strength and function occurred when the repetitive tasks were combined with sensory stimulation.”

A New Target

These findings provided encouraging preliminary evidence that sensory input helps improve hand function, but Dr. Field-Fote wanted to know more about the therapy’s effect – is it useful in reorganizing the brain? Is there more that could be learned about *how* the volunteers recovered function?

Describing current work in Dr. Field-Fote’s laboratory, Larisa Hoffman, M.S., P.T., a Ph.D. student, puts the research question this way, “If we do intensive hand training wherein we require volunteers to use their hands for two hours a day for 3 weeks and

combine that with sensory stimulation, can we induce the hand region in the brain to shift back to its normal location and get bigger?”

In a case study published recently in the journal *Physical Therapy*, Ms. Hoffman and Dr. Field-Fote were the first to document beneficial changes in neural circuitry of the brain in a spinal cord injured volunteer. The changes, seen after receiving the therapy, could account for the volunteer’s improvement in hand function.

Ms. Hoffman used an examination called transcranial magnetic stimulation (TMS) to thoroughly map out the areas of the brain that control specific functions of the hand and arm. This examination was used before and after the research volunteer – a 22-year-old man with impaired hand function due to C6 tetraplegia – participated in a specific training intervention for 3 weeks. Similar to previous studies, he practiced repetitive tasks such as popping the bubbles on bubble wrap, typing on a keyboard, plugging plugs into an extension cord, or tying knots and threading needles all while receiving an electrical stimulation to a sensory nerve in the wrist.

In this gentleman’s case, changes in the size and location of the cortex that controls the function of the biceps muscle were seen. His brain had in fact changed. He also experienced improvements in sensation, strength and functional abilities such as grip.

“We are the first to use this mapping technique to assess training-related cortical plasticity in individuals with spinal cord injury,” states Dr. Field-Fote. “It’s also the first time anyone has looked at cortical plasticity in SCI with the idea that improving the function of the cortex might be a means of improving hand and arm function.” It’s a new way of thinking.

Through ongoing research, the investigators are collecting more data from other research volunteers. They are interested in knowing how modifications in the therapy influence the responses in the brain. For example, Ms. Hoffman is looking at whether training involving two hands results in different patterns of excitability in the brain compared to when the volunteer trains only one hand at a time.

People with incomplete SCI usually still have nerve pathways to and from the brain that are available but that may not be as functional as they could be. Part of the reason they aren’t as functional is because changes in the brain occur after SCI. Traditionally, therapies have focused on the muscles you’re trying to improve. “Everyone has heard, ‘if

you don’t use it, you lose it,’ explains Ms. Hoffman. “Now rather than focusing on the muscles, we are focusing the therapy on the brain.”

Ms. Hoffman who affirms she will always be a clinical therapist says, “It’s so exciting to know that we can make such a difference in the brain and that change seems to be associated with improvement in hand function. It’s amazing that we can change the nervous system.” As Ms. Hoffman introduces potential research volunteers to the hypothesis of the study, they get the concept. “So you are telling me,” remarked Michael, a recent participant, “I’m training my brain and not so much my muscles?”

The focus of rehabilitation is shifting to interventions that induce changes in the brain. Twenty years ago, an approach to maximizing function after SCI was “practice makes perfect.” What The Miami Project is learning today is practice and sensory stimulation makes use of plasticity – the neurophysiological reorganization that is important for recovery. It’s exciting to know that even though we don’t yet know how to make new connections after an injury, we can make available nerve pathways more functional, making people more independent and improving their quality of life. 



Deborah Thompson works on improving finger function by practicing a musical keyboard. Larisa Hoffman looks on, enjoying the results.

Experimental Treatments: What You Should Know

For people with SCI, their families, friends and caregivers, the decision to receive an experimental treatment or enter a clinical trial is a challenging one. Increasingly, advances in SCI research are finding their way into clinical practice. Many of these experimental therapies are currently undergoing clinical trials or are preparing to enter the clinical trial phase of their development. However, a number of experimental therapies, such as cellular transplants, are being introduced into clinical practice without having been tested in a valid clinical trial program. This leaves the safety and efficacy of the treatment untested and is a great concern to researchers, clinicians and most importantly people with SCI.

In order to establish a set of guidelines for the design and conduct of valid clinical trials for SCI, an expert panel of researchers and doctors with extensive scientific and clinical experience in SCI was formed in 2004. The Miami Project's James Guest, M.D., Ph.D., neurosurgeon and scientist, contributed to the work of this important panel that was supported by the International Campaign for Cures for spinal cord injury Paralysis (ICCP).

The panel developed a set of 4 papers outlining guidelines for the conduct of SCI clinical trials. These papers for the medical and scientific community were published in the Nature journal, *Spinal Cord*. In addition to these peer-reviewed publications, the panel summarized these guidelines in a booklet entitled **Experimental Treatments for Spinal Cord Injuries: *What you should know if you are considering participation in a clinical trial.***

The booklet is an important resource on the conduct, concerns and issues surrounding clinical trials in SCI. Two easy-to-read versions, produced by ICCP, are available free to anyone interested. One

Guidelines for the conduct of clinical trials for spinal cord injury

(as developed by the ICCP panel and published in the journal, *Spinal Cord*)

1. Spontaneous recovery after spinal cord injury and statistical power needed for therapeutic clinical trials
2. Clinical trial outcome measures
3. Clinical trial inclusion/exclusion criteria and ethics
4. Clinical trial design

For free access to these journal articles, visit the *Spinal Cord* website at <http://www.nature.com/sc/index.html>

is a 10-page summary and overview of the full guide for people considering participation in an SCI related clinical trial.

The full guide is a 40-page booklet that provides detailed answers to the following questions:

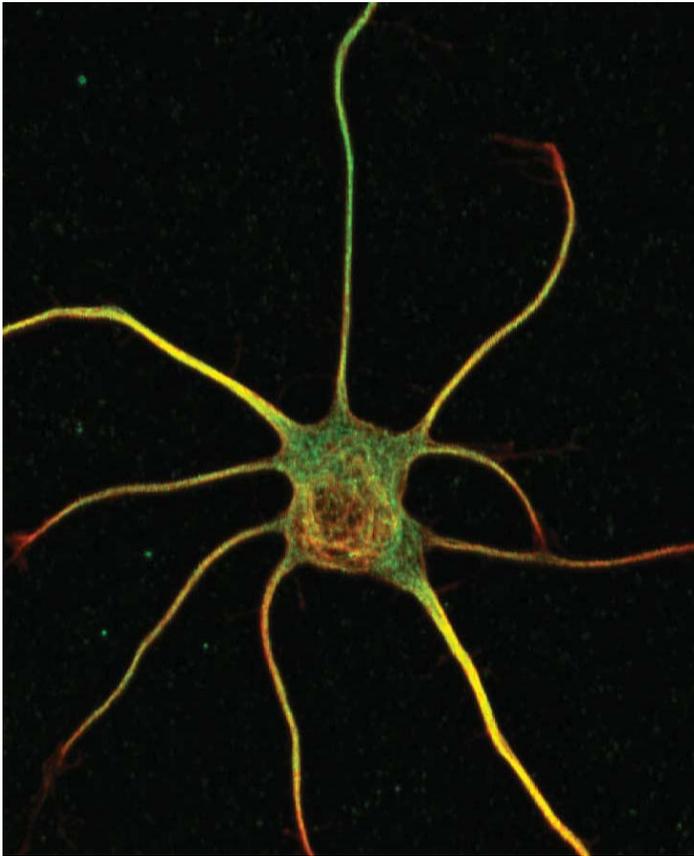
- What are the chances that you will see some functional improvement after spinal cord injury (SCI) without a drug treatment or transplantation of cells?
- What are the risks of undergoing a treatment that has not completed a valid clinical trials program or been approved by an appropriate regulatory agency?
- What is a clinical trial and what is the pre-clinical process for developing a therapeutic treatment for SCI?
- What is ethical and unethical in the conduct of a clinical trial and what is informed consent?
- What can jeopardize the accurate interpretation of the outcomes for a clinical trial and what can be done to prevent this from happening?
- How are functional benefits of an experimental treatment measured for SCI?
 - If you participate in a clinical trial, how does it effect your participation in future SCI clinical trials?
- What are some of the current experimental treatments proposed for the treatment of SCI and at what stage are they in terms of their validation as beneficial?
- What should you ask before agreeing to take part in a clinical trial?

The booklets feature a checklist of questions to pose to a researcher and that might be helpful in making a decision whether or not to participate in the trial.

"This booklet is an incredible resource for people who truly want to make an informed choice about participating in current or future clinical trials," remarked the Miami Project's Director of Education, Maria J. Amador, BSN, CRRN. "As a member of the ICCP, The Miami Project has been closely involved with the development of the guidelines and now this lay publication. I'm excited that we are now able to offer a comprehensive and thoughtful guide on the issue of clinical trials in SCI."

Both versions of ***Experimental Treatments for Spinal Cord Injuries: What you should know if you are considering participation in a clinical trial*** are available as free downloads from The Miami Project's website.

Log on at www.themiamiproject.org/participation.xml To have a copy sent by mail, email us at MPINFO@med.miami.edu or call 305-243-7108.



ARMED WITH CUTTING-EDGE TECHNOLOGY, RESEARCHERS JOHN BIXBY, PH.D., AND VANCE LEMMON, PH.D., ARE DRAMATICALLY ACCELERATING THE SEARCH FOR WAYS TO REGENERATE NERVE FIBERS TO TREAT SPINAL CORD INJURY.

Making Connections

- Twenty years ago, John Bixby, Ph.D., had little concept of how his neurobiological basic research could be applied in clinical medicine.
- Ten years ago, Vance Lemmon, Ph.D., could not even begin to envision the research projects he would be designing today.
- Today the two scientists at The Miami Project to Cure Paralysis have vastly increased the scope of their groundbreaking research while exponentially

shortening the time frame of vital steps in their work.

- New equipment, software, and laboratory techniques are helping them identify genes that can promote nerve regeneration, screen thousands of drug compounds that may stimulate an effect on those targeted genes, and accurately measure the impact of their laboratory manipulations. Work that previously would have taken a small army of researchers and thousands of hours can now be accomplished in a few days. That translates into a critical acceleration of the search for effective treatments for spinal cord injury.

A FAILURE TO COMMUNICATE

On August 14, 2003, a breakdown in the Cleveland-Akron power grid caused the largest blackout in North American history, shutting down electricity from the Midwest to New York City. In the simplest terms, that is comparable to the body's reaction after spinal cord injury. Bones heal, but damage to the power grid that is the central nervous system (CNS) has devastating consequences.

The CNS, composed of the brain and the spinal cord, coordinates the body's movement and sensation via a complicated network of neurons (also called nerve cells). After a spinal cord injury (SCI), CNS neurons lose their connections to nerves located below the site of injury. These neurons may still be alive, but they've lost their ability to communicate and to control movement.

Nerve cells in the adult central nervous system lose their ability to regrow shortly after birth. In the last two decades, scientists

have shown that some nerve cells in the brain and spinal cord can regrow under certain conditions.

Drs. Bixby and Lemmon are pursuing two lines of research to develop novel treatments for spinal cord injury. They want to discover how to influence nerve fibers to regenerate across long distances and how to make meaningful connections.

BIXBY AND LEMMON CONVERGE

A few years ago, Bixby was working in the Department of Molecular and Cellular Pharmacology at the University of Miami Miller School of Medicine, and Lemmon was a professor of neuroscience at Ohio's Case Western Reserve University.

One of Bixby's areas of research was exploring the ways in which specific nerve connections are formed and maintained. Specifically, he looked at axon growth regulation and the control of synapse formation at neuromuscular junctions. Bixby was trying to

“Scientists are largely driven by wanting to know the answers... If you can pursue your thirst for fundamental knowledge and at the same time have it be useful, that’s quite a combination.”

find how the nerve cells make the appropriate connections and how those synaptic wires are strung so that when your brain tells you to move your arm, you move your arm and not your leg.

Originally a “dyed-in-the-wool cell biologist” with an interest in neural development, Bixby was drawn into this field because of its potential in the treatment of spinal cord injuries. It was a new way of thinking for the scientist. Through graduate and post-graduate work, Bixby conducted basic science research without much interest in how his findings could be used in medicine. But as he delved more into the neurosciences, he began to see how therapies could evolve and he was “seduced by this idea of clinical research.”

“Scientists are largely driven by wanting to know the answers. We just want to know stuff,” Bixby says. “But we also want to know stuff that’s useful. If you can pursue your thirst for fundamental knowledge and at the same time have it be useful, that’s quite a combination.”

Meanwhile, Vance Lemmon was taking his own look into nerve cells. As a postdoctoral student at Washington University in St. Louis, Lemmon was more interested in cell biology and neural development than axons, but his interest in that area of neuroscience would be sparked by his colleagues in St. Louis. Two of the top neuroscience researchers at Washington University, a husband and wife team, were gracious hosts who enjoyed fostering stimulating conversation among guests they invited to their home. These fellow scientists were Mary Bartlett Bunge, Ph.D., and the late Richard P. Bunge, M.D.

The Bunges would leave St. Louis to move to Florida and direct the research team at The Miami Project. The Bunges had made a lasting impression on the young Lemmon.

In the late 1980s, Lemmon and his colleague Carl Lagenaur were working in the anatomy department at the University of Pittsburgh when they discovered that a certain adhesion molecule and receptor found in nerve cells (dubbed “L1”) stimulates axon growth. “L1 signals neurons to make them want to send out axons,” says Lemmon. “L1 is a switch that tells neurons to send specific signals that make axons grow as well as direct the axons to where they need to go.” This was the first adhesion molecule from the brain shown to have this property, pointing the way to several promising approaches for future research.

Dr. John Bixby checks an experiment on the BioRobot.



The Miami Project was fortunate to recruit Lemmon who came to the University of Miami Miller School of Medicine as the Walter G. Ross Chair in Developmental Neuroscience. In June 2003, Lemmon and Bixby teamed up to create the Laboratory for Axon Growth and Guidance, otherwise known as the Lemmon/Bixby Lab. Each scientist's team works on individual projects stemming from the researchers' previous work, such as honing in on the properties of L1, and on joint projects, where the two teams focus on how cell adhesion molecules can promote axon growth and influence axon guidance.

Bixby and Lemmon also were able to pool their financial resources to purchase

“Ten years ago, I thought this was crazy. I thought it was too difficult to do, not anymore,” said Lemmon of high content screening (HCS) technology in the field of neuroscience.

sophisticated, state-of-the-art and previously out of reach laboratory equipment.

Two such instruments, the Cellomics KineticScan HCS Reader and the QIAGEN BioRobot 3000, are key tools for their studies and significantly reduce the time to conduct research. The QIAGEN BioRobot is used to create different concentrations of 6,000 drug compounds to determine if they have an effect on the cells. By hand, it would take countless hours to investigate these thousands of compounds. “You could not do four a day,” Lemmon says. The BioRobot could look at 1,000 per day.

The Cellomics Reader, relatively new technology which is available at only a handful of major research institutions, rapidly reads and analyzes pictures of cells to measure any axon or dendrite changes.

The two pieces of equipment together gather and analyze a huge amount of information for the researchers. Scientists realized early on, in order to find a “magic bullet,” they had to investigate tens of thousands of drugs, but that kind of exhaustive research would require far more time and scientists than anyone was able to commit.

“Ten years ago, I thought this was crazy. I thought it was too difficult to do,” says Lemmon. Not anymore. Lemmon and Bixby have revolutionized the use of high content screening (HCS) technology in the field of neuroscience. They just recently developed an efficient HCS technique to identify regeneration-related genes, a technique that because of its lower cost and higher efficiency will likely replace earlier research methods. With their technique, they can study the effects of thousands of genes on the ability of neurons to extend axons in an inhibitory environment, such as is found in the spinal cord.



Dr. Vance Lemmon reflecting on the progress of the various projects in the Laboratory for Axon Growth and Guidance.

It is not possible to overestimate the impact new technology will have on spinal cord injury research. “It takes years off the process,” he adds. “Smaller and smaller groups of people can work on bigger projects.”

Still, given the complexity of SCI, researchers in the field have concluded that there will be no single magic bullet. “But I didn’t think ten years ago you could find the ten magic bullets that could push things through to a possible treatment,” Lemmon says.

Technology, techniques, and closer ties between basic and clinical researchers are helping neuroscientists zero in on cures for spinal cord injury. Bixby and Lemmon now see no limit to the research they can undertake. Says Bixby, “This is just the beginning.” 

This article was adapted from an original by Robyn Nissim that appeared in the Fall 2004 issue of Miami Medicine.

Edelle Field-Fote, Ph.D., P.T., has been named the 2007 Spinal Cord Exchange Fellow by the Ministry for Science and Medical Research of New South Wales, Australia. The fellowship is designed to bring international experts in the field of SCI to NSW and will focus on introducing clinicians and individuals with SCI to cutting-edge techniques, treatments and therapies for the improvement of rehabilitation and quality of life. Dr. Field-Fote's expertise is in neuroplasticity after SCI; she is the first physical therapist to be awarded this fellowship.



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Damien Pearse, Ph.D., received notification from the National Institutes of Neurological Disorders and Stroke that his project entitled "Axon Regeneration: Synergistic Actions of the MAPK and Cyclic AMP Pathways" will be funded. It is a notable accomplishment that Dr. Pearse, as a young investigator, has received his first federally funded grant at a time when obtaining federal funding is extremely competitive.

Vance Lemmon, Ph.D., was awarded funding from The Ralph Wilson Medical Research Foundation for a research proposal entitled "Identification and Testing of Corticospinal Track Regeneration Associated Genes." Studying the corticospinal track is of great relevance to human spinal cord injury as this nerve pathway is important for the control of walking.

Mark Nash, Ph.D., presented two scientific posters at the 33rd Annual Scientific Meeting of the American Spinal Injury Association (ASIA). Patricia Burns, M.S., Senior Research Associate from the Nash Laboratory, presented a third study. For the third year running Dr. Nash's research

has been nominated for either ASIA's annual Best Paper or Best Poster Award. Dr. Nash was also the lead speaker at the Symposium on Health in June in Reykjavik, Iceland. His address was given to the Joint Scientific Congress of the International Spinal Cord Society (ISCoS) and Nordic Spinal Cord Society (NoSCoS). Additionally, Dr. Nash was invited to speak on "Resistance Exercise after Spinal Cord Injury: Cholesterol and Beyond" for the The Stepping Forward-Staying Informed Lecture Series hosted by the New England Regional Spinal Cord Injury Center. While there, he also provided a talk to professional colleagues at Boston Medical Center.



Mary Bartlett Bunge, Ph.D., recently traveled to South Africa where she was in a delegation of women scientists participating in the People to People Ambassador Program. This is a program created by President Eisenhower in 1956, now under the leadership of his granddaughter. The delegation met with a variety of organizations and professors in Johannesburg and Cape Town to learn about their innovative efforts to advance technology and science and to create opportunities for improved education of the disadvantaged in South Africa.



Eva Widerström-Noga, D.D.S, Ph.D., served as keynote speaker for the Veterans Administration (VA) National Research Week conference at the VA Medical Center Miami. The title of her talk was "Pain after SCI: Central mechanisms and psychosocial contributors." At the

American Pain Society meeting, she presented a symposium together with Bryan Hains, Ph.D., (moderator) and Susan M. Carlton, Ph.D. The symposium focused on above-level pain after SCI. Additionally, at the annual conference of the American Spinal Injury Association, Dr. Widerström-Noga gave two presentations in the conference general sessions. She also coordinated and moderated an instructional course entitled "Pain in the Brain" that provided an up-to-date overview concerning the various brain areas that are important for the experience of pain in persons with SCI. Her co-presenters for the instructional course included University of Miami/Miami Project colleague, **Diana D. Cardenas, M.D., M.H.A.**, professor and chair of the Department of Rehabilitation Medicine, and Claire E. Hulsebosch, Ph.D., professor of Anatomy & Neurosciences at the University of Texas Medical Branch in Galveston, TX.



Suzie Sayfie, executive director of The Miami Project, was recently honored with the Inside Out Award from the University of Miami Alumni Association for her efforts to bring more alumni back to support and volunteer for the University. The Inside Out Award is the highest award given by the Association to a member of the University's administration, faculty or staff.



Clinical Trials Initiative Moves Forward

The goal of The Miami Project's recently announced Clinical Trials Initiative is to take discoveries found to be useful in laboratory studies and carefully fast-track them to clinical trial. One of the most exciting discoveries in the area of regeneration research is one in which cells are transplanted into the spinal cord to bridge the injury. Schwann cells, the so-called helper cells that surround nerve cells in the peripheral nervous system, stimulate axonal regeneration.

In a publication in 1975, the late Richard P. Bunge, M.D., scientific director for The Miami Project from 1989 to 1996, was the first to speculate that areas of spinal cord injury might be bridged by autologous Schwann cell transplantation. An autologous transplantation is advantageous as the cells are obtained from the same individual, thus circumventing an immune response. Through a series of laboratory experiments starting in the late 1980s, Dr. Bunge, his collaborator and wife, Mary Bartlett Bunge, Ph.D., and their colleagues gathered evidence that showed the credibility of the speculation. Both animal and human Schwann cell transplants in laboratory experiments could support regeneration of damaged spinal cord nerve fibers. To investigate the feasibility of using Schwann cell transplants in humans, Patrick Wood, Ph.D., and colleagues focused on developing reliable techniques to prepare the cells for transplantation.

In 2004, Drs. Damien Pearse and Mary Bunge presented exciting results that showed significant walking recovery in animals with acute spinal cord injury when Schwann cell transplants were combined with injections of rolipram, a drug that enhances levels of the messenger molecule cyclic AMP. These pre-clinical research findings prove the concept that combination treatment strategies can promote regeneration and functional recovery after spinal cord injury.

With this evidence of functional recovery as well as findings that suggest the feasibility of using human Schwann cells, The



Drs. Damien Pearse and Mary B. Bunge

Miami Project is taking steps to translate these new pre-clinical discoveries to clinical trials in humans.

To Gain FDA Approval

Up until the late 1990s, all that would have been needed to test Schwann cell transplantation in humans was approval by a university-based Institutional Review Board (IRB). In the late 1990s, however, new regulations required that if cell and tissue transplantation was to be tested in humans, an application for an Investigational New Drug (IND) would need to be filed with the Food and Drug Administration (FDA).

To get approval from the FDA, several scientific steps are required that go beyond the current evidence that shows the treatment is beneficial in experimental models of acute and chronic injury. Further studies need to determine the best dose of the drugs and cells and whether unwanted side effects occur, such as the formation of tumors and the development of pain or toxic reactions.

The Miami Project has already initiated the pre-clinical research to answer several of these questions. Dr. Pearse and colleagues are now nearing completion of follow-up studies that will provide important information about whether Schwann cell implants increase pain and whether they are useful in models of chronic spinal cord injury. They have also initiated studies to test the cells in larger animal models.

In addition to assessing the cells, they are in the midst of a series of studies to determine optimum doses of rolipram. Rolipram is known to cause side effects such as vomiting, inflammation and leaky blood vessels, so it will be important to learn what dose provides benefit with the least side effects. They are also looking at the therapeutic window – the period of time the drug exerts its effect.

As these important scientific steps are underway, The Miami Project is also taking important administrative steps toward the goal of initiating clinical trials. "Our chances of moving our pre-clinical findings to the clinic in a timely fashion," says Dr. W. Dalton Dietrich, scientific director of The Miami Project, "will be greatly enhanced by the ability to interact with individuals with expertise in the FDA and other regulatory organizations."

The Miami Project is identifying consultants who will assist in coordinating the process of obtaining FDA approval for a

The progress in the Clinical Trials Initiative – moving discoveries made in Miami Project laboratories from the pre-clinical phase into actual clinical trials – is encouraging.

clinical trial involving the transplantation of Schwann cells. This process has many aspects and requires coordination among all investigators and the several divisions within the FDA that will be involved with the approval process. It will require someone to communicate directly with the FDA since the agency frequently updates regulations and guidelines when new findings and technologies become available.

One of the FDA's guidelines relates to the preparation of the Schwann cells prior to their use in humans. To control the quality of the cells, they must be studied and tested under what is known as GLP standards and manufactured under GMP standards. GLP stands for Good Laboratory Practice, and GMP stands for Good Manufacturing Practice, which are sets of regulations set forth by the FDA to assure the safety and quality of products intended for human use. The University of Miami Miller School of Medicine recently established the Wallace H. Coulter Center for Translational Research, a facility that provides the infrastructure needed to carry out these GLP and GMP studies. Through collaborations established with the Coulter Center, The Miami Project will be able to gather the essential data needed to submit an IND application to test Schwann cell transplants in people with spinal cord injury.

Human Clinical Trials

While Schwann cell transplantations are still in the translational research phase – the phase where findings in laboratory experiments are carefully transformed into clinical treatments – other research results from University of Miami/Miami Project investigators have moved beyond this phase and are actually being tested in human clinical studies. Laboratory experiments dating back to the 1950s had shown that cooling the nervous system appears to be beneficial in slowing down injury processes and decreasing cell damage after injury to the nervous system. In the 1970s and early 1980s, a few preliminary clinical studies were carried out to test local spinal cord cooling in people with acute spinal cord injury. The results were encouraging but “in those days,” says Dr. Barth Green, “we weren't very sophisticated. Cooling was induced by performing a laminectomy, or bone removal, and perfusing iced saline over the injury site. It was very difficult to reach and maintain the temperature of the spinal cord at the desired level.” Further studies were abandoned partly because of the technical challenges.

Today, however, state-of-the-art technologies that use cooling catheters placed in a blood vessel of the patient can efficiently and precisely lower body temperature. The Alsius CoolGard 3000® Thermal Regulation System utilizes a feedback system to monitor and adjust the cooling of the blood as it passes by the catheter. It is this technology that is allowing investigators to more accurately evaluate the promise of hypothermia. Pioneering pre-clinical research at the University of Miami in the mid 1980s by W. Dalton Dietrich, Ph.D., and colleagues led to clinical trials that have recently shown hypothermia to be beneficial in patients with brain injuries and heart attacks.

The effects of hypothermia in patients with spinal cord injury, however, have yet to be evaluated properly. After recently obtaining approval from the University of Miami IRB, surgeons Jonathan Jagid, M.D. and Allan Levi, M.D., Ph.D., at the Department of Neurological Surgery have now initiated a study to examine the effect of hypothermia in patients with spinal cord injury. The prospective study is looking at long-term functional outcomes by assessing motor and sensory function as well as overall function in daily living. The results will help determine if hypothermia provides important neuroprotective benefits in patients with newly acquired complete spinal cord injury.



CoolGard 3000® in use in the operating room

In addition to evaluating the use of hypothermia, the Department of Neurological Surgery and The Miami Project are also considering participation in an on-going multi-center Phase II clinical trial sponsored by Alseres Pharmaceuticals, Inc. This clinical trial is currently evaluating Cethrin®, a protein applied directly to the spinal cord that promotes neuroregeneration and is administered to newly injured patients who receive surgery to stabilize their spine. Key Miami

Project personnel have met with representatives from Alseres Pharmaceuticals to discuss the possibility of having a role in this clinical trial.

The progress in the Clinical Trials Initiative – moving discoveries made in Miami Project laboratories from the pre-clinical phase into actual clinical trials – is encouraging. Though the task is time consuming, expensive and challenging, The Miami Project is confident it has the expertise, knowledge and drive to navigate through the FDA approval process to initiate new human clinical trials. 

Current Trends in Fertility



New father, Javier Padilla with his newborn daughter

How many men are still being told they won't be able to father biological children after spinal cord injury? How many, when they learn this is not true, are also led to believe that the only way to achieve pregnancy is with the most expensive, complicated and invasive fertility procedure currently available?

When a young man at the peak of his reproductive health sustains a spinal cord injury, his fertility potential is often severely impaired. To father children, ninety percent of these men will require medical assistance either from a urologist or a reproductive endocrinologist (fertility specialist). The reasons, in part, are due to the effect SCI has on the man's ability to have erections and ejaculations, as well as the impact on the quality of his semen.

Nancy L. Brackett, Ph.D., HCLD, director of the Male Fertility Research Program at The Miami Project has been at the forefront of research to understand and improve fertility impairments associated with SCI. "Most men with SCI are unlike other men with fertility problems. Most infertile men have little or no sperm. On the other hand, men with SCI often have normal numbers of sperm, though the percentage of those sperm that are motile and viable is typically very low."

When Dr. Brackett, along with Charles Lynne, M.D., a professor of urology at the University of Miami Miller School of Medicine, initiated their studies in the early 1990s, little was known about the underlying causes of poor sperm motility in men with SCI.

Over the years, their studies have led to the discovery of a potential reason for the impaired semen quality. Dr. Brackett's group found that the semen of men with SCI contains abnormally high concentrations of toxic cytokines. When these cytokines are neutralized in the semen, sperm motility improves. Research is currently underway to take this new finding and develop it into a treatment.

Reproductive Options

Advances in the field of reproductive endocrinology in the last 20 to 25 years have improved the chances for infertile couples to achieve pregnancy. Assisted Reproductive Technologies (ART) such as in-vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) are now options that make it possible for couples to attempt pregnancy with very few motile sperm. Dr. Brackett and colleagues believe that less invasive procedures such as intravaginal insemination (IVI) or intrauterine insemination (IUI) may also be options for couples with male partners with SCI. However, some centers do not offer these options if the man cannot ejaculate.

"When a man with SCI and his partner consult with a fertility specialist, the doctor will often make recommendations for a specific procedure based on whether an ejaculated semen sample is available," says Dr. Brackett. "Since men with SCI often have difficulty with ejaculation, semen retrieval is certainly an issue when seeking assistance from a fertility specialist."

Before the 1980s, there was no reliable way to retrieve semen from a man with SCI who was unable to ejaculate. Since the 1980s, the introduction of procedures known as penile vibratory stimulation (PVS) and electroejaculation (EEJ) have significantly improved the chances of retrieving semen from men with SCI. "Much of our early research evaluated the feasibility and reliability of using PVS and EEJ for semen retrieval," reports Dr. Lynne. "These procedures are relatively simple to perform. In fact, in the case of PVS, couples may be taught how to safely use this method on their own at home."

But in a recent survey of professionals involved in the treatment of infertility, Brackett and colleagues found that more than one in four fertility centers rely on surgical sperm retrieval as the first line of therapy for anejaculation (lack of ejaculation) in men with SCI.

(Continued on page 21)

Barth A. Green Inducted into the SCI Hall of Fame



SCI Hall of Famer Dr. Barth A. Green

We are proud to announce that Barth A. Green, M.D., co-founder and president of The Miami Project to Cure Paralysis was inducted into the 2006 Spinal Cord Injury (SCI) Hall of Fame in the category for Research in Basic Science.

Formed by the National Spinal Cord Injury Association (NSCIA) in 2005, the SCI Hall of Fame™ was created to recognize excellence, and honor individuals and organizations that have made significant contributions to quality of life and advancements toward a better future for all individuals with spinal cord injury. Participation in this year's process was strong, with nearly 100 nominees nationwide in 14 different categories.

Dr. Green and the other inductees were honored on October 30th at the second annual SCI Hall of Fame™ induction ceremony and gala at the John F. Kennedy Center for the Performing Arts in Washington, D.C. The evening event was

emceed by author and journalist, John Hockenberry, and hosted by NSCIA in conjunction with the second SCI Summit™ held on October 29th – November 1, 2006, at the Hyatt Regency in Bethesda, MD.

Dr. Green accepted the honor with an account of his experience as a medical student in the laboratory of pioneer L.W. Freeman. "For the first time in my life, I was exposed to people who were paralyzed...I quickly became overwhelmed with their extraordinary courage, their attitude and their tremendous energy...I knew what I had to do...I made a commitment to use my medical career to do something about their quality of life and to work toward a cure someday."

Dr. Green has had a long career of involvement in issues related to SCI. In the early 1970s, he became involved with the NSCIA and served as a board member for many years. After coming to Miami in 1975, he established a successful neurosurgical practice and in 1985 co-founded The Miami Project to Cure Paralysis with the promise of working to find a cure. "I haven't fulfilled my promise yet. Though I may look like it," joked Dr. Green, "I'm not out of gas." Upon receiving his medal, Dr. Green stated, "I accept this on behalf of the scientists and colleagues not only at The Miami Project but around the world who truly believe it isn't a matter of if, it's a matter of when."

(Current Trends continued)

A disadvantage to this approach is it commits the couple to the most invasive and expensive reproductive option (ICSI), when less invasive and less expensive options (such as IVI or IUI) may be possible.

Dr. Brackett's group found that these centers were not examining the semen of men with SCI as a source of sperm for ART. Professionals cited a lack of training and equipment as their main reasons for not offering PVS or EEJ.

In an effort to get the word out to medical professionals who offer fertility services to couples where the male partner has a SCI, Brackett has presented data on semen quality and pregnancy outcomes that support a rationale for examining the semen as a



source of sperm for ART. Her findings were highlighted in a Modern Trends article in the October 2006 issue of *Fertility and Sterility* where she emphasized that fertility specialists need to explore all reproductive options, rather than proceeding immediately to the most invasive and expensive ART in these couples. Likewise, men with SCI and their partners should be aware that less invasive options are available. In consultation with their infertility specialist, couples should explore all available options. 

For further reading on fertility following SCI, see www.scifertility.com for a "Guide and Resource Directory to Male Fertility following Spinal Cord Injury/Dysfunction" as well as a bibliography of Dr. Brackett's studies.

THE 21ST ANNUAL GREAT SPORTS LEGENDS DINNER

An Evening of Historic Proportions

Leaders from the world of sports, entertainment and business gathered together to help break a major fundraising record at the 21st Annual Great Sports Legends Dinner to benefit The Buoniconti Fund. More than 1,300 guests marveled as Nick Buoniconti announced that on this historic night in September, the dinner raised \$4.5 million dollars for paralysis research. "I am simply humbled and in awe by the continued support of so many individuals and corporations who are committed to seeing Marc and millions of paralyzed individuals walk again," said Buoniconti.

This year's event broke the world's record for the most money ever raised in one evening for spinal cord injury research. The Louis F. and Virginia C. Bantle Charitable Foundation and an anonymous donor were so moved during the event, they donated an additional \$500,000 each to help us reach the \$4.5 million for paralysis research.

For the past twenty-one years, the Great Sports Legends Dinner has honored athletes and individuals whose achievements have set a new standard for what can be accomplished by the human spirit. As Honoree Beverly Kearney said, "I have the mentality that failure is not an option for me. Like The Miami Project, no one could have ever envisioned where it is. But it is, because one man had the



The 2006 Class of Great Sports Legends

courage to stand up and say I don't like what is, so I am going to create what can be."

"The Miami Project and The Buoniconti Fund's success has been achieved by every person who has supported us," said Marc Buoniconti. "I especially want to thank our Board of Directors and Dinner Chairman **Mark Dalton** because without them, this event would never have happened."

The 2006 Sports Legends honored were: **Lance Armstrong, Patrick Ewing, Emmitt Smith, Wade Boggs, Michael Irvin, Dean Smith, Tony Hawk, John Vanbiesbrouck, Michael Chang and Beverly Kearney**. Michael Irvin accepted his Legend medal and one on behalf of his former teammate Emmitt Smith to go along with their Super Bowl rings. Smith was unable to attend the dinner because of his live appearance on the TV show, *Dancing with the Stars*. That evening, Smith announced on air that he was dancing for The Buoniconti Fund and part of the proceeds will go to the cause.

Desert Storm Military Commander **General H. Norman Schwarzkopf** was recognized as the *Great American Icon*. **The Chambers Family** received *The Buoniconti Fund Humanitarian Award* and Ameristar Casinos Chairman and CEO **Craig H. Neilsen** was honored as this year's *Outstanding Business Leader*. **Tom Brokaw** made the evening a hit as the Master of Ceremonies for the fifth year in a row. 



Sports Legend Lance Armstrong at the podium



Hockey Legend John Vanbiesbrouck with Dr. Barth Green



Tennis Legend Michael Chang with University of Miami President Donna Shalala



Sports Legends Dean Smith and Tony Hawk



Artist Romero Britto with Marc Buoniconti and Academy Award winning actor Tommy Lee Jones



Football Legend Michael Irvin with Dany Garcia Johnson



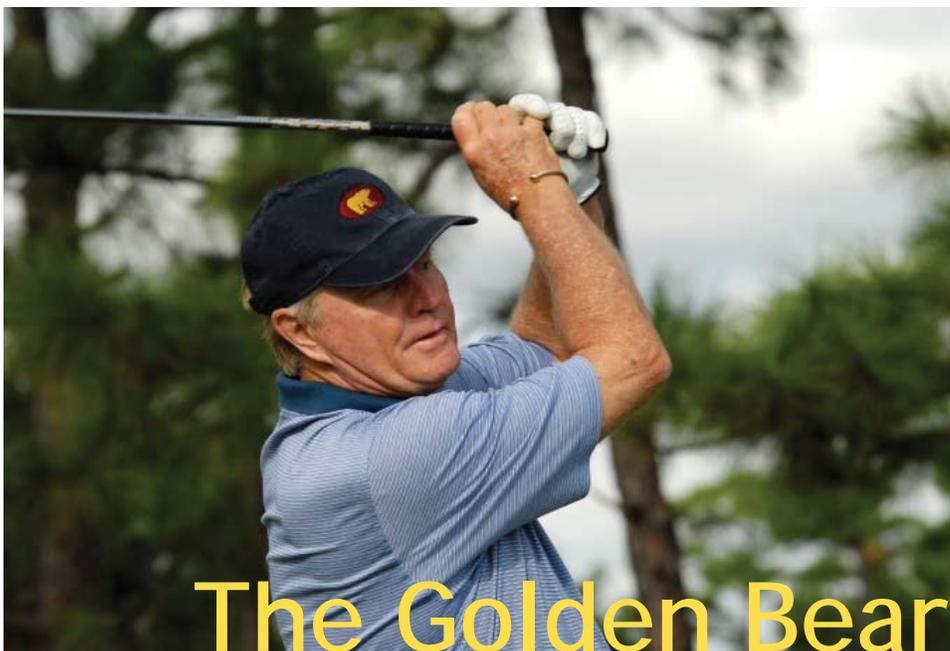
Buoniconti Fund Board Members Mark Dalton, Jack Schneider and James Pallotta



General H. Norman Schwarzkopf at the podium



Nick and Marc Buoniconti with Ray Chambers and Basketball Legend Patrick Ewing



“It should come as no surprise when I tell you that, through the direct efforts of Jack and Barbara Nicklaus, over \$2.5 million have been raised the past five years through this tournament.”

The Golden Bear Champions Our Cure

Golfing legend Jack Nicklaus has done it again. The Golden Bear hosted the 5th Annual Buoniconti Celebrity Golf Invitational at his exclusive golf course, The Bear’s Club in Jupiter, Florida to help raise more than \$500,000 this past November. Celebrity friends included: NFL Hall of Famers Nick Buoniconti and Bob Griese, NBA Hall of Famers John Havlicek and KC Jones, and MLB Hall of Famer Gary Carter (to name a few). The celebrities and supporters teed off on the phenomenal course for a beautiful day filled with on-course contests, an awards ceremony and a sumptuous luncheon. Our gracious Presenting Sponsors, Mark Dalton of The Tudor Group and Kenneth Tropin, helped make this tournament a huge success.



Marc Buoniconti with Jack Nicklaus and Ashley Moore

“If you’ve followed Jack’s life, you know that his standards are high as a husband, father, friend, gentleman and businessman,” said Nick Buoniconti. “It should come as no surprise when I tell you that, through the direct efforts of Jack and Barbara Nicklaus, over \$2.5 million have been raised the past five years through this tournament.” 

Save the Date for the 2007 tournament:
November 4th and 5th.



Mark Dalton, Marc and Nick Buoniconti with Ken Tropin at the awards ceremony

AMERISTAR NATIONAL CHARITY GOLF CLASSIC RAISES OVER \$1 MILLION FOR THE BUONICONTI FUND TO CURE PARALYSIS

The second annual Ameristar National Charity Golf Classic, hosted by Ameristar Casino and Hotel Kansas City, held September 12, 2006 at the top-ranked Staley Farms Golf Club, raised more than \$1.1 million with the proceeds benefiting The Buoniconti Fund to Cure Paralysis. The golf tournament was presented by Ameristar Casinos and the Craig H. Neilsen Foundation, and was sponsored by more than 100 Ameristar vendors and business associates from across the country. Title sponsors were Hensel Phelps Construction Company, International Game Technology and Walton Construction. Ameristar created the annual tournament to provide its key vendors and business associates with an opportunity to make a significant contribution toward spinal cord injury research.

“Over the years, we have been fortunate to have many friends stand up for those who can’t. We appreciate the tremendous support and generosity of Ameristar Casinos and Craig H. Neilsen,” said Marc Buoniconti. “The Buoniconti Fund is delighted to be the beneficiary of this second annual tournament.”

“On behalf of all of the tournament sponsors, I am very pleased to make this donation to the Buoniconti Fund and the cutting-edge research it supports at The Miami Project,” said Craig H. Neilsen, Ameristar Chairman and CEO. “Their work is showing very promising results in finding a cure for paralysis and in improving the quality of life for those living with a spinal cord injury.” 



Lenny Dawson with Marc and Nick Buoniconti at the golf tournament



NFL Hall of Famers and longtime friends Len Dawson of the KC Chiefs and Nick Buoniconti with Marc Buoniconti and Senior Vice President and Co-Chairman of the Board for Ameristar Casinos, Inc., Ray Neilsen



Marc Buoniconti thanking Craig Neilsen following the check presentation

Save the Date for the 2007 tournament: October 8th and 9th.

The Miami Project is saddened at the recent passing of our dear friend Craig H. Neilsen. He will be greatly missed by everyone fortunate enough to have known him.



DESTINATION FASHION 2007
 PRESENTED BY TOVA LEIDESDORF
 Phenomenal Event Produced by Barton G.

Bal Harbour Shops hosted Destination Fashion "Seasons," presented by Tova Leidesdorf, when it closed its doors for a huge bash produced by Barton G. and raised more than \$2 million to benefit The Buoniconti Fund to Cure Paralysis.

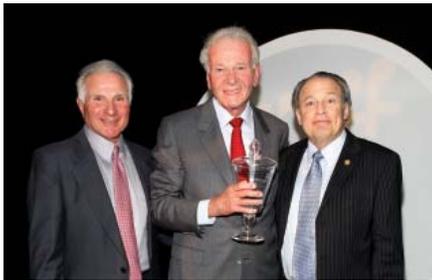
Event Honorary Chair Gloria Estefan kicked off the spectacular evening where more than 2,000 celebrities and notables partied together while high-profile couture fashion designer Michael Vollbracht for Bill Blass showcased his Fall/Spring Collection, presented by Saks Fifth Avenue Bal Harbour. One major highlight included the announcement of the Women of Substance & Style after which partygoers were dazzled by the change of "Seasons" to reveal a special concert performance by Donna Summer.

Bal Harbour Shops' stores donated one of a kind limited edition items. Thanks to our sponsors: Tova Leidesdorf; Bal Harbour Shops; Barton G.; Edie Laquer; Bal Harbour Village; Brenda Nestor Castellano; Barbara Ceuleers Salazar and Dr. and Mrs. Geraldo Aguirre in memory of Christopher G. Aguirre; St. Regis Resort & Residences-Bal Harbour; Carnival Cruise Lines; Dawn



Michael Vollbracht, Marc Buoniconti, Dawn Jones, Tommy Lee Jones and Deborah Slack

and Tommy Lee Jones; Gretchen and Jay Jordan; Dorothy Barrie; Paula and Bob Brockway; Bunny Bastian; The Miami Herald Media Company; Southern Wine & Spirits of America; Continental Airlines; Dr. and Mrs. Jose Armas; Lady Monica Heftler; Lola and Donald Jacobson; Saks Fifth Avenue-Bal Harbour; Michael Vollbracht for Bill Blass; and Selecta Magazine. 



Nick Buoniconti, Norman Braman, Barth A. Green, M.D.



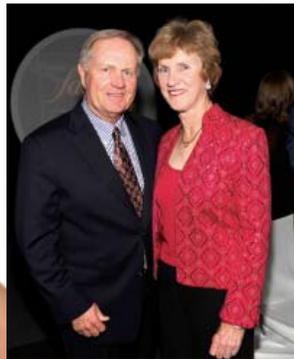
John "Footy" Cross and DJ Kerr



Jill Viner and Diana Steinger



Judy George and Nick Buoniconti



Jack and Barbara Nicklaus



Dwayne "The Rock" Johnson
Dany Garcia Johnson



Tova Leidesdorf, Edie Laquer,
Matthew Whitman Lazenby, Randy Whitman



Paula Brockway, Tina Carlo and
Brenda Nestor Castellano



Barbara Salazar and Dick Anderson



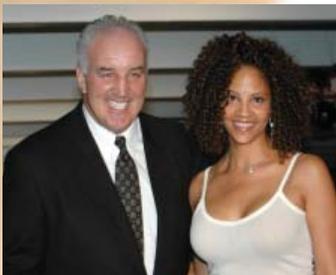
Bunny Bastian and Jim Kiick



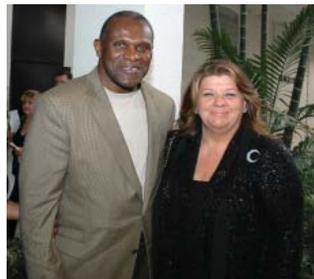
Jennifer Valoppi and John Havlicek



Peggy Armaly and Earl Morrall



Gerry Cooney and Tracy Mourning



Harry Carson and Terry Schechter



Madeleine Arison



Lady Monica Heftler, Miami Police Chief John
Timoney, Lola Jacobson and Tova Leidesdorf



Martha De Cespedes, Marla Bergmann, George Bergmann and
Denny Feinsilver



Rosy Cancela and Bob Beamon



Emilio Estefan, Marc Buoniconti and Gloria Estefan



WPLG Anchors Laurie Jennings and Dwight Lauderdale present Paul and Swanee DiMare with the 2007 Ann Bishop Spirit of Excellence Award

Swanee and Paul DiMare receive the Ann Bishop Award for outstanding service to their community

The Women's Guild of The Miami Project to Cure Paralysis held its annual luncheon at Indian Creek Country Club on April 11, 2007. Over 250 women watched philanthropists Swanee and Paul DiMare receive the Ann Bishop Spirit of Excellence Award for outstanding service to their community. Saks Fifth Avenue, Bal Harbour produced a fabulous fashion show of the "Best of the Best" in design. David Morris Jewelers not only showcased their fabulous collection but also underwrote the entire luncheon. Chairwomen Terry Buoniconti and Lenore Elias thanked everyone for their incredible generosity and support.

WOR Radio 710 - Operation Good Neighbor

WOR Radio 710's community outreach program, *Operation Good Neighbor*, was held on May 10 from 5am to 6pm in support of *The Buoniconti Fund*. Throughout the 13-hour radiothon, WOR listeners, in the NYC area and streaming on the web, received information on issues surrounding paralysis and how they can support The Buoniconti Fund from enlightening segments on *The WOR Morning Show with Joe Bartlett and Donna Hanover*; *The Joan Hamburg Show*; *Food Talk with Michael Colameco*; *The Dr. Joy Browne Show*; and *Henican & White*.

Dr. Barth Green and NFL Hall of Fame linebacker Nick Buoniconti, founders of The Buoniconti Fund and The Miami Project, along with Nick's son, Marc, were joined on the airwaves by friends and celebrity guests including former New York Rangers hockey player John

Vanbiesbrouck; former heavy-weight boxer Gerry Cooney; former NFL linebacker Brian Kelly for the New York Giants; Baseball Hall of Famer Wade Boggs from the New York Yankees; and Stanley Cup winner Kenny Daneyko with the New Jersey Devils.

In addition to the radiothon, WOR has made a year-long commitment to donate 100% of ticket proceeds from their yearly listener events to *The Buoniconti Fund*. Over \$30,000 has been raised so far from last year's *Classic Taste of New York*, from *WOR's Bridal Fair*



Marc Buoniconti accepts a check from Richard Buckley

in March and from *WOR's Get Healthy Expo* which was held in June at the New Jersey Convention and Exposition Center.

ACE for a Cure

The 3rd annual "ACE for a Cure" Event to benefit The Buoniconti Fund was again held at the Sony Ericsson Open in March. Nick Buoniconti, Marc Buoniconti and Dr. Barth Green were joined by their celebrity friends, including South Florida radio icon Footy and CBS-WFOR TV's Lisa Petrillo, who served as event emcees. An amazing fashion show was presented courtesy of The Village of Merrick Park and one lucky winner won the Grand Prize of a new 2007 Mercedes-Benz C230.



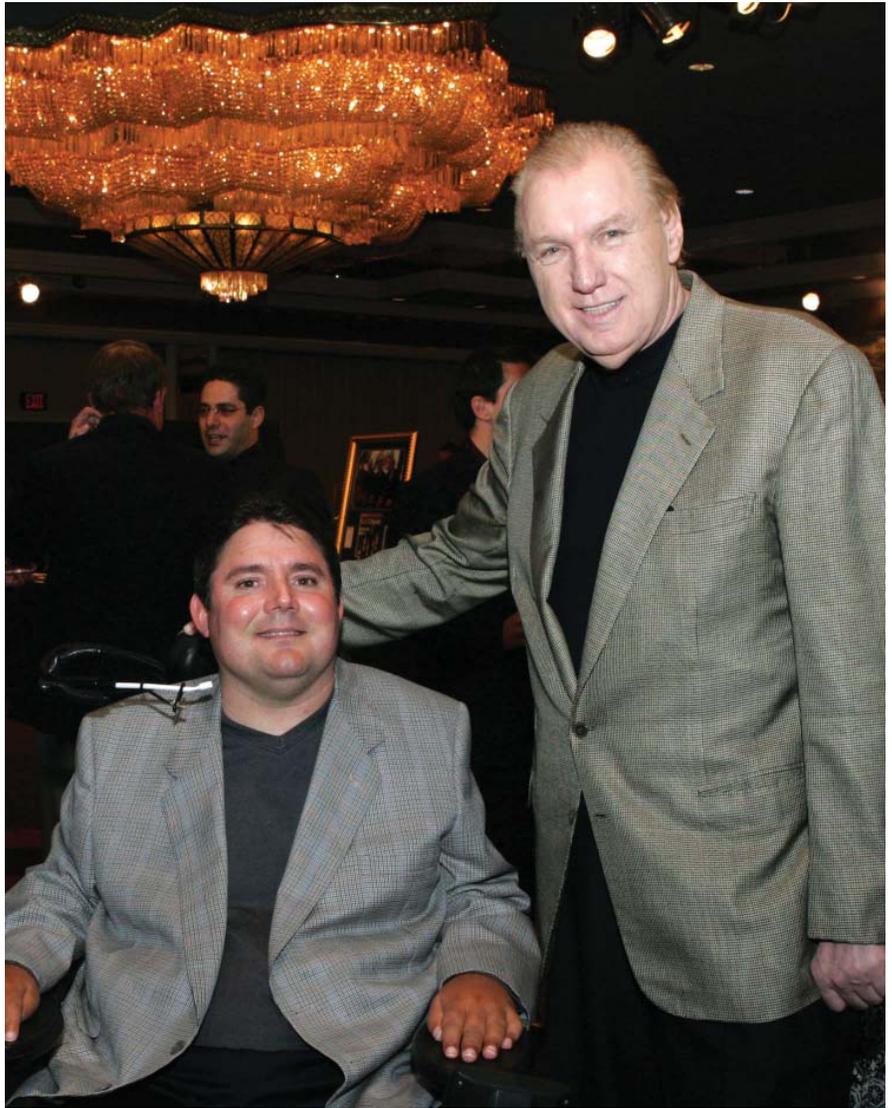
Winner of the new 2007 Mercedes-Benz C230 kisses his new car.

A special thank you to Sony Ericsson Open tournament founder and chairman Butch Buchholz, Mercedes-Benz, the Village of Merrick Park for producing the incredible fashion show, to Nexxus for taking care of the fashion show's models and to Adam Barrett, Wendy Elkin and Dagny Potter from the Sony Ericsson for their tireless efforts on behalf of this event.

8TH ANNUAL ROGER KING GOLF INVITATIONAL

Media mogul and Buoniconti Fund Board Member, Roger King was honored by the National Television Industry with a gold medal for his outstanding achievements in the television media markets. Roger accepted the award with dignity but true to his unselfish and generous nature spoke of his commitment to The Buoniconti Fund and the mission to cure paralysis.

On May 19th and 20th, Roger hosted the Eighth Annual Roger King Golf Invitational in Atlantic City. His friend, entrepreneur Donald Trump, sponsored this one-of-a-kind golf weekend at the Trump Taj Mahal. Celebrity guests included Bob Griese, Danny Aiello, Joe Piscopo, Bob Beamon, Gerry Cooney, Dick Anderson, Brian Kelly, Ronnie Lippett, Terry Kirby, Mike Torrez and Stan Bahnsen to name a few. Danny Aiello and Joe Piscopo sang a few songs and had the audience ready to bid on the amazing silent auction items. Roger's many friends and business associates helped him raise much of the needed research monies while they dined at "The Golf Ball" with Master of Ceremonies Don Criqui from *Inside Edition*. A fabulous time was had by all. 



Marc Buoniconti with media mogul Roger King



Nick and Marc Buoniconti accept a check from Joe Grande from the Trump Taj Mahal



Thomas Van Dell, Danny Aiello, Joe Piscopo and Roger King

3rd Annual Buoniconti Fund Golf Invitational



Paul and Swanee DiMare accept an award from Nick Buoniconti

Buoniconti Fund friends and benefactors Swanee and Paul DiMare hosted The Buoniconti Fund Golf Invitational at the Indian Creek Country Club on April 27th for the third year. Celebrity golfers included Lawrence Taylor, Nick Buoniconti, Nat Moore, OJ McDuffie, John Kidd, Terry Kirby and Ki-Jana Carter to name a few. Golfers and guests enjoyed a Champions Luncheon before teeing off for a dazzling day of golf and on-course contests. A special awards ceremony dinner and “buy-it-now” auction completed this incredibly successful event. A big thank you to Swanee and Paul for their continuing generosity and hard work.

Jennifer Ireland Climbs for a Cure

The thought of being paralyzed never even entered Jennifer Ireland's mind until May 17, 1997. On that day, while driving home, she and her girlfriends were hit by a drunk driver.

Although she was wearing a seatbelt and had an airbag as protection, she broke her neck. But she was lucky and her bones did not crush the spinal cord, which meant that she wasn't paralyzed. Her body didn't move and her breathing



Jennifer and friend display Miami Project t-shirts at the top of Mount Kilimanjaro

was shallow, but Dr. Barth Green and her other doctors assured her that she would regain movement over time.

It has now been ten years since the accident and as promised, she can walk again. To celebrate being able to walk, Jennifer climbed Mount Kilimanjaro – the highest peak in Africa – in October 2005. Through personal letters, pledges and appeals to friends and family, she was determined to raise money for The Miami Project in honor of Dr. Green. Jennifer raised more than \$55,000 for our research programs and took a big step for those who can't.

Upcoming Events:

August 4, 2007

Ricky Palermo Spinal Injury Golf Tournament

Benefits The Miami Project to Cure Paralysis - Batavia, New York

August 7, 2007

Celebration of Baseball (New York Mets vs. Atlanta Braves)

Benefits the New York City Chapter of The Buoniconti Fund
Shea Stadium - Flushing, New York

August 19, 2007

Third Annual Crab Feast

Benefits the Baltimore Chapter of The Buoniconti Fund
Carroll County Farm Museum - Westminster, Maryland

September 17, 2007, **MONDAY**

Twenty-Second Annual Great Sports Legends Dinner

Benefits The Buoniconti Fund
Waldorf=Astoria - New York, New York

September 18, 2007

Annual Directors' Research Briefing

Waldorf=Astoria - New York, New York

September 19, 2007

Annual Fall Celebration of Baseball

Benefits the New York City Chapter of The Buoniconti Fund
Yankee Stadium - Bronx, New York

October 8 & 9, 2007

Ameristar National Charity Golf Classic

Benefits The Buoniconti Fund to Cure Paralysis
Ameristar Casino & Hotel and The National Golf Club
Kansas City, Missouri

October 12 & 13, 2007

Golf Tournament & 2nd Annual Tailgate Party - The Citadel vs Furman

Benefits the Charleston Chapter of The Buoniconti Fund
The Citadel - Charleston, South Carolina

October 13, 2007

Miami Executive Aviation "Boys and Their Toys"

Benefits the Miami Chapter of The Buoniconti Fund
Miami Executive Aviation Airport - Miami, Florida

October 13, 2007

ChoicePoint Annual Golf Classic

Benefits The Miami Project to Cure Paralysis
Boca Raton, Florida

October 21, 2007

Detroit Free Press Marathon "Run for a Reason"

Benefits the Southeast Michigan Chapter of The Buoniconti Fund
Detroit, Michigan

November 4-5, 2007

Sixth Annual Buoniconti Fund Golf Classic at The Bear's Club with Jack Nicklaus

Benefits The Buoniconti Fund The Bear's Club - Jupiter, Florida

November 12, 2007

Atlanta Chapter Golf Classic

Benefits the Atlanta Chapter of The Buoniconti Fund
Dunwoody Country Club - Dunwoody, Georgia

November 15, 2007

Fourth Annual Raise A Glass For A Cure

Benefits the Philadelphia Chapter of The Buoniconti Fund
The Diamond Club at Citizen Bank Park - Philadelphia, Pennsylvania

February 13, 2008

Nordstrom Opening Gala at The Aventura Mall

Benefits The Buoniconti Fund - Aventura, Florida



Pascal Goldschmidt, M.D., Vincent Vento, Nick Buoniconti, John H. Kathe, M.D., Donna E. Shalala, Ph.D., Ira Jacobson, M.D., Marc Buoniconti, Allan Greenberg, M.D., George F. Daviglius, M.D., Jorge L. Garcia, Cesar J. Sastre, M.D., Prospero G. Herrera, II, W. Dalton Dietrich, Ph.D.

North Dade Medical Foundation has most generously given \$1 million to fund neuroprotective strategies targeting inflammation and axonal injury to improve functional recovery of spinal cord injury with the ultimate goal of translating discoveries to clinical settings in the near future. The gift will also allow The Buoniconti Fund to recruit two outstanding young investigators in the field of research per year for three years to enhance research collaborations between different laboratories and scientists. The long term goal is to increase the number of scientists and laboratories to obtain the necessary data and knowledge to initiate clinical trials targeting paralysis.

A celebration dinner was held on January 9th honoring the North Dade Medical Foundation and this most important gift, spearheaded by Ira Jacobson, M.D.

George F. Daviglius, M.D., Chairman of the Board of the North Dade Medical Foundation spoke of his foundation's important appropriation to The Buoniconti Fund.

UM President Donna E. Shalala and Dean of the Miller School of Medicine, Pascal J. Goldschmidt, M.D. gave their thanks to the foundation. Nick and Marc Buoniconti as well as Barth A. Green, M.D. emphasized the necessity of this most generous gift to the Human Clinical Trials Initiative.

The Buoniconti Fund salutes:
2006-2007 North Dade Medical Foundation Board Members

Sandra R. Giblin, Chief Executive Officer
George F. Daviglius, M.D., Chairman
Cesar J. Sastre, M.D., Vice Chairman
John H. Kathe, M.D., Secretary
William J. Heffernan, Treasurer

THE LONG TERM GOAL IS TO INCREASE THE NUMBER OF SCIENTISTS AND LABORATORIES TO OBTAIN THE NECESSARY DATA AND KNOWLEDGE TO INITIATE CLINICAL TRIALS TARGETING PARALYSIS.

Jorge L. Garcia
Allan M. Greenberg, M.D.
Prospero G. Herrera, II
Ira S. Jacobson, M.D.
Chester H. Morris, M.D. 

PENNIE AND GARY ABRAMSON

Pennie and Gary Abramson are leaders in the philanthropic and business world. Each has diverse interests, but both are major supporters of The Miami Project to Cure Paralysis and The Buoniconti Fund.

Gary Abramson joined The Tower Companies as a partner in 1969, and his inventive ideas, creativity, and commitment to excellence are today evident in some of Greater Washington, DC's most significant development projects. His passion in the development of Tower properties is evident in the architectural exterior and interior design elements; commissioning selective original pieces of art and deciding on aesthetic compliments for his projects fusing a sense of tranquility and productivity. Mr. Abramson's experience in Greater Washington's development truly leads the local industry.

Mr. Abramson was recently appointed as Chairman of the Board of American University in Washington, D.C. and serves The Buoniconti Fund Board of Directors, Sun Trust Bank, UJA Federation of Washington, The American Committee and the International Board of Governors for the Weitzmann Institute of Science (ACWIS), United Jewish Endowment Fund and the Heifetz International School of Music. He also serves as Executive Vice President for the Greater Washington Jewish Community Foundation.

Pennie's contributions range from arts to sciences, from creating education seminars to funding educational buildings. Her influence is as much local as it is national and international.

Pennie's involvement with the ACWIS spans 25 years. She is currently serving as President Elect of the American Committee and on the International Board of Governors. Pennie is also the current Chairman of the Montgomery County Public Schools Educational Foundation where she raises and disperses funds for projects which are not supported by the county schools. Pennie is an active volunteer for The Miami Project to Cure Paralysis and The Fisher Island Philanthropic Foundation, a fund which supports children's charities based in Miami, FL. She also sits on the Board of Trustees for Friends of Cancer Research. She is a past women's Division Chairman for the State of Israel Bonds, the Leukemia Society of America, and Make a Wish Foundation. The Abramson's support and funding at The Miami Project includes laboratory research, educational programs, and event sponsorships. They are now focused on The Human Clinical Trials Initiative.

Pennie and Gary Abramson have been married for 37 years. They have three children and one grandchild. The Miami Project salutes the Abramsons and their legacy of support.



Gary Abramson, James Berlin, Madeline Berlin and Pennie Abramson

MADELINE AND JAMES BERLIN

Madeline and James Berlin have made giving to others their mission in life. Their philanthropic projects involve a wide spectrum of recipients including the arts, community and medical foundations and institutions.

They are major supporters of the Akron Art Museum, Cleveland Playhouse Square Foundation, Miami Art Museum, and Florida International Art Museum.

Believing that the community shapes families, the Berlins are very active in the Boys Hope Girls Hope Program, Jewish Welfare Fund, Aspen Valley Community Foundation, Jewish Community Board, United Way of Summit County and Fisher Island Philanthropic Fund.

Madeline and James are supporters and volunteers in various medical arenas including The Miami Project to Cure Paralysis, The Buoniconti Fund, Mid-Fairfield AIDS, Mount Sinai Medical Foundation, Summa Health System, University Hospitals, and Akron General Hospital.

Their devotion to The Miami Project to Cure Paralysis and The Buoniconti Fund has included basic science and, SCI educational funding, event sponsorship, and now major support for The Human Clinical Trials Initiative.

The Berlins have been married for 44 years with two children and five grandchildren. The Miami Project salutes the Berlins and their legacy of support. 



Flanked by his family, former teammates, Citadel President Lt. Gen. John Rosa and Director of Athletics Les Robinson, Marc Buoniconti accepted this honor and invited those around him to share in the special moment.

The Citadel / Charleston

The Citadel retired the jersey of former football player Marc Buoniconti on September 30, 2006 in an inspiring and emotional halftime ceremony. Marc was a sophomore linebacker for the Bulldogs in 1985 when he suffered a spinal cord injury in a game played at East Tennessee State University. In addition and as a special surprise by alumni and fellow team members, Marc was one of a select few to receive a class ring as a non-graduate.

There was also a tailgate party fundraiser that raised \$55,000 to benefit The Citadel's Brigadier Foundation and The Buoniconti Fund. The Brigadier Foundation has established a scholarship in Marc's name and The Buoniconti Fund raises money for, and awareness of, The Miami Project's spinal cord injury research programs.

Chicago Chapter

What an amazing evening! The Chicago Chapter held its Eighth Annual Indulgence Night at Gibson's Steakhouse and Hugo's Frog Bar in November raising more than \$127,000. With more than 200 people in attendance, all enjoyed a fabulous dinner, live and silent auction, 50/50 drawing and an incredible time. This annual event was held in memory of Michael Bucheleres, who had become spinal cord injured in 1988 and was the brother of the Chapter's Volunteer Regional Director John Bucheleres. Mark your calendars for the Ninth Annual Indulgence Night to be held at Gibson's on Thursday, November 29th!

New York Chapter

On Thursday, May 17, the New York Chapter held its Second Annual "Poker4Life" charity tournament and silent auction to benefit The Buoniconti Fund. More than 160 players competed for the top prize of a coveted seat in an exclusive World Poker Tour (WPT) celebrity invitational tournament to be held in California early 2008. More than two hundred people filled the

Manhattan Auto Company, a premier car dealership located in the city. Great times were had by all including local NY Knicks David Lee, professional actors Jason Weiss and Amy Ruttberg, local Playmate Colleen Marie, and WPT host Sabina Gadecki. Thanks to the dedication of our volunteers, support of our sponsors, and enthusiasm of our guests, we raised more than \$110,000.



NY Chapter enjoys a night out at the Yankees game.

Baseball will fill the air in New York this summer and fall with the Chapter hosting a series of events with both the New York Yankees (June 13 and September 19) and New York Mets (August 7). We've been able to secure tickets in special sections at both parks. Family and friends are welcome to come out and celebrate America's favorite pastime while raising funds and awareness.

The Buoniconti Fund

We are pleased to announce the new Director of National



Kristin Wherry joins The Buoniconti Fund as Director of National Chapters.

Chapters, Kristin Wherry. Kristin has been a volunteer with The Buoniconti Fund and The Miami Project for 13 years. She has been a member of the Miami Chapter as well as Volunteer Regional Director for two years. Kristin has also been involved in activities including planning and implementation of the recent National Chapter Summit. Her vast experience working with volunteers, events, media relations, and strategic planning for corporate and non-profit arenas provides a new outlook and skill-set for the

expansion and awareness of our National Chapter base and grassroots efforts. Kristin Wherry can be reached at kwherry@med.miami.edu or 1-888-STAND UP.

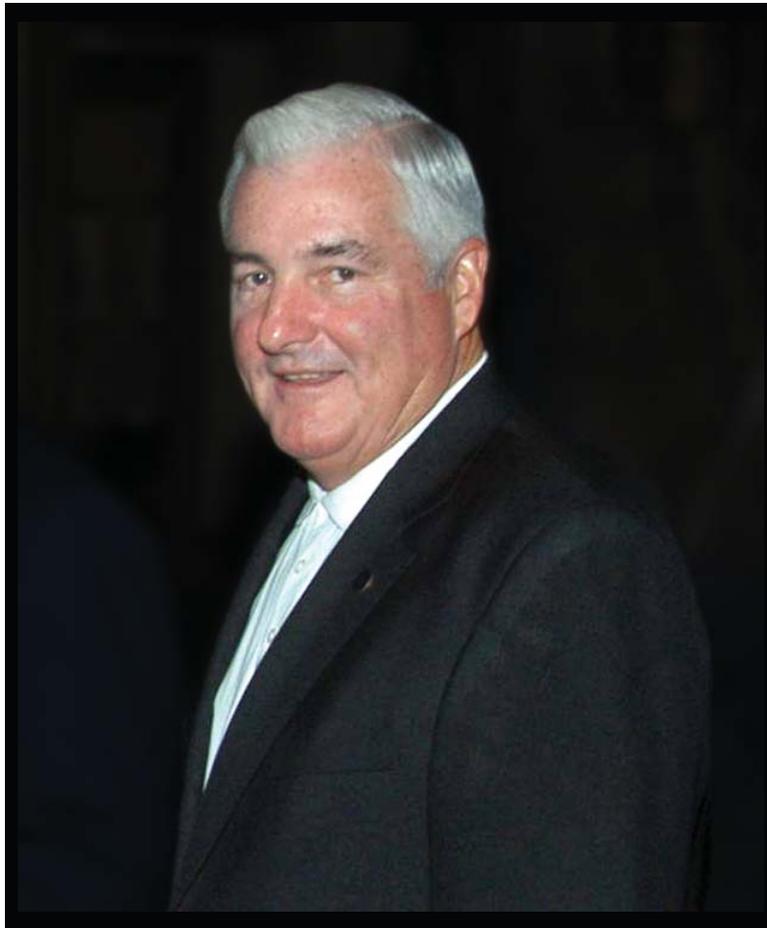
His devotion to the mission of the Claddagh Foundation and The Buoniconti Fund for “standing up for those who can’t” will never be forgotten as progress is made toward keeping his dream of finding a cure for paralysis alive.

Gerald T. Callahan, Buoniconti Fund Board Member, passed away on Thursday January 25, 2007. He was born on October 7, 1945 in Evergreen Park to Eugene and Dorothy Callahan, the fourth of five boys and one girl. Jerry married Peggy (Newton) in September of 1968.

He was employed at Xerox Corporation from June of 1967 to July 1971 as a sales representative and national accounts manager. In July of 1971 Jerry began work for Posen Oil Terminal, Inc. as Vice-President of Marketing and Operations. He purchased Posen Oil in August of 1974 and served as CEO and owner until the company was sold in January of 2005.

Jerry co-founded the Claddagh Foundation in 1996 to raise funds for research in the spinal cord injury field. He served as trustee for the Claddagh Foundation and was responsible for administering, raising, and distributing funds. To date, the Claddagh Foundation has given in excess of \$1.2 million to various charities including The Miami Project to Cure Paralysis, The Buoniconti Fund, the Illinois Spinal Cord Association, the Transverse Myelitis Association, the Rehabilitation

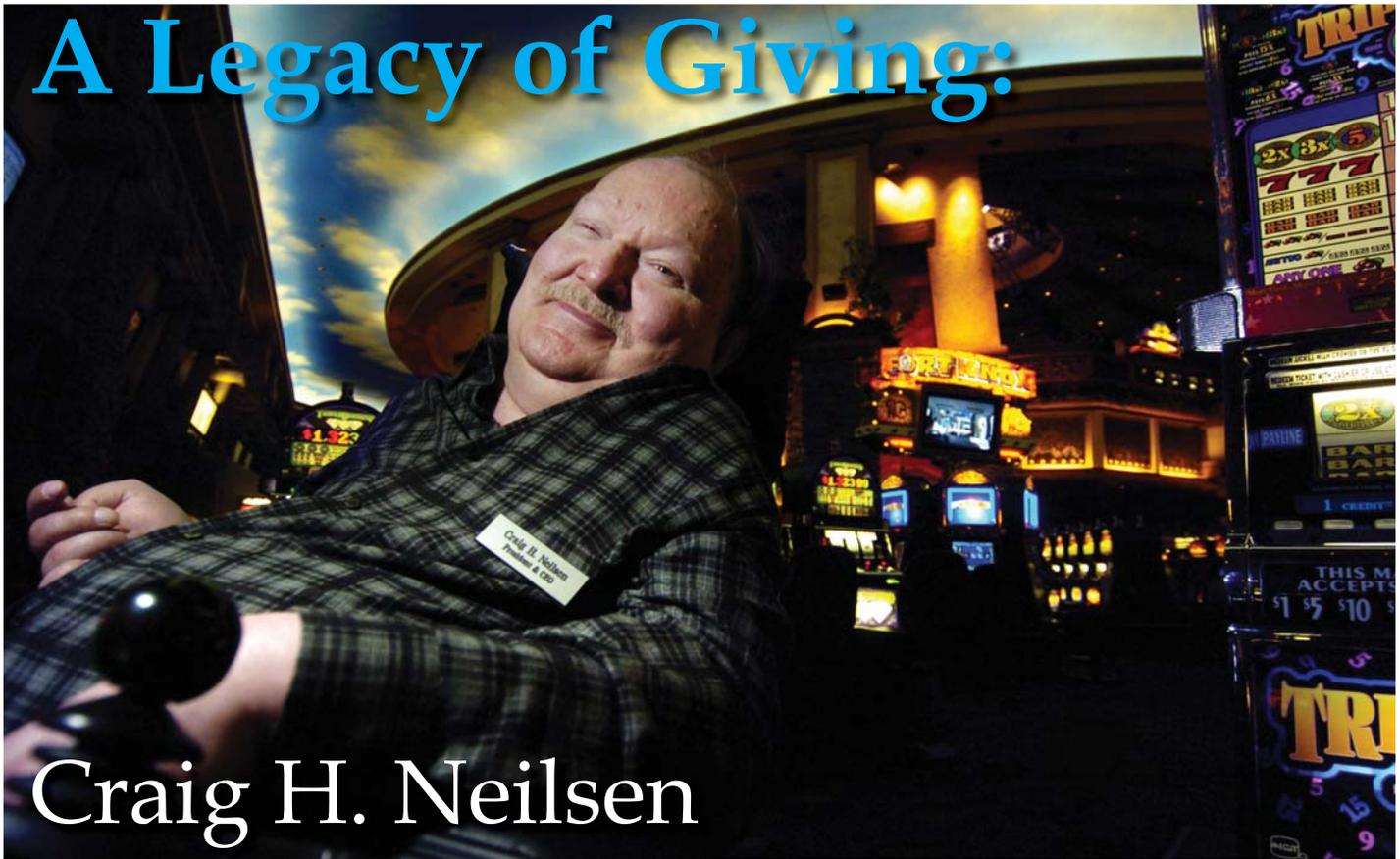
Institute of Chicago and several local charities in the metropolitan Chicago area. In 2006, Jerry was appointed to the Board of Directors for The Buoniconti Fund, which is the national fund-raising arm of The Miami Project. His devotion to the mission of the Claddagh Foundation and The Buoniconti Fund for “standing up for those who can’t” will never be forgotten as progress is made toward keeping his dream of finding a cure for paralysis alive.



Jerry’s love of God, family, friends and golf were second to none. In the celebration of Jerry’s life, one theme continues to ring through, he was “Simply The Best”.

The passing of Gerald T. Callahan has been deeply felt by many, especially his wife, Peggy; his children, Kati, Lori, Liz, Courtney, Jennifer, and Michael; and his grandchildren, Kaitlyn, Emma, and Ella.

The family of The Miami Project and The Buoniconti Fund mourn the passing of our dear friend and we extend our sincere condolences to his family, friends, and all who knew and loved him. 



The Miami Project and The Buoniconti Fund were deeply saddened by the sudden passing of Craig H. Neilsen a few months ago. Mr. Neilsen’s advocacy and philanthropic support for spinal cord injury research was immeasurable. “Craig was a true humanitarian and visionary who believed in people and always tried to help those less fortunate obtain a better quality of life,” said Nick Buoniconti.

Craig H. Neilsen was founder of The Craig H. Neilsen Foundation and Chairman and CEO of Ameristar Casinos. In 1985, he was in a serious car accident that left him with a spinal cord injury. Despite his injuries and new challenges, Craig bought out his partners in two small casinos in Jackpot, Nevada. He made major renovations to the Jackpot casinos and in 1993, Craig established Ameristar Casinos. Through his leadership and guidance, Ameristar has invested more than \$1.55 billion in the development and expansion of eight properties. In 2002, Craig was recognized as the “Best Performing CEO” by the American Gaming Association. In 2005, Craig was inducted into the American Gaming Associations’ 2005 Hall of Fame. In 2006, Mr. Neilsen received The Buoniconti Fund’s Outstanding Business Leader Award at the 21st Annual Great Sports Legends Dinner at the Waldorf=Astoria in New York City.

Even before establishing The Craig H. Neilsen Foundation, Craig had a long-standing history of giving back to those in need. Craig’s generosity, matched by that of Ameristar, was evident with the establishment of the Ameristar National Charity Golf Classic which is held at one of their premier properties, Ameristar Casino and Hotel Kansas City. In two years, the event raised nearly \$2 million - making it one of the largest and most successful golf tournaments in the country. The Buoniconti Fund has been the beneficiary of these funds.

“Craig left the world a better place and we are all grateful for having the opportunity to have known him,” said Marc Buoniconti.

The family of The Miami Project and The Buoniconti Fund mourn the passing of our dear friend and we extend our sincere condolences to his family, friends, and all who knew and loved him. 

Children Should Grow Into These,



Not These.



We can cure paralysis in this lifetime.

THE PROJECT

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