

THE PROJECT

Fall 2012

A Publication of The Miami Project To Cure Paralysis & The Buoniconti Fund To Cure Paralysis

FDA APPROVED

The Miami Project to Cure Paralysis has received
its first FDA approval to begin a Phase I Trial of
Autologous Schwann Cell Transplantation



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

A Message from the President Marc Buoniconti



I am honored to announce that for the first time ever, The Miami Project to Cure Paralysis has been granted approval by the FDA to begin the much anticipated human safety trial of autologous Schwann cell transplantation.

Friends,

It is with tremendous pride and unbridled enthusiasm that we make one of the biggest announcements in the history of The Miami Project to Cure Paralysis. I am honored to announce that for the first time ever, The Miami Project to Cure Paralysis has been granted approval by the FDA to begin the much anticipated human safety trial of autologous Schwann Cell Transplantation.

The Miami Project team of scientists and staff has been working diligently for the past few years with the FDA to garner this approval. Imagine 50 full time scientists, technicians and the core staff working around the clock to make this a reality. It has always been the cornerstone of The Miami Project to improve the quality of life of all people with brain and paralyzing spinal cord injuries and to ultimately find a cure. This new Schwann Cell Trial will be among the 10 other clinical trials for brain and spinal cord injuries already in progress.

Collectively, these human trials will go a long way in accomplishing our scientific goals of neuroprotection and cell transplantation to improve the quality of life of persons with brain and spinal cord injury, and to ultimately find a cure.

In addition to these incredible advances, The Miami Project has a pipeline of major breakthroughs that are currently being developed in the laboratories and will be translated to human trials as quickly and safely as possible.

I am so grateful to all of The Miami Project and Buoniconti Fund supporters who have led us to this moment of achievement. Thank you for everything you have done to change my life and the lives of the millions of paralyzed people around the world who look to The Miami Project for a cure.

Together, let's deliver on my father's promise!

Respectfully,

A handwritten signature in black ink that reads "Marc Buoniconti".

Marc A. Buoniconti
President, The Miami Project to Cure Paralysis
President, The Buoniconti Fund to Cure Paralysis

Living Proof

Twenty-seven years is a very long time to wait for a cure, but it is a very short time to make medical history. With our recent FDA approval, we are now beginning the first phase of our Human Schwann Cell Transplantation Therapy Program for those suffering from spinal cord injury paralysis.

What an incredible accomplishment this is! My son Marc's courage and steadfastness under fire, and the groundbreaking work of our remarkable team of scientists, continue to amaze me and make me want to continue to do whatever I can to help bring about a cure.

Each time I walk into the Lois Pope LIFE Center, the home of The Miami Project to Cure Paralysis, I am awestruck by the overwhelming breadth of research being conducted.

Very soon our doctors will begin to test the first protocol for our Human Schwann Cell Initiative. This is no longer a dream but – living proof. Each of you is the reason for this great scientific advance in the search for a cure. Your support and work have moved this previously impossible process in medical history along. It's been a long, long journey and a tough fight, but our best days are in front of us.

I'd like to thank our dedicated Buoniconti Fund Board of Directors, University of Miami President Donna Shalala, Dean Pascal Goldschmidt of the UM Miller School of Medicine, and all those who have been instrumental in ensuring that The Miami Project's scientific researchers are on their way to cure paralysis.

Your concern for the welfare of others sets you apart. We are fortunate to have you as supporters of The Miami Project and The Buoniconti Fund. You are all living proof that because we stayed strong and resolute, the cure is in reach.

Nicholas A. Buoniconti, Co-Founder
The Miami Project and The Buoniconti Fund

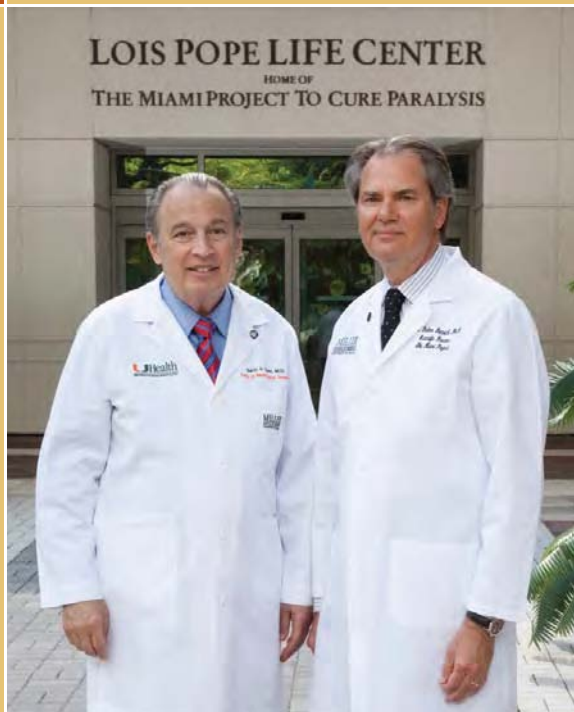


A Letter from Buoniconti Fund Co-Founder Nick Buoniconti



A message from the Chairman and the Scientific Director

Barth Green, M.D., F.A.C.S.
W. Dalton Dietrich, Ph.D.



Dear Friends and Colleagues,

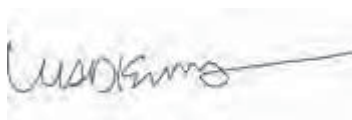
This year promises to be one of the most exciting periods of discovery and translational progress for The Miami Project to Cure Paralysis. Having now received permission from the FDA to initiate a Phase I safety trial in people with subacute spinal cord injury (SCI) using our human Schwann cell transplantation procedures, launches us forward in ways we could only imagine a few short years ago. Therapeutic hypothermia studies continue to move forward and federal funding for a 17-center trial to test the efficacy of early cooling in a large number of individuals with acute spinal cord injury is being requested this year. Basic science discoveries are providing exciting information regarding novel mechanisms of axonal regeneration and combination approaches to promote more complete functional recovery in preclinical models of SCI.

In the area of repair for chronic injuries, the scientific field could not be more exciting. Novel molecules are being identified that can potentially target both intrinsic and extrinsic mechanisms for successful axonal regeneration and provide therapies for the chronically injured subject living with paralysis. Other therapies utilizing new gene therapies are targeting molecules that one day could be used in combination with other therapeutic strategies including human Schwann cell transplantation. Because SCI is a heterogeneous condition, it is envisioned that different therapeutic interventions may be most appropriate depending on the severity of injury and degrees of structural damage. Thus, investigating multiple ways to protect and repair the nervous system is extremely important.

Neurorehabilitation work is also being initiated to be used in future trials as a means to enhance reparative strategies in individuals living with chronic spinal cord injury. A new study has been initiated to establish baseline responses to protocols involving exercise conditioning and neurorehabilitation strategies in the different groups of chronic SCI (complete, incomplete, thoracic, cervical). The potential use of recently developed robotic exoskeleton systems to enhance walking as well as novel brain-machine interface technology could be coupled with our established rehabilitation studies to further enhance function. Thus, the potential merging of biological and engineering approaches to target SCI is a very exciting area of investigation for Miami Project researchers.

We continue to concentrate on quality of life issues which affect people living with paralysis. Our pain group is testing novel therapies and continuing to understand the underlying mechanisms for abnormal sensation in our subjects. New concerns regarding the effects of aging with SCI are prompting our researchers to further target their clinical investigations in this area. Currently, approximately 17 active clinical trials are ongoing in the Lois Pope LIFE Center that are hypothesis-driven programs resulting in new information that is changing the way we think about consequences of spinal cord injury. The Project therefore represents a unique scientific environment by which discovery, translational and clinical research comes together with the ultimate goal of advancing new therapies to protect and promote recovery in our SCI population.

These indeed are exciting times, and we again thank our friends and colleagues for their long-term support and commitment to our program. 2012 is going to be an outstanding year, and we thank everyone for the support of our research program.



W. Dalton Dietrich, III, Ph.D.
Scientific Director
The Miami Project to Cure Paralysis
Kinetic Concepts Distinguished Chair in Neurosurgery
Senior Associate Dean of Discovery Science
Professor of Neurosurgery, Neurology, and
Cell Biology & Anatomy
Vice-Chair for Research, Neurological Surgery
University of Miami Miller School of Medicine



Barth A. Green, M.D., F.A.C.S
Co-Founder and Chairman
The Miami Project to Cure Paralysis
Professor and Chairman, Department of
Neurological Surgery
Professor, Departments of Orthopaedics and
Rehabilitation Medicine
University of Miami Miller School of Medicine

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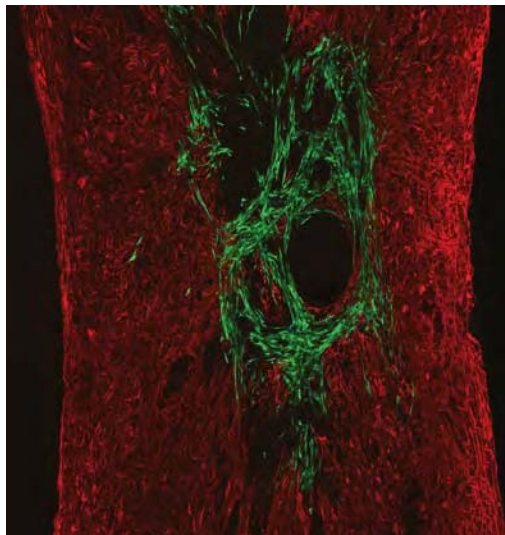
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Mesenchymal Stem Cells: Are they useful for spinal cord injury?

A stem cell is a stem cell is a stem cell...right? Wrong! There are many different types of stem cells. Embryonic stem cells, umbilical cord blood stem cells, fetal stem cells, and adult stem cells from different organs are all different from each other and there are pro's and con's of each in regard to their potential as future cellular therapies for spinal cord injury (SCI). In this article, we are focusing on one type of adult stem cells – mesenchymal stem cells.

- No reliable effect on motor function
- No enhancement of myelin preservation
- No effect on axonal growth into lesion
- No effect on promoting angiogenesis
- No effect on reducing astrocyte reactivity
- No reduction of sensory fiber sprouting or reducing pain hypersensitivity

An easily accessible source of mesenchymal stem cells is from the bone marrow and their normal “job” is to be a continuous source of bone cells, fat cells, and cartilage cells throughout life. They are interesting from a cellular therapy point of view in that you can get them from your own body, i.e. autologous, which reduces the risk of rejection. They are surrounded by controversy, however, in regard to their usefulness as a cellular therapy for repairing SCI. A convincing amount of evidence is coming out, from multiple laboratories, demonstrating that mesenchymal stem cells cannot become neural cells. They may be useful, however, in modifying the injury environment to be more permissive of repair.




Mesenchymal stem cells (green) transplanted into the spinal cord injury site (red) of an experimental animal model.

Modifying the mesenchymal stem cells may be a better approach, however. Promising data, currently under review for publication, suggest that modifying the mesenchymal stem cells to pump out a “super” growth factor is a much better route toward repairing damaged tissue.

Caution should be taken in regard to the stem cell tourism that abounds on the internet. There are many options for buying “stem cell treatments”, bone marrow derived mesenchymal stem cells or others, often costing tens of thousands of dollars. Many times the stem cells derived from bone marrow are not purely mesenchymal stem cells;

rather, they are mixtures of cells which are then processed with unregulated chemicals before being re-injected back into the body. The bottom line is that there have been no stem cell treatments approved as medical care for SCI. Therefore, everything is still experimental, even if it is in a regulated clinical trial. If something is experimental, it means we do not yet know the true risk:benefit ratio, and, therefore, it is unethical to charge people money for such unknown interventions.

From our team's results it appears that bone marrow derived mesenchymal stem cells by themselves are not so great, aside from reducing inflammation. Modifying the mesenchymal stem cells to be “super pumps” appears to be a much more promising route to explore. 

Drs. Dietrich, Bramlett, and Tsoulfas have been collaborating with Dr. Ian McNiece (University of Miami Interdisciplinary Stem Cell Institute) and Drs. Gentaro Kumagai and Satoshi Toh (Hirosaki University, Japan) to generate preclinical evidence demonstrating what bone marrow derived mesenchymal stem cells can do when they are transplanted one week post-injury. It seems that mesenchymal stem cells by themselves primarily act in an anti-inflammatory manner, which may be beneficial as a neuroprotective intervention when administered early after injury. The jury is still out as to whether their anti-inflammatory properties will be beneficial for chronic injuries. The team's animal data demonstrates that unmodified mesenchymal stem cells had:

Mary Bartlett Bunge, Ph.D., Feted for Her Many Accomplishments, Including Renewal of 39-Year-Old Schwann Cell Grant



Dean Pascal Goldschmidt, M.D., Mary Bartlett Bunge, Ph.D. and W. Dalton Dietrich, Ph.D.

Mary Bartlett Bunge, Ph.D., and colleagues, recently learned that the Bunge-Wood-Monje Laboratory's 39-year old NIH grant to investigate Schwann cell biology and transplantation would be funded for another five years.

To commemorate the rare milestone, Bunge's colleagues gathered in the Lois Pope LIFE Center on July 19 to celebrate the grant renewal and her longstanding contributions to The Miami Project's research at the Miller School. Dean Pascal Goldschmidt, M.D., and Miami Project Scientific Director W. Dalton Dietrich, Ph.D., officially presented Dr. Bunge with the Distinguished Faculty Scholar Award medal she was awarded in April but unable to accept in person because of a previously scheduled trip. Drs. Goldschmidt and Dietrich also lauded Bunge's contributions to the field of neuroscience and spinal cord injury as well as to the Miller School.


Over the years, the grant funded all the preparation of Schwann cells, which was used to obtain FDA approval for a Phase I safety trial, and some of the variety of transplantation studies at The Miami Project. A type of "support" cell found mainly in the peripheral nervous system that insulates (myelinates) individual nerve fibers (axons), Schwann cells are necessary for sending appropriate electrical signals throughout the nervous system.

When the grant first started in 1971, it supported some of the seminal work Mary Bunge, her late husband Richard Bunge, Ph.D., and Patrick Wood, Ph.D., pursued to develop purified cultures of Schwann cells, dorsal root ganglion neurons and fibroblasts and their various combinations in order to discern interactions between these cell types.


In their first discovery, they found a mitogenic signal was present on the axonal surface of the Schwann cells. Other studies showed the importance of the extracellular matrix for Schwann cell function. Now at the NIH, Naomi Kleitman, Ph.D., also made important contributions to Schwann cell biology while working with the laboratory. In recent years, Paula Monje, Ph.D., has been an important participant in the grant and helped to acquire funding in the previous cycle. Patrick Wood also has been involved in continuing the grant throughout its duration.

Over the years, the grant received a remarkable three Javits Investigator Awards. Given to scientists for superior research and outstanding productivity, the Javits Award is for seven years of funding, rather than the more typical five years. They provide longer-term support to investigators with a history of scientific achievement and are based on the quality of the proposed work for the next funding cycle. Administered by the National Institute of Neurological Disorders and Stroke (NINDS), the grant also funded the purchase of two electron microscopes.

To inject new energy into the grant, Mary Bunge invited John Bethea, Ph.D., to be co-principal investigator. Miami Project faculty members Paula Monje, Ian Hentall, Ph.D., and Kevin Park, Ph.D., also joined the grant team and added their unique areas of expertise. Dr. Wood will continue to be an important contributor to the grant work.

Acknowledging that it takes a village to do the combination strategy Schwann cell transplantation work, Bunge said the grant renewal shows the village concept continues to work well at The Miami Project. She left the celebrants with the words of an old African proverb she strongly believes: "If you want to go quickly, go alone. If you want to go far, go together." 

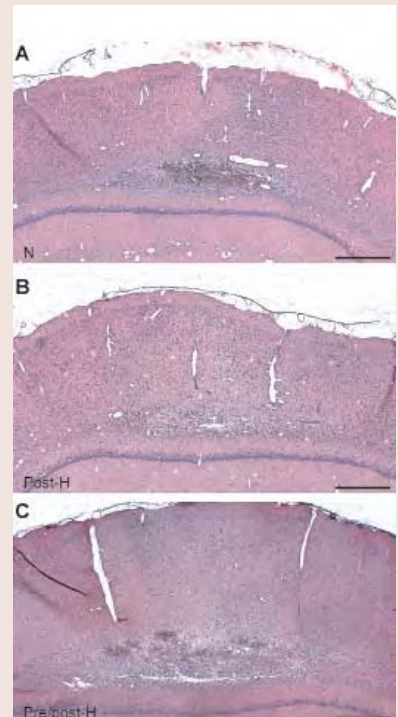
TBI Study Leads to New Funding from the National Football League Charities and Department of Defense for Miami Project Scientists

Recent published observations showing the importance of temperature on the consequences of mild traumatic brain injury (TBI) or concussion have resulted in new funding from NFL Charities and Department of Defense. Dr. Dalton Dietrich and colleagues at The Miami Project to Cure Paralysis, Department of Neurological Surgery including Drs. Helen Bramlett and Coleen Atkins, have reported that raised brain temperature (hyperthermia) before and after a relatively mild head injury converts a mild pathology into a moderate degree of damage. These results indicate that brain temperature may have a critical role in long-term consequences of single or repetitive concussions. The new study that was published in the *Journal of Neurotrauma* (Sakurai et al., 2012) shows that in a rodent model of mild TBI elevated brain temperature (39° C) significantly worsens the amount of histopathological damage (i.e. brain tissue damage). These studies therefore have a high impact in terms of athletes and military personnel sustaining mild concussions in environments with elevated ambient temperatures or when levels of physical exertion increase core temperatures. With the growing concern regarding a link between head trauma and age-related neurodegenerative disorders, these recent observations are extremely important to the field. New funding will support the continuation of these studies and evaluate mechanisms underlying the effects of mild hyperthermia on outcome as well as new therapeutic interventions including therapeutic hypothermia to protect against concussive brain injury. 



Drs. Coleen Atkins, Dalton Dietrich, and Helen Bramlett

Comparison of cortical contusions. There were no significant differences in pathology between the normothermic (A, N) and post-hyperthermic groups (B, post-H) in H&E stained sections. However, larger cortical contusions were noted in the pre/post-hyperthermic (C, pre/post-H) group. Images were taken at bregma level -5.8 mm. Scale bars 300 μ m.



Faculty Spotlight – Allan D. Levi, M.D., Ph.D., F.R.C.S.(C), F.A.C.S.

Dr. Allan Levi has a long history with The Miami Project (TMP), which now spans over 2 decades. After earning his MD, and during his Neurosurgery Residency training at the University of Toronto, he was invited by Dr. Richard P. Bunge to join a team of scientists at TMP who were unraveling the critical steps in bringing human Schwann cell (SC) transplantation to patients with spinal cord injury (SCI). During a three year span culminating in his PhD in 1994 – Dr Levi 1) established that human SC can divide in response to growth factors (heregulins), 2) demonstrated that cultured human SC continued to function normally, including producing myelin, when transplanted in immune deficient animals, and 3) characterized the survival of SC when cooled in transport media – a necessary step in cell transplantation. After his PhD and neurosurgical residency, he completed a spine fellowship as well as further research in primate SC biology at the prestigious Barrow Neurological Institute in Phoenix, AZ.

In 1997, Dr. Levi returned to Miami permanently and started the equivalent of two careers. He began his clinical career in neurosurgery specializing in the surgical treatment of spine and peripheral nerve disorders. In 1998, he became Director of the Neurosurgical Spine Fellowship Program. A year later he took over as the Chief of Neurospinal Services and Co-Director of the Acute SCI Unit at Jackson Memorial Hospital. Then, in 2007, he became the Chief of Neurosurgery at the newly acquired University of Miami Hospital. At the same time he was advancing in his clinical career, he was equally successful in his basic science research career. When he rejoined the University of Miami (UM) in 1997, he also became a staff scientist with The Miami Project to Cure Paralysis. He led a basic science laboratory for 15 years studying human Schwann cell biology, the pathology of human SCI, and the effects of cellular transplantation after SCI in a



Dr Levi seen with the scientific team in 1991– who under the guidance of Drs. Richard and Mary Bunge - were involved in carrying out some of the initial experiments using autologous Schwann cells



Dr Levi returned to become faculty in the department of Neurosurgery and a staff scientist in the Miami Project in 1997



Dr Levi seen with x-rays and the cooling device used for the SCI hypothermia trial which began in 2007


variety of animal models. He trained a number of students, post-doctoral fellows, and neurosurgical residents in the lab. The research culminated in obtaining funding from the National Institutes of Health to help further advance studies related to Schwann cell regeneration.

Dr. Levi also began doing more clinical research involving topics such as robotics in neurosurgery, artificial cervical disc technologies, characterizing SCI syndromes, and pioneering certain aspects of minimally invasive spine surgery techniques. By 2007, he was a fully tenured Professor in Neurosurgery and began evaluating the safety and efficacy of therapeutic hypothermia as a neuroprotective treatment for severe SCI. Over the last 6 years as Principal Investigator (PI) on the hypothermia clinical trial for acute SCI – over 35 patients have been treated leading to 3 original publications.

Now, in 2012, Dr. Levi has been appointed the Robert M. Buck Distinguished Chair in Neurological Surgery. He is “retiring” his basic science laboratory so he can focus more of his efforts on clinical trials. Dr. Levi is Co-PI, along with Dr. James Guest, of the recently FDA approved Phase I clinical trial evaluating “The Safety of Autologous Human Schwann Cells (ahSC) in Subjects with Subacute

Spinal Cord Injury”. He is also continuing the therapeutic hypothermia clinical trial and, along with his colleagues Drs. Michael Wang, Steve Vanni, and Barth Green, expanding towards prospective, randomized multi-center trials.

What you might not know about Dr. Levi is that he is an avid long distance runner – working towards his 10th marathon in the upcoming Washington Marine Corp. Dr. Levi has also helped lead the UM neurosurgical residents and fellows to New York City for the last 3 summers to compete in a national soft ball tournament – last year they brought home the championship, rising above the 27 other university-based teams from across the U.S.

Dr. Levi counts himself as having been enormously fortunate to have worked for the last 20 years in an environment in which the basic sciences and clinical care/research are so seamlessly integrated. The resources from The Miami Project, The Buoniconiti Fund, and the Department of Neurosurgery have helped facilitate the groundbreaking research and, most importantly, the journey would not have been possible without exceptional mentors such as Drs. Tator, Bunge, Sonntag, Dietrich and Green. 



Dr. Allan Levi, Buck Distinguished Chair

One of the great advances in modern medicine has been the development of biomarkers for specific human diseases. In medicine, a biomarker is typically a protein that can be measured from bodily fluid, such

Predicting Injury Severity and Tailoring Clinical Management – The Realm of Biomarkers


as blood, whose concentration levels can be used to predict the severity or presence of a diseased state. Biomarkers allow doctors to detect a disease early, monitor its progress, predict its severity, and tailor treatments to any specific patient's problem. Examples of clinically relevant biomarkers in current use include the monitoring of cholesterol to manage cardiovascular disease and the measuring of prostate-specific antigen levels to detect and track prostate cancer.

In the spinal cord injury (SCI) arena, early predictors of injury may have important diagnostic and prognostic significance, helping to detect the presence and severity of injury within the first few hours and to aid physicians in directing the best patient care in a timely manner. The diagnostic value of this would be very powerful since the current gold standard of early magnetic resonance imaging (MRI) remains limited. It is not always available in the emergency setting, cannot be used for patients with metal implants or shrapnel, remains of limited utility for predicting the degree of neural injury, and cannot be repeated in a real time fashion to track the progress of an injury or the effect of a medical or surgical therapy. The prognostic value of improved biomarkers for SCI may be particularly important given the length of time people with SCI have to be monitored clinically to detect any neurological improvement.

For researchers, a SCI biomarker may give early insight into the effects of experimental treatments, speeding study results and reducing the research subjects sample sizes needed. Over the past two years, a team of Miami Project and Neurosurgery Department

researchers (Drs. Ross Bullock, Michael Wang, Helen Bramlett, Dalton Dietrich, Robert Keane, Pablo de Rivero Vaccari, and Stephanie Adamczak) have been investigating the use of surrogate biomarkers to predict the outcome of acute SCI in a study sponsored by Banyan Biomarkers.

In this study, blood and spinal fluid samples were obtained from 7 newly injured people who were already undergoing spinal fluid drainage as a part of their necessary clinical treatment. The presence of several breakdown products from spinal cords tissue or inflammatory mediators were found to be elevated in blood and cerebrospinal fluid at early time points after injury. Similar results were observed in a rat model of SCI. Samples indicating severe neural damage were found to be correlated with the degree of neurological impairment as well as native recovery. In other words, higher levels of these breakdown products circulating in the blood or cerebrospinal fluid were predictive of less recovery. The team's preliminary results, and that of others, suggests that a panel of spinal tissue structural protein breakdown products have potential as promising biomarkers in an animal SCI model and in humans with SCI.

This study may reveal keys to early interventions for acute SCI. Ultimately, biomarkers may be used to tailor the intervention (surgical, pharmacologic, rehabilitation) to each individual SCI patient, much as cancer phenotyping is beginning to be used to target chemo- and immunotherapies, as well as to identify candidates for clinical trials targeting acute neuroprotection. 



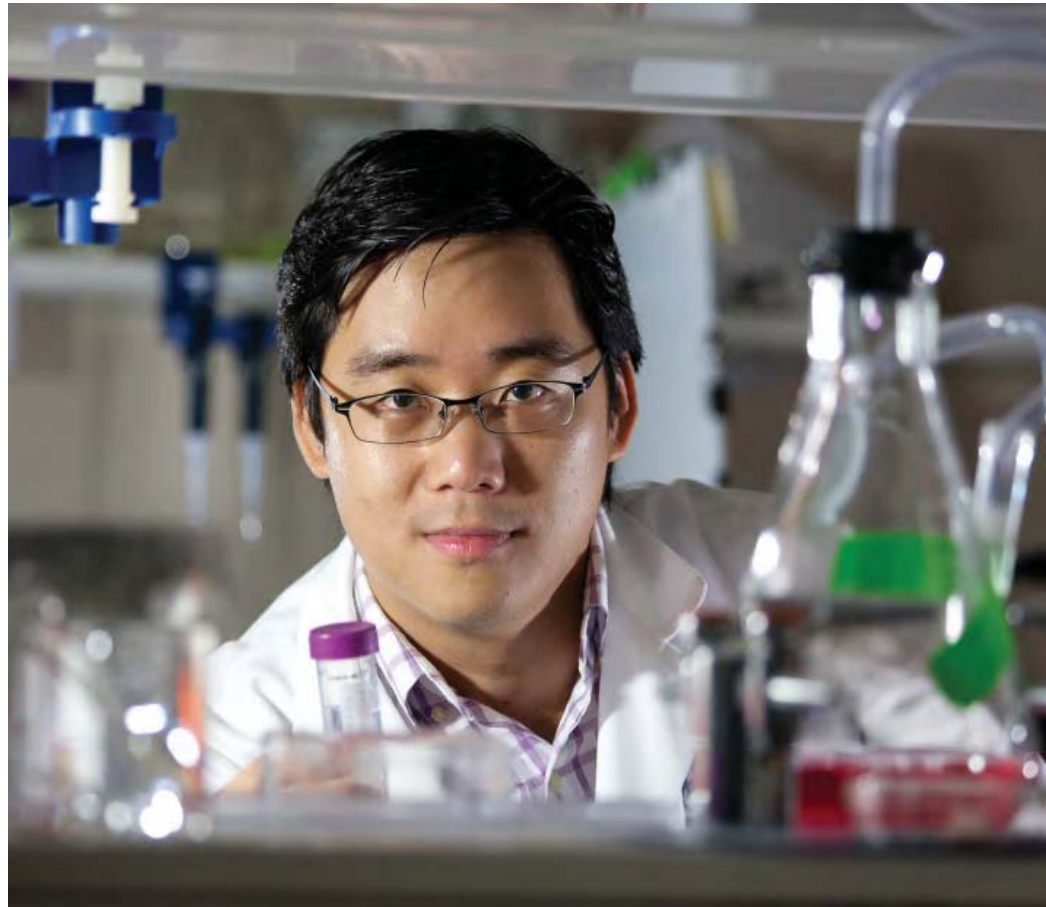
Dr. Pablo de Rivero Vaccari in the laboratory evaluating biomarker data

Dr. Kevin K. Park Selected as 2012 Pew Scholar in The Biomedical Sciences

Twenty-two of the nation's most innovative young researchers, including Miami Project to Cure Paralysis' Dr. Kevin Park, were recently named Pew Scholars in the Biomedical Sciences by The Pew Charitable Trusts. The Scholars join a prestigious community that includes Nobel Prize winners, MacArthur Fellows, and recipients of the Albert Lasker Medical Research Award.

"Damaged nerves in the central nervous system, like those found in the spinal cord and optic nerve, do not inherently re-grow, causing permanent loss of motor and sensory functions. My research explores strategies to stimulate injured nerve fibers to re-grow and reconnect to their targets, with hopes of restoring these lost functions. As a researcher, being named a Pew Scholar is a tremendous honor," said Dr. Park. "The award reflects the outstanding research environment and support I have received as a principal investigator at the University of Miami Miller School of Medicine's Miami Project to Cure Paralysis, which has allowed my work to be carried out and be acknowledged by the Foundation. The award will provide not only resources to perform research into promoting nerve regeneration, but also allow irreplaceable opportunities to interact with other young investigators."


The new class of scholars is exploring a range of human health issues from antibiotic-resistant infections to liver disease and cancer. Launched in 1985, the Pew Scholars Program in



Dr. Kevin K. Park

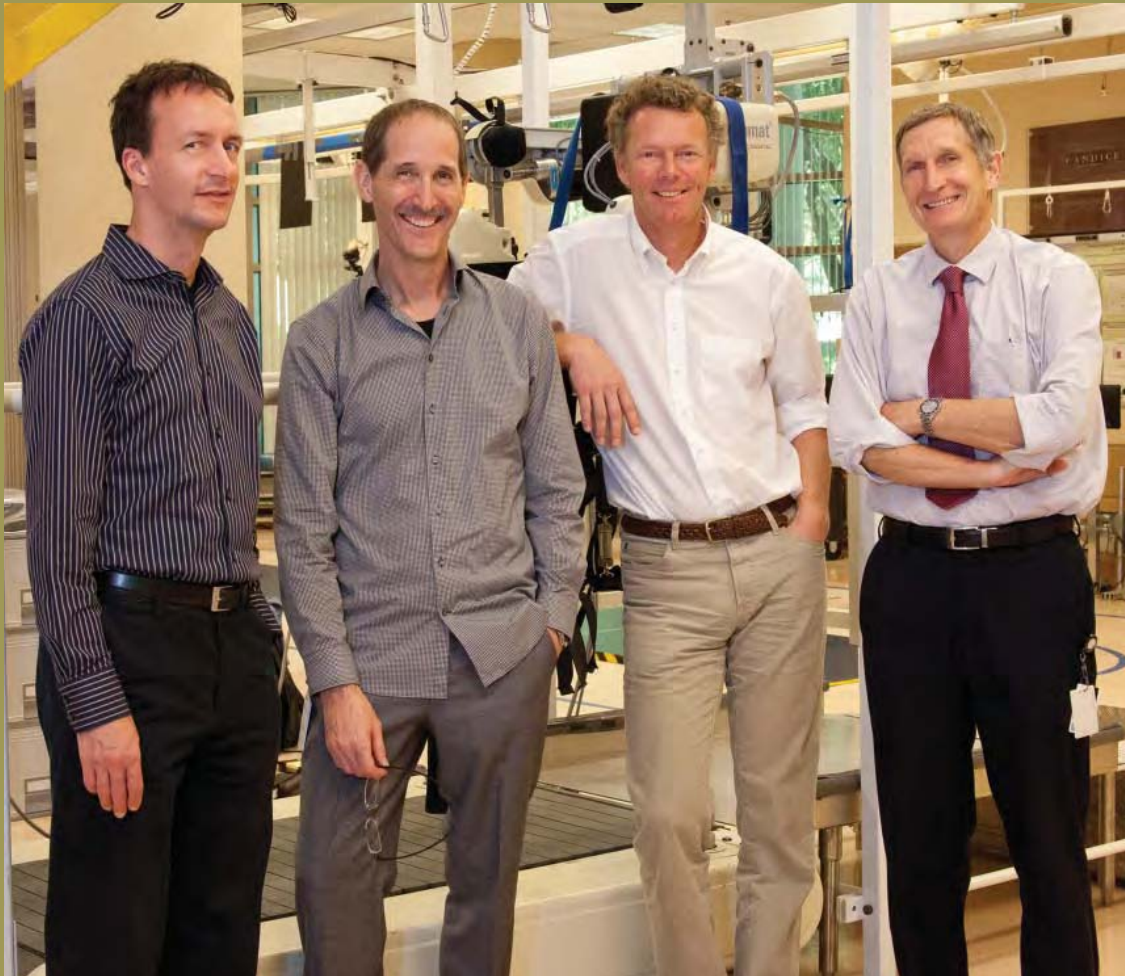
the Biomedical Sciences identifies and invests in talented researchers in medicine or biomedical sciences. In that time, over 500 Pew Scholars have received more than \$130 million in funding. By backing them early in their careers, this program enables our most promising scientists to take calculated risks and follow unanticipated leads to advance human health.

"During these challenging budgetary times when traditional sources of funding are becoming even harder

for scientists to obtain, we are proud to back our country's most promising scientists," said Rebecca W. Rimel, President and CEO of The Pew Charitable Trusts. "This funding comes at points in the Scholars' professional lives when they often are the most innovative. While this program is a bold investment for us, it has paid incalculable dividends due to our Scholars' record of producing groundbreaking research." 

Miami Project - Miller School Researchers Receive \$2.5 Million Grant to Create Database for Nerve Regeneration and Protection

"For example, in our experiments, we might find a class of genes whose expression changed dramatically after injury. By using RegenBase, we may find these same genes were implicated in neuroprotection, so we could search for compounds that inhibit the activity of the proteins that are coded for by these genes, and test to see if they prevent cells from dying, or improve regeneration. RegenBase will help us open that door."



Stephan Schürer, Ph.D., Vance Lemmon, Ph.D., Ubbo Visser, Ph.D. and John L. Bixby, Ph.D.

With the ultimate goal of accelerating the discovery of drugs to regenerate or protect nerves after spinal cord injury, Miller School researchers have received a \$2.5 million grant to develop a novel database to enable neuroscientists to search the voluminous and growing number of studies related to nervous system repair, and link relevant data from those studies to other resources. “Right now there is no simple way, short of spending years reading papers, to find genes that have been linked to nerve regeneration, which is the ultimate goal of spinal cord and nervous system research,” said the NIH grant’s principal investigator, Vance Lemmon, Ph.D., Professor of Neurological Surgery, the Walter G. Ross Distinguished Chair in Developmental Neuroscience and member of The Miami Project to Cure Paralysis research faculty. “There are just too many studies for investigators to keep up with, so we need ways to allow them to much more efficiently search the literature and find information relevant to spinal cord injury. That’s what we propose to do.”

The four-year grant, which the National Institute of Neurological Disorders and Stroke awarded to Lemmon and co-principal investigators John L. Bixby, Ph.D., Professor of Molecular and Cellular Pharmacology and Neurological Surgery and fellow Miami Project member, Stephan Schürer, Ph.D., Research Assistant Professor of Molecular and Cellular Pharmacology, and Ubbo Visser, Ph.D., Associate Professor of Computer Science, solidifies UM’s growing reputation as the go-to institution for the development of chemoinformatics tools and ontologies that allow massive and diverse data sets to be integrated, queried, interpreted and analyzed across multiple disciplines.

Tentatively called RegenBase – for Regeneration Database – the proposed knowledge-based system will incorporate and build on the BioAssay Ontology that Schürer, Lemmon and their team of UM programmers and computer scientists developed with a federal stimulus grant to enable chemists and biologists on the hunt for new therapeutic agents to quickly search huge repositories of thousands of experiments on hundreds of thousands of small-molecule compounds.

Until the BioAssay Ontology was released into the public domain last year, the value of such chemical compound repositories to the drug discovery process was limited

because researchers could not easily search, compare or query their voluminous data sets, nor integrate them with other data sources.

RegenBase is designed to remove the same roadblocks scientists encounter while searching the diverse data produced by neuroscientists and cell biologists studying nervous system injury, disease and cell motility, all


“One of the goals is to allow us to find compounds that are active on specific genes or proteins and then use those in new experiments on regeneration and protection,”

with the hope of regenerating nerve function and promoting nerve protection. Currently, their efforts are slowed by the difficulty of collecting, analyzing, and displaying information from thousands of different experiments conducted on nervous system injury and interpreting them based on knowledge from other areas,

such as genomics, cell biology, cancer, immunology and drug discovery.

To resolve that issue, the UM team plans to link RegenBase with the BioAssay Ontology, as well as other biomedical domain-level ontologies, which will allow scientists anywhere in the world to link data and results from studies on gene expression in nervous system injury and disease to data and knowledge from other domains that emphasize molecular targets and small molecules that perturb their function, ultimately speeding the development of novel therapeutics.

“One of the goals is to allow us to find compounds that are active on specific genes or proteins and then use those in new experiments on regeneration and protection,” Lemmon explained. “For example, in our experiments, we might find a class of genes whose expression changed dramatically after injury. By using RegenBase, we may find these same genes were implicated in neuroprotection, so we could search for compounds that inhibit the activity of the proteins that are coded for by these genes, and test to see if they prevent cells from dying, or improve regeneration. RegenBase will help us open that door.”

Underscoring UM’s growing prominence in chemoinformatics, the BioAssay Ontology project, which is ongoing, was recently leveraged into a new NIH-funded collaboration with scientists at Harvard, The Broad Institute, Columbia, Yale and the University of Arizona to incorporate more molecular and biochemical data from the Library of Integrated Network-based Cellular Signatures (LINCS) program. 



THE MIAMI PROJECT WANTS YOU!

Join SCI Boot Camp

We want you to “be all you can be”! As we launch into the era of reparative clinical trials for spinal cord injury (SCI) many of you have noticed the lack of trials for those living with chronic SCI. The reasons for this are many fold, as explained in previous communications from us. However, *trials targeting chronic injury are certainly on the near horizon*. We need to know a few things first, though. Let’s take Schwann cell transplantation as an example. Administering Schwann cells involves an inpatient surgical procedure on the spinal cord. Someone with a chronic SCI may have a more difficult time with anesthesia and recovering from surgery than someone newly injured. Also, once the Schwann cells (or combination of treatments) begin to repair the spinal cord damage, atrophied muscles may not be able to respond to new input. Hence, we need to prepare people with chronic injuries for these types of situations.



Scott Roset and Kelly Ginnity training a research volunteer in the Ekso Bionics exoskeleton walking device


Clinical research faculty include (left to right) Drs. Kim Anderson-Erisman, Edelle Field-Fote, Nancy Brackett, Eva Widerstrom-Noga, Justin Sanchez, Mark Nash, Rachel Cowan, and Christine Thomas

Enter the idea of “Boot Camp”. Boot Camp is the concept, coined by Scientific Director Dr. Dalton Dietrich, of combining proven, individual clinical disciplines into a multi-disciplinary program designed to maximize the fitness and neurologic function of individuals with chronic SCI prior to enrolling in reparative clinical trials. In addition to monitoring changes in fitness and neurologic impairment, it is also important to evaluate changes in global function, neuromuscular physiology, spasticity, sensation, pain, autonomic function, and mobility. The Miami Project is the ideal center to lead this work as we have clinical research faculty members that are experts in each of these areas (see Table 1).

Table 1

Faculty Member	Expertise
<i>Dr. Kim Anderson-Erisman</i>	Global function, consumer priorities
<i>Dr. Nancy Brackett</i>	Autonomic dysfunction, male fertility
<i>Dr. Rachel Cowan</i>	Mobility skills, biomechanics
<i>Dr. Edelle Field-Fote</i>	Neurorehabilitation, neural plasticity
<i>Dr. Mark Nash</i>	Exercise conditioning, metabolism
<i>Dr. Justin Sanchez</i>	Bioengineering, neuroprosthetics
<i>Dr. Christine Thomas</i>	Neuromuscular physiology, spasticity
<i>Dr. Eva Widerström-Noga</i>	Sensation, neuropathic pain

Boot Camp will involve many studies as we’ll need to develop different “priming” protocols for complete thoracic injuries versus complete cervical injuries versus incomplete injuries. Dr. Anderson-Erisman will be heading up one of the first studies targeting complete thoracic injuries. In this study, we will combine upper extremity exercise, lower extremity electrical stimulation, and upright locomotor rehabilitation. The results will enable us to define the minimum amount of exercise and rehabilitation needed to bring individuals with chronic complete thoracic SCI to a “level playing field” and understand how this influences global function, neuromuscular physiology, spasticity, sensation, pain, autonomic function, and mobility. We will use the results to design our next clinical trial transplanting Schwann cells into chronic injuries. Dr. Field-Fote will be heading up a study aimed at improving the effect of locomotor training in incomplete versus complete chronic injuries by adding whole body vibration. Dr. Nash will be heading up another study evaluating the usefulness of robotic exoskeletons for enhancing fitness, rehabilitation, and mobility. We will use results from all of these studies to design exercise and rehabilitation add-ons for future reparative clinical trials.

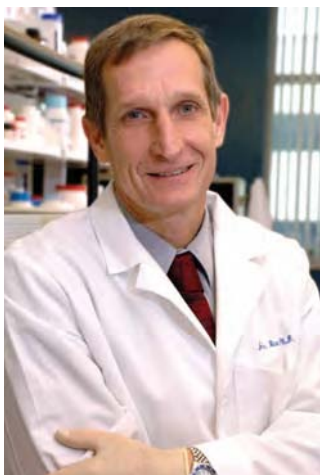
Just like boot camp is a strenuous challenge for our military men and women, so it will be for our community with chronic SCI. The different studies will involve a large time commitment for the participants and research personnel, but we value all of their efforts and dedication. The end results will help us design the best possible reparative clinical trials for individuals with chronic SCI. Contact the Education Department to “enlist”! 

FACULTY notes



Mark S. Nash, Ph.D. FACS

Mark S. Nash, Ph.D. FACS, has been named the 2012 Apple Award winner by the American Spinal Injury Association (ASIA). The award is named after David F. Apple, M.D., founding member and past-president of ASIA, as well as Medical Director Emeritus at the Shepherd Center (Atlanta), and is awarded annually for publishing excellence in spinal cord injury rehabilitation research. The award was presented to Dr. Nash in April at the Annual ASIA Scientific Conference, along with a crystal sculpture commissioned for the occasion. Dr. Nash will also keynote the Annual Research Day at the Shepherd Center in the fall.



John Bixby, Ph.D., was recently appointed Vice Provost for Research. Dr. Bixby will work closely with research deans on all UM campuses to advocate and build support for our research mission. In addition, he will have oversight of research compliance, research misconduct, conflicts of interest, and the faculty conflict disclosure process.



John Bixby, Ph.D., and **Vance Lemmon, Ph.D.**, received a four year, \$2.5 million grant from the National Institutes of Health / National Institute of Neurological Disorders and Stroke (NIH / NINDS). Their project is titled: Regenbase: A Searchable Database to Organize Regeneration Knowledge via Ontologie. The overarching goal of this proposed RegenBase (Regeneration dataBase) system is to allow scientists to link data and results from studies on nervous system injury and disease to data and knowledge from other domains with an emphasis on molecular targets and the small molecules that perturb their function to speed the development of novel therapeutics.

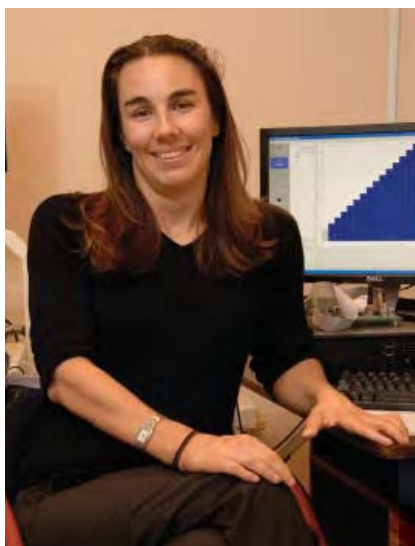
Edelle C. Field-Fote, Ph.D., P.T., was honored by the American Physical Therapy Association with the 2012 Maley Lecture Award. The intent of this award is: "To acknowledge and honor a physical therapist who has made a significant contribution to the profession in the area of clinical practice." Dr. Field-Fote also has been named a Trustee of the Foundation for Physical Therapy at this year's American Physical Therapy Association annual meeting. She was also honored with the 2012 Chattanooga Research Award. This award honors an author whose publication demonstrates a significant contribution to the science of physical therapy based on excellence of research design and the potential impact on practice.

Mary Bartlett Bunge, Ph.D., recently gave a talk at the Reeve Irvine Research Center.

Ian Hentall, Ph.D., and colleagues, recently published, *Promotion of recovery from thoracic spinal cord contusion in rats by stimulation of medullary raphe or its midbrain input* in the journal *Neurorehabilitation and Neural Repair*. *Intraspinal transplantation of GABAergic neural progenitors attenuates neuropathic pain in rats: a pharmacologic and neurophysiological evaluation* in *Experimental Neurology*, and *Fluorescent reporters of monoamine transporter distribution and function* in *Bioorganic & Medicinal Chemistry Letters*.



Juan Pablo de Rivero Vaccari, Ph.D., was selected as a recipient of a 2012 American Association of Immunologists (AAI) - Minority Scientist Travel Award for travel to the 99th AAI Annual Meeting that was held in Boston, MA.



Rachel Cowan, Ph.D. was recently a Distinguished Visiting Scholar at the International Collaboration on Repair Discoveries (ICORD) meeting in Vancouver, British Columbia. She was also named a scientific committee member at the North American Federation of Adapted Physical Activity 2012 Conference, and

was accepted to the 2012 American College of Sports Medicine Level 3 Leadership & Diversity Training Program. Dr. Cowan also presented “*Exercise is Medicine for Underserved Populations: Challenges and Opportunities*” at the 2012 American College of Sports Medicine Annual Meeting and 3rd World Congress on Exercise is Medicine in San Francisco, California.

Damien Pearse, Ph.D., received a \$420,750 grant from the National Institutes of Health / National Institute of Neurological Disorders and Stroke (NIH / NINDS). The work is titled *Therapeutic Targeting of Intracellular Mechanisms Involved in Glial Scar Formation*.



The proposed work will define, through molecular manipulations, a role for the cyclic AMP phosphodiesterase signaling cascade in astrogliosis, a pathway known to play a central role in the cellular reactivity and pathological functioning of other cell types such as immune cells, as well as provide a novel therapeutic direction for glial scar ablation.

Nancy L. Brackett, Ph.D., HCLD, received a Craig H. Neilsen Foundation grant to research *Improving reproductive function in men with spinal cord injury*. The outcome of the study will lead to improved fertility in men with SCI, as well as contribute fundamental new knowledge regarding the biology of sperm and their motility.

Daniel Liebl, Ph.D., received a Craig H. Neilsen Foundation grant to study *A novel mechanism to block oligodendrocyte cell death following SCI*. This study will examine the role of dependence receptors in cell death after spinal cord injury, and take advantage of genetic modifications in mice to demonstrate the importance of these proteins. They hope to provide evidence that will provide a thorough understanding of mechanisms that regulate cell loss after injury and develop a therapeutic strategy to improve recovery in SCI patients.

Kevin Park, Ph.D., received a Craig H. Neilsen Foundation grant to study *Novel combinatorial approaches to promote axon regrowth after chronic SCI*.

Mousumi Ghosh, Ph.D. a postdoctoral associate in Dr. Damien Pearse’s lab received a Paralyzed Veterans of America (PVA) Research Foundation grant to study *Down-regulating PDE4A in Astrocytes to promote axon regeneration after SCI*.

Gillian Hotz, Ph.D., has been granted extensions on three of her current Florida Department of Transportation Safe Routes to School Program (FDOT/SRTS) grants for one more year, a total sum of \$450,000. Her BikeSafe Program received a \$1,500.00 donation recently from the Everglades Bike Club. Dr. Hotz was nominated to a two year post for the SRTS/National Partnership Steering Committee. She chaired the Concussion Task Force that advocated for the passing of concussion legislation in the State of Florida. She collaborated with IMPACT Sports Performance to manage concussions for Florida Scholastic Hockey League, the Florida Youth Soccer Association and the American Youth Football League to assist them with their concussion management programs.

Jessica Ashbaugh, a student of **John R. Bethea, Ph.D.**, received an award from the American Association of Immunologists to attend their annual meeting in May.

What began
as an idea
is now a
reality

Picture of human Schwann cells in the final product generated from the sural nerve of an organ donor. The final product is of high purity and similar cells from a subject with spinal cord injury would be suitable for clinical transplantation.

Back in 1975 Dr. Richard Bunge had an idea, “to use a person’s own cells to repair damaged spinal cord tissue”. He shared that idea with Drs. Mary Bartlett Bunge and Patrick Wood and together they began a scientific journey. Fast forward 37 years and here we are with United States Food and Drug Administration (FDA)



Drs. Richard and Mary Bunge at the electron microscope (1991)

approval to begin testing the safety of injecting Schwann cells into humans with spinal cord injury (SCI). This was not just a journey of three people; it was literally a growing village. For 33 years, multitudes of scientists contributed to building our knowledge of the basic biology of Schwann cells and discovering how they can be utilized to facilitate repair of damaged tissue.

In 2008, we took the first step toward translating Schwann cells from the basic science laboratory to the clinic. We began generating all of the pre-clinical safety and efficacy data to justify the testing of Schwann cell transplantation in humans. This incredible effort was led by Drs. Mary Bartlett Bunge, Dalton Dietrich, James Guest, Allan Levi, Damien Pearse, and Patrick Wood. Dr. Mary Bartlett Bunge spearheaded investigations to evaluate the ability of Schwann cells to repair spinal cord damage in animal models for many years. Dr. Patrick Wood led the Chemistry Manufacturing and Control (CMC) studies to develop a human Schwann cell product manufacturing process. Dr. Damien Pearse took the lead on conducting the pharmacology, toxicology, and tumorigenicity studies in rodent models, while Dr. James Guest did the same with our pig model to develop procedures for safely injecting different doses of Schwann cells into the spinal cord. The team of individuals working in our Animal Core facility, run by Dr. Alex Marcillo, enabled us to take on the massive

work load required to generate the extra data to submit to the FDA. Input from Dr. Donna Avison, a university veterinarian who works closely with our researchers, was invaluable during this process. Drs. Allan Levi, James Guest, and Diana Cardenas added their multi-disciplinary clinical expertise to develop the Phase I clinical trial. Mr. Anil Lalwani and Dr. Kim Anderson-Erisman were responsible for pulling all of the different components together for the Investigational New Drug (IND) application. Finally, Dr. Dalton Dietrich, our Scientific Director, assumed responsibility for the entire clinical trial as the Sponsor.

In 2011, that first step was completed when in September 2011 we submitted an IND application to the FDA requesting permission to begin a Phase I clinical trial to evaluate the safety of autologous human Schwann cell transplantation in sub-acute SCI. At that point we began the second step in this process to obtain FDA approval. From October 2011 through July 2012 our team worked with the FDA to answer all questions and clarify all of our data. It was a long process, but by teamwork we were able to achieve success. On July 26, 2012 we had a wonderful



Drs. Damien Pearse and Mary Bunge

conversation with the FDA during which they released us from clinical hold. The second step was complete! Now, we are moving on to the third step, conducting a Phase I clinical trial to determine the safety of transplanting autologous Schwann cells.

What will the trial involve?

After we receive human subject research approval from the University of Miami Institutional Review Board, a potential research subject would be someone with a T3 to T11 motor and sensory complete SCI. The person would have to agree to participate within 5 days after his/her injury, which is considered the acute phase. At that point, he/she would undergo a biopsy of a nerve in one leg to obtain his/ her Schwann cells. The Schwann cells then need to grow in a culturing facility for 3 to 5 weeks to multiply in number and undergo purification. By the time the Schwann cells are actually transplanted into the site of SCI, the participant would actually be 26-40 days post-injury, which is considered the sub-acute phase. All procedures would be conducted in Miami at The Miami Project, the University of Miami Hospital, and at Jackson Memorial Hospital. We will be following participants for 1 year after the transplantation surgery and evaluating their neurologic status, medical status, pain symptoms, and muscle spasticity very closely.

What is the goal of the clinical trial?

Safety. The goal of every phase I clinical trial is to demonstrate safety. We have designed a clinical trial that will minimize risk and maximize evaluation of safety. First, we hope to demonstrate that we can insert a needle into the center of the spinal cord injury site without causing any damage. Second, we hope to demonstrate that transplanting one's own Schwann cells into the thoracic cord does not cause additional damage.

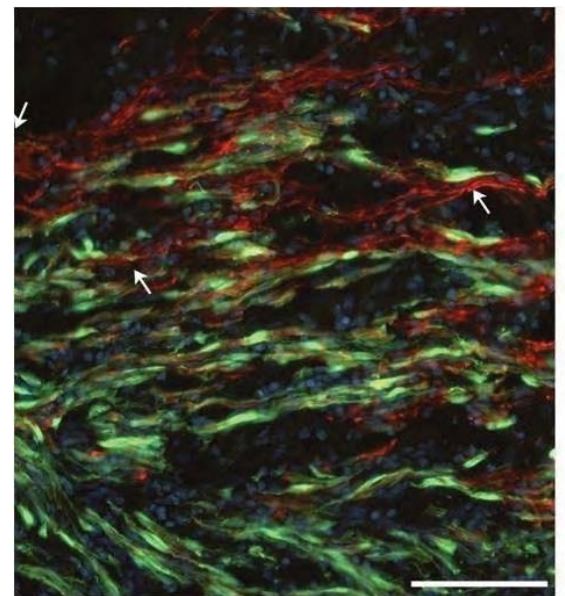
How long will it take to complete this trial?

It could take 2-3 years from the time we enroll the first subject until the final subject is 1 year post-transplantation. There are many reasons for this. 1) Only about 25% of all spinal cord injuries are between T3-T11 and, of those, many sustain additional trauma during the accident, which will exclude them from this particular trial. 2) For the first 2 subjects, there is a 1 month waiting period between the time of transplantation surgery and enrollment of the next subject; this leads to about 2 ½ - 3 months between enrollments. Realistically, it could take 7 ½ - 9 months to enroll and transplant the first 3 subjects in the trial. After that, we can enroll 1 subject each month. So, best case scenario, it could take 12 – 15 months to get all 8 subjects enrolled and transplanted. 3) Each subject will be followed for 1 year following the transplantation procedure to analyze safety. Therefore, it could take 2 – 2 ½ years from enrolling the first subject to collecting the final data from the last subject. The data will then need to be analyzed and submitted to the FDA.

Is this a cure for paralysis?

No, Schwann cells by themselves will not cure all of the damage caused by SCI. The spinal cord is a very complex organ, after all it, in combination with the brain, controls every single aspect of our body. Hence, when the spinal cord sustains damage people lose more than just the ability to walk. Aside from the loss of movement and sensation, almost every single SCI results in the loss of bladder and bowel control. Depending on where in the spinal cord the injury occurs, there may be additional impairments in sexual function, loss of the ability to regulate body temperature and blood pressure, reduced breathing and coughing capacity, and inefficient metabolism of food.

Inside the spinal cord, there is a multitude of damage. First, there is primary damage. In regard to traumatic injury, the primary damage is a direct result of the impact of whatever caused the injury (eg. fall, gunshot, car crash, etc.). Second, waves of biological events are triggered by the primary damage that ends up causing secondary damage. The main




Pig Schwann cells (green) transplanted into the spinal cord injury site, 3-4 weeks post-injury, interacting with axons (red).

contributor to the secondary damage is the immune system. The end result is that spinal cord tissue around the site of injury that was not damaged by the primary impact ends up dying. Third, cells die in and around the injury site. These include motor nerve cells (motoneurons), sensory nerve cells (sensory neurons), relay nerve cells (interneurons), and multiple types of support cells called “glia” (astrocytes, oligodendrocytes). Fourth, individual nerve fibers (axons) running up and down the spinal cord get severed. The cell bodies of these severed axons are located away from the injury site and often remain alive; however, they can no longer communicate. Fifth, inhibitory scar tissue develops around the injured area.

So, it does not make sense then, to expect one intervention to be able to repair all the different types of damage that occur and restore all of the different functions that are impaired. Schwann cells are one component of a multi-faceted cure.

The Future

This specific clinical trial will not include chronically injured people. We are currently conducting more animal chronic transplantation preclinical studies and we will soon begin a combined upper extremity exercise and locomotor rehabilitation study for chronically injured people to determine the minimum exercise and rehabilitation needed to prepare people for transplantation surgery and to ensure that they are neurologically stable. We will take all of those data and design another clinical trial specifically for people with a chronic injury. We will submit that in addition to safety data generated by the sub-acute trial to the FDA for approval.

Think of this as our building block to developing the most effective treatments for people living with SCI. The best way for anyone to get access to these treatments fastest is to keep healthy and in very good condition so that he/she can qualify for clinical trials as they become available. We are dedicated to moving basic science discoveries forward into clinical trials. As we discover promising treatments in the laboratories we will move them into Phase I and II clinical trials where they can be thoroughly evaluated. 



The group of faculty, research staff, and administrative staff that were essential to our successful IND application to the FDA for our Phase I safety trial of Schwann cell transplantation in humans with subacute spinal cord injury



Twenty-Sixth Annual Great Sports Legends Dinner



2011 Great Sports Legends and Honorees

Sports legends, celebrities, philanthropic heroes and corporate leaders came out in force again in support of Nick and Marc Buoniconti and The Buoniconti Fund to Cure Paralysis for the 26th Annual Great Sports Legends Dinner, presented by Phil Knight of Nike, and Chaired by long-time supporter Mark Dalton. The sold-out celebration, held each year at the New York City's famed Waldorf=Astoria, benefits The Buoniconti Fund to Cure Paralysis and raised more than \$10 million to support the ground-breaking spinal cord injury research being done by researchers at The Miami Project to Cure Paralysis in the Lois Pope LIFE Center at the University of Miami Miller School of Medicine.

Sports Broadcasting Legend **Bob Costas** returned as the Master of Ceremonies for the fourth year in a row and the evening's honorees included legendary Coach **Don Shula** who received the 2011 Buoniconti Fund Award and **Jerry Rice** who was honored with the 2011 Humanitarian Award. The 2011 Great Sports Legends included **Ernie Els, Chris Mullin, Andre Dawson, Harry Carson, Clark Gillies, John Force and Nancy Kerrigan**.

"After 26 years of coming together with legendary figures to stand up for those who can't, we are closer than ever to finding a cure for paralysis," said Nicholas A. Buoniconti, Co-Founder of The Buoniconti Fund and The Miami Project. "What started out as a promise to my son has been transformed into a promise from our family and researchers to the millions of people around the world affected by paralysis."



Coach Don Shula, Nick and Marc Buoniconti



Bob Costas and Nancy Kerrigan



Mark Dalton, Liezl and Ernie Els

Notables in attendance included: Mr. Las Vegas Wayne Newton, 10 time Olympic medalist and track and field legend Carl Lewis; long jump Olympic gold medalist Bob Beamon; hockey hall of famer and NY Rangers Legend Rod Gilbert; former Miami Dolphins 17-0 quarterback Earl Morrall; NY Giants football great Brian Kelley; three time world boxing champion Carlos Ortiz; Olympic gold medalist in swimming Janet Evans; former Miami Dolphins Pro Bowl wide receiver Nat Moore; pioneering sportscaster from CBS Lesley Visser; former Miami Dolphins player Dick Anderson; Hall of Famer, NBA champion and finals MVP Rick Barry; Olympic four man bobsledding gold medalist Steve Holcomb; Tony Winning Broadway Legend Michael Cerveris; Former NY Giant and ESPN Sports Analyst Jesse Palmer; former NY Giants receiving great Amani Toomer; former MLB All Star and World Series Champion pitcher Scott Erickson; sports personality, actress, host and model Lisa Guerrero; star of the HBO series *Luck* Richard Kind; former Super Bowl MVP from the Redskins, Mark Rypien; and so many others.

The Legends and celebrities walked the red-carpet into a luxurious evening that included Tiffany & Co.'s Mystery Blue Box Wall and a Buy It Now Store where attendees purchased one of a kind sports memorabilia and other unique items. The auctions raised more than \$800,000 and proved a thrilling experience with participants competing for larger than life experiences, including a once in a lifetime opportunity to play in a foursome with golfing legend Jack Nicklaus at the Tenth Annual Buoniconti Fund Celebrity Golf Invitational, Azamara Club Cruises International Trip for Two, BMW 328i Sedan, Soccer Game for Two and a 4.6 karat diamond Bracelet; and a luxury package to the 2012 Summer Olympic Games in London. A surprise gift of \$1 million was given by Buoniconti Fund Board Member James Ferraro for the Human Clinical Trial Initiative.

Since the Great Sports Legends Dinner was created in 1985, the event has honored more than 286 sports legends and honorees and raised more than \$75 million for The Miami Project's spinal cord injury research programs.

Sponsors for the evening included Phil Knight of Nike, United Airlines, Diageo, HBO Sports and Tiffany & Co., and Barton G. 

GREAT SPORTS LEGENDS DINNER



Christine E. Lynn, Terry Buoniconti
and Dr. Barth A. Green



Harry Carson, Carl Lewis and Andre Dawson



Chris Mullin



Brad Leland



Janet Evans



Coach Don Shula and Jack Schneider



Richard Kind



Clark Gillies and Ernie Els



Harry Carson, Andre Dawson and John Force



Lisa Guerrero, Scott Erickson



Nancy Kerrigan, Jerry Rice, Harry Carson,
Wayne Newton, Nick and Marc Buoniconti



Ernie Els, Jerry Rice and Dick Anderson



James Ferraro



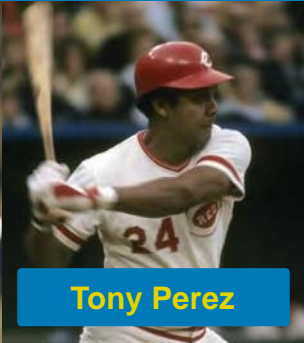
Shaquille O'Neal



Joe Torre



Marshall Faulk



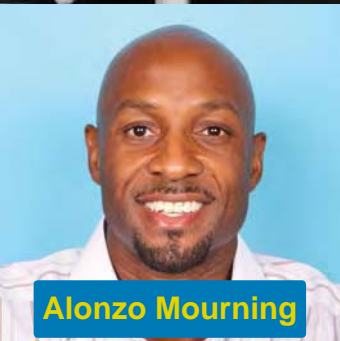
Tony Perez



Mark Martin



Jake La Motta



Alonzo Mourning



Bob Costas



Emilio Estefan

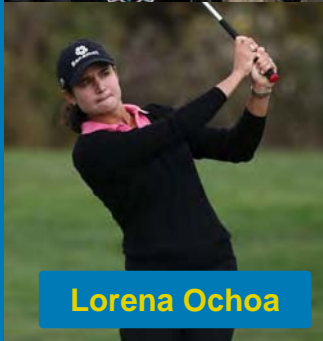


EARTH, WIND & FIRE

**Congratulations and thank you to our
2012 Legends, Honorees, Sponsors,
Supporters and The Buoniconti Fund
Board of Directors for their
support of the
Twenty-Seventh Annual
GREAT SPORTS LEGENDS DINNER**



**Nick and Marc
Buoniconti**



Lorena Ochoa



Lisa Leslie

The Buoniconti Fund to Cure Paralysis

The Fundraising Arm of The Miami Project to Cure Paralysis

For more information, please contact
Stephanie Sayfie Aagaard at 305-243-4656 or
email to saagaard@miami.edu or visit
www.thebuonicontifund.com



**Save the date for our 28th annual
Great Sports Legends Dinner**

Scheduled for Monday, September 23, 2013

Waldorf=Astoria, New York City

GOLF LEGEND JACK NICKLAUS HOSTS THE BUONICONTI FUND TO HELP RAISE MORE THAN \$5 MILLION TOWARDS FINDING A CURE FOR PARALYSIS


10th Anniversary of Buoniconti Fund Celebrity Golf Invitational Provides Critical Funding for Research & Clinical Trials

Golf icon and philanthropist Jack Nicklaus, along with Nick and Marc Buoniconti, hosted the 10th Annual Buoniconti Fund Celebrity Golf Invitational in May at Nicklaus' home club and course, The Bear's Club in Jupiter, Florida. Since its inception 10 years ago, this event has attracted the world's top business leaders and sports heroes, coming together to find a cure for spinal-cord injury. To date, more than \$5 million has been raised by this event to fund research programs at The Miami Project to Cure Paralysis.

"My wife Barbara and I are proud to host this event which provides critical funding for such a worthy cause," Jack Nicklaus said. "We gladly opened the doors of The Bear's Club to The Buoniconti Fund a decade ago, but it was people sharing the passion and commitment of Nick and Marc who opened their hearts and made this happen."

"I have always admired Nick. He's been the leader of a cause born out of the unconditional love of family, and a promise made between a father and son—a promise on its path and with an end in sight. Marc has been both inspirational and aspirational. Through his personal and professional dedication, he has waged a war against spinal-cord injuries. His fight has inspired and motivated all of us. Because of him, all of us aspire to give, to help and to stand up for those who can't. I feel confident The Miami Project will make it possible that one day, Marc will be able to leave his wheelchair behind and walk up the 18th fairway with me."

Funds raised through the Buoniconti Fund Celebrity Golf Invitational provide direct support for research into effective treatments, and eventually a cure for paralysis.

"We cannot begin to thank Jack Nicklaus and his amazing family for all they continue to do for us," said Marc Buoniconti, the President of The Buoniconti Fund. "He has a big heart, a generous spirit and has opened his home to us for 10 years. Not only is he the greatest golfer who ever lived, but one of the most giving." 



Jack Nicklaus, Nick and Marc Buoniconti



Tico Torres, drummer for Bon Jovi

As the result of the ongoing hard work our good friends, Ethan Ruby and Jeremy Schwartz, through Poker4Life (P4L) The Buoniconti Fund family had another strong rooting

"These are two of the classiest gentlemen in the game of poker, and they have always been supportive of our efforts," said Ethan of Brown and Banerji. "I think they were happy and

7th Annual Poker4Life Another Success as the Winners Play at The World Series of Poker for The Buoniconti Fund


interest in this year's World Series of Poker (WSOP) Main Event that took place this past summer in Las Vegas, Nevada. By winning the 2012

energized to play for something bigger than themselves, and that is what Poker4Life is all about."



Andrew Brown with Ethan Ruby

Ethan and Jeremy's group of poker playing friends at the WSOP who are determined to use poker as a vehicle for great causes, including The Buoniconti Fund through P4L.

Who do you Play For? If you or someone you know would like to use the Positive Power of Poker, visit www.poker4life.org to learn more about how you can get your player patch, and how P4L's efforts through the poker community can make a difference in the lives of many. 



The final table at Poker 4 Life 2012

P4L Tournament this past March 29th in New York City, professional poker players Andrew Brown (1st place) and Neehar Banerji (2nd place) received seats at the Main Event, and both agreed to don the P4L patch to indicate that they intended to donate a percentage of their Main Event winnings to The Buoniconti Fund.

Both Brown, a past WSOP bracelet winner, and Banerji, a NYC cash game specialist, have been longtime friends and supports of Ethan and Jeremy's efforts to put forth the Positive Power of Poker in New York City and beyond, and this year was no different. This year they were the most prominent in a field of dozens of players from



Poker 4 Life Winner's Bracelet



Chapters Challenge is a campaign that encourages our volunteers and supporters participating in local, regional, national and international races (i.e. marathon, triathlon, community walk, bike race) to utilize our web-based program to raise funds and awareness on behalf of The Buoniconti Fund and The Miami Project to Cure Paralysis. Race participants can establish their own page, establish fundraising goals, contact friends and family, track their success, and make donations directly to The Buoniconti Fund. The 2011 campaign raised more than \$25,000 and we hope to exceed that this year. Our goal is to have our volunteers and supporters walk, run, swim, bike and wheel their way across the finish line! <http://chapterschallenge.thebuonicontifund.com>

Please visit www.thebuonicontifund.com Events Calendar for the latest events and news in your area.

October 21 ~ Southeast Michigan's "Run for a Reason in the Detroit Marathon"

October 22 ~ Nashville Chapter's "10th Annual Golf Tournament"

November 9 ~ Philadelphia Chapter's "9th Annual Raise A Glass"

November 10 ~ Tampa Chapter's "5th Annual Golf Classic hosted by Rick Hart"

November 29 ~ Chicago Chapter's "14th Annual Indulgence Night"

CHAPTERS SUMMIT 2012

The Buoniconti Fund hosted its seventh **Chapters Summit 2012 presented by Hollister Incorporated** on August 2-5, 2012. More than 50 volunteers, representing twelve Chapters from around the country, came to Miami to exchange ideas, promote volunteerism, learn new and innovative fundraising skills, and increase awareness of spinal cord injury research. The weekend conference featured educational workshops, social and appreciation events, Research Update, and tours of The Miami Project to Cure Paralysis.

NATIONAL VOLUNTEER CHAPTERS

Let us know if your city could benefit from a Volunteer Chapter which develops fundraising events and awareness campaigns to help us reach our goal of finding a cure for paralysis. The Chapters are located throughout the country, including Baltimore, Boston, Charleston, Chicago, Cleveland, Miami, Nashville, Orlando, Palm Beach-Broward County, Philadelphia, Pittsburgh, Southeast Michigan and Tampa.

There's no better time for you to help! Send an email to bfchapters@med.miami.edu or contact Kristin Wherry, Director of National Chapters, at (305) 243-3863.

The Philadelphia Chapter of The Buoniconti Fund was awarded the **#1 Fundraising Chapter of the Year** award for 2011-12 in August 2012. The Chapter is led by Dan and Caren Jones and supported by a strong committee. The Chapter has held this leading position for the past 5 years, raising more than \$100,000 each year through special events and community outreach.



Members of the Philadelphia Chapter at Chapters Summit 2012



Chapters Summit 2012 at Smith & Wollensky Miami Beach “Appreciation Dinner”

Attendees heard the amazing news of the FDA approval for The Miami Project to begin human clinical trials, and the latest scientific achievements and progress from Dr. James Guest, an esteemed group of researchers and Director of Education Kim Anderson. The Research Update and Sponsor Product Fair were open to the South Florida spinal cord injury community.

The Miami Chapter of The Buoniconti Fund hosted a “Summer Celebration” event at Nikki Beach South Beach on August 3 welcoming the Summit volunteer attendees and more than 100 guests from the local community.

Hollister Incorporated has been the presenting sponsor of Chapters Summit since 2001, and a loyal partner in the Volunteer Chapters’ overall fundraising and awareness goals. Six members of the Hollister executive team attended the Summit and had the opportunity to network with the Volunteer Chapters and share the latest corporate news after the Research Update.

Chapters Summit 2012 presented by Hollister Incorporated was also graciously supported by Permobil, Sunset Mobility, and UroMed, as well as hospitality partners including Loews Miami Beach, Smith & Wollensky Miami Beach, Shorty’s Bar-B-Q, Coca-Cola and Dasani Water, E & J Gallo Winery, Zuni Transportation and Dolphin Limousine.



Hollister Incorporated-presenting sponsor:
Sean Haines, Michael Gresavage, Marc Buoniconti,
Midge Willson and Scott Webb

On Thursday May 17, The Woody Foundation held its ***Inaugural Golf Classic*** at the International Links Miami golf course. Nearly 100 golfers, sponsors and volunteers came out to support this great day of golf, community and spinal cord injury research awareness. The Woody Foundation generously donated \$50,000 to The Buoniconti Fund to Cure Paralysis, the fundraising arm of The Miami Project to Cure Paralysis.

The Woody Foundation, Inc. is a 501(c)(3) not for profit organization formed in 2011 to raise funds for the recovery of spinal cord injured persons. James “Woody” Beckham suffered his spinal cord injury making a rugby tackle in January 2011. His family and friends have bonded together to support Woody by making donations to local charities which help others with similar spinal cord injuries.



James “Woody” Beckham and father, Bill Beckham

In a continuing effort to recognize the devastation paralysis causes to families across the nation, Senator Marco Rubio of Florida again introduced U.S. Senate Resolution 531 which designates September 2012 as “National Spinal Cord Injury Awareness Month”. This designation is especially timely given the progress being made toward a cure for spinal cord injury at The Miami Project and the awareness initiatives of our friends at the Darrell Gwynn Foundation.

U.S. SENATE AGAIN RECOGNIZES SEPTEMBER AS NATIONAL SPINAL CORD INJURY AWARENESS MONTH

“We are incredibly grateful to Senator Rubio and the entire U.S. Senate for recognizing National Spinal Cord Injury Awareness Month” stated Marc Buoniconti, President of The Miami Projects.


“This designation will go a long way in generating more awareness and support for the cutting edge research that is leading us closer to a cure. Our innovative approaches, discoveries, clinical trials, and scientific breakthroughs are offering real hope that a cure will be found soon.”

The resolution passed by the U.S. Senate states, in part “...every 48 minutes a person will become paralyzed, underscoring the urgent need to develop new neuroprotection, pharmacological, and regeneration treatments to reduce, prevent, and reverse paralysis...”. It continues, “...increased education and investment in research are key factors in improving outcomes for victims of spinal cord injuries, improving the quality of life of victims, and ultimately curing paralysis.”

Added Senator Rubio, “The stories of Americans who suffer from paralysis due to spinal cord injury are often tragic – they are athletes, troops and accident victims whose lives were dramatically changed in a split second. Spinal cord injuries don’t just change the lives of those injured, but also their loved ones who often become caregivers and deserve special recognition for all they do. This is the second consecutive year I have sponsored the Senate

resolution designating September as National Spinal Cord Injury Awareness Month, and I am proud to support this cause. It’s important that we continue raising awareness about spinal cord injury prevention and the work being done to find a cure.”

The resolution further states that the Senate, “continues to support research to find better treatments, therapies, and a cure for paralysis” and “supports clinical trials for new therapies that offer promise and hope to those persons living with paralysis”.

The designation of National Spinal Cord Injury Awareness Month will build awareness and even more support for the efforts of The Miami Project and the Darrell Gwynn Foundation. 



Marc Buoniconti, Lisa and Darrel Gwynn

KiDZ

Neuroscience Center



BikeSafe training

Throughout this year, The KiDZ Neuroscience Center (KNC), under the direction of Gillian Hotz, Ph.D., at The Miami Project has continued working on its various injury prevention programs to decrease serious brain and spinal cord injuries among children and adolescents. This summer, The Toral Family Foundation, a Florida-based nonprofit organization dedicated to providing help and hope to families affected by these serious injuries, has made a significant donation to support The Miami Project's community education and prevention arm, namely its signature programs WalkSafe™, BikeSafe™ and Sports Concussion. This new partnership is a big step toward combating the influx in injuries during the high-risk months in which participation in recreational activities, such as swimming, bicycling and playing sports, increases.

Safety precautions continue to be the best measures to prevent devastating brain and spinal cord injuries. Through its 3-day educational

program, the WalkSafe™ curriculum is taught annually in 100% of the public elementary schools in Miami-Dade County reaching more than 135,000 students at 222 schools in this past year alone. In addition to implementing the 3-day educational program, WalkSafe™ comprehensively addresses non-infrastructure pedestrian safety issues in high risk districts by establishing new school safety patrol programs and health promotion initiatives such as Walking School Buses. The program has been successfully disseminated in seven different counties in South Florida reaching 42,403 students and 1,052 teachers at 77 schools outside of Miami-Dade County. By



A special education student demonstrates the meaning of pedestrian signals

using epidemiological tools to identify risk factor for injuries in children ages 5-13, the The WalkSafe™ program is considered to be one of the best pediatric pedestrian injury prevention programs in the country.


The BikeSafe™ program has been in existence for three years with the goal of reducing the number of bicyclists-hit-by-cars, especially in middle school-age children, ages 10-14. In the past year BikeSafe has really begun to expand – in January 2012 BikeSafe created its first bike safety curriculum and trained Miami-Dade County (Middle School) P.E. coaches on the basics of bicycle

safety. The BikeSafe partnership with Miami-Dade Parks and Recreation (MDPR) summer camps and after-school programs has also expanded by training MDPR employees on the BikeSafe curriculum and Helmet Promotion. Training MDPR personnel allowed for an increase in the number of children that were able to receive the BikeSafe “On-Bike” Camps curriculum.

The Concussion Program, in existence since 1995, is a comprehensive and model program that includes neuroimaging, neurological evaluation, computerized neuropsychological testing program (ImPACT) and continued outreach education. Funded by the efforts of David Goldstein and his school Ransom Everglades, since 2011, the Countywide Concussion Care program has provided ImPACT baseline testing to students playing contact sports in MDC High Schools. The program also provides educational concussion management to all coaches, athletic trainers, athletes and parents.



Walk event

By continuing, sustaining and expanding these pediatric prevention programs and providing education training and outreach in the community, the KiDz Neuroscience Center directly impacts the lives of many children and adolescents in our community by reducing the number of sports concussions and pedestrian injuries and fatalities in our youth. 

Annual Giving



Virginia, Ricky and Pat Palermo

Ricky Palermo Spinal Injury Golf Tournament

In 1981, Ricky Palermo was involved in a car accident that left him paralyzed from the chest down and a few years later he became one of The Miami Project's very first research participants. Realizing the lack of funding for paralysis research, the Palermo family was determined to do what they could to increase funding. Fast forward to today and the past 16 years,

the Ricky Palermo Spinal Injury Golf Tournament has raised more than \$800,000 for The Miami Project's research programs. The Palermo's have expanded their Foundation's outreach and now put together basketball, soccer, tennis and lacrosse clinics for students throughout Western New York. In addition, the Foundation supports the Genesee County YMCA, United Memorial Medical Center and Strong Memorial Hospital.

Kevin Kitchnefsky Foundation for Spinal Cord Research

In 1996, while on the job for a construction company, Kevin Kitchnefsky was unloading two stacks of chain-link fence from a tractor-trailer. As he jumped off the truck removing a wooden pallet, the remaining 27 units of chain-link fence, each weighing about 100 pounds, slid off the truck and pinned him against the tractor-trailer. The injury resulted in paralysis from the chest down. Determined to raise much needed funds for paralysis research, Kevin organized his first golf tournament in 1999. Fifteen years later, the Kitchnefsky Foundation has raised more than \$500,000 for paralysis research and quality of life programs.




Tom Gruen and Kevin Kitchnefsky

Bryon Riesch Paralysis Foundation

In 1998, Marquette University student, Bryon Riesch's life changed forever. A devastating accident left Bryon paralyzed from the chest down. Since then, through donations and fundraisers close to \$2,000,000 has been raised by the Foundation in the fight against paralysis. The BRPF works within the paralysis community providing charitable grants to help make life easier for people suffering from paralysis. Equally important, the BRPF provides scholarships to individuals suffering from paralysis or families with a parent dealing with a neurological disorder.

The Morton Cure Paralysis Fund

In 1995, Peter Morton broke his neck in a bicycle accident that left him paralyzed and unable to breathe without a ventilator or move anything from the neck down. Devastated by the tragic accident, friends turned their hurt into hope. With little more than a dream, they launched a small-town golf tournament to raise funds for spinal cord injury research—and the Morton Cure Paralysis Fund was born. Seventeen years later, Peter Morton and the Morton Cure Paralysis Fund has raised over \$2.8 million for cutting-edge research. 

Upcoming Events

September 24, 2012

Twenty-Seventh Annual Great Sports Legends Dinner
Benefits The Buoniconti Fund
Waldorf=Astoria
New York City, New York

October 22, 2012

Tenth Annual Golf Tournament presented by Saint Thomas
Neurosciences Institute
Benefits the Nashville Chapter of The Buoniconti Fund
Hillwood Country Club
Nashville, Tennessee

October 25, 2012

Too Good To Be Silent Auction Kick Off Party
Benefits The Buoniconti Fund
Bal Harbour Shops
Bal Harbour, Florida

November 9, 2012

Ninth Annual Raise A Glass For A Cure
Benefits the Philadelphia Chapter of The Buoniconti Fund
National Museum of American Jewish History
Philadelphia, Pennsylvania

November 10, 2012

Destination Fashion 2012
Presented by Micky and Madeleine Arison
Benefits The Buoniconti Fund
Bal Harbour Shops
Bal Harbour, Florida

November 10, 2012

Fifth Annual Tampa Golf Classic
Benefits the Tampa Chapter of The Buoniconti Fund
Westchase Golf Club
Tampa, Florida

May 5 & 6, 2013

11th Annual Buoniconti Fund Celebrity Golf Invitational
Hosted by Jack Nicklaus
Benefits The Buoniconti Fund
The Bear's Club
Jupiter, Florida

September 23, 2013

Twenty-Eighth Annual Great Sports Legends Dinner
Benefits The Buoniconti Fund
Waldorf=Astoria
New York City, New York



Quirch Cares recently presented a check to Stephanie Sayfie Aagaard (center) of The Miami Project. Delivering the check on behalf of Quirch Cares was; Jorge Roza, Monica Quirch, Teri Del Calvo and Dina Figarola



Gulliver Prep School held a Swim-a-Thon that raised funds for The Miami Project, student Connor Kuci with Bill Beckham and former student James "Woody" Beckham presented the check to Suzie Sayfie, Executive Director of The Miami Project.

SPINAL



National Spinal Cord Injury & Disorder Support Group Network



Sustaining a spinal cord injury or being diagnosed with a spinal cord disorder is one of life's most challenging events. Spinal cord injuries and disorders (SCI/D) may prevent a person from doing things the "old" way, but it doesn't prevent him or her from learning new ways to live. SCI/D requires an examination of goals, aspirations and skills. Learning new paths to independence, finding sources of self-esteem, and becoming part of new social systems are all part of successfully adapting to SCI/D. **SPINAL NETWORK** peer support groups can have a significant positive influence on efforts to adjust to SCI/D, particularly related to social interactions and self-management of daily health needs. Mentors can assist a peer to re-evaluate previous life and career goals to assist with day-to-day challenges of living with SCI/D, to help develop new interests and hobbies, set new goals and develop effective strategies for achieving these goals.

The **SPINAL NETWORK** is dedicated to establishing and managing a nationwide network of support groups. Together, with the partnership of The Buoniconti Fund, National Spinal Cord Injury Association and United Spinal, and thanks to the tremendous support from **Hollister** and **VPG**, we will create a movement to inspire all persons with spinal cord injuries and disorders to live life to the fullest by exploring a world of possibilities.

To learn more about the **SPINAL NETWORK** peer mentoring program, please go online to:

www.spinalnetwork.org

or contact the NSCIA's Resource Center at:

peers@spinalcord.org or by phone to **800-962-9629**

JEFFREY KRAMER



Originally from Pittsburgh, Pennsylvania, Jeffrey Kramer resided in Miami-Dade County for most of his life. He and his family have been very active in the business, social and charitable communities throughout South Florida, especially The Buoniconti Fund and The Miami Project. He was married to his beautiful wife Kandy, and his son, Spencer graduated from the University of Miami.

Jeff established his first professional venture in South Florida more than 35 years ago. For the past three decades, he served as Founder and CEO of the fifteenth largest specialty products company in the United States. During his tenure, his company grew to over five hundred domestic and international employees. In 2006 Jeff sold his company to Polyconcept, the largest promotional product supplier in the world. He then concentrated on individual ventures including developing cooperative projects between the Orient and the United States, and his thoroughbred horse stables.

Jeff was an active member of The Buoniconti Fund Board of Directors, participating in all facets of volunteerism, funding, and education. He is greatly missed by the entire Buoniconti Fund team and was respected and loved by all who had the pleasure of knowing him. Our condolences go out to his family Kandy and Spencer.

DESTINATION FASHION 2009



Get ready for
even more
FUN on
November
10th, 2012



DESTINATION FASHION

Presented by Micky and Madeleine Arison

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SATURDAY, NOVEMBER 10, 2012

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Tom Brokaw
Master of Ceremonies



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Tommy Lee Jones and his wife Dawn Jones
Honorary Chairs



International Polo sensation
Ignacio "Nacho" Figueras and his wife Delfina Blaquier
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- Buy amazing auction items donated by the stores of Bal Harbour Shops
- Travel through Bal Harbour Shops and witness the presentation of the 2012 Women of Substance & Style and this year's Destination Fashion Honorees

For sponsorship, table and ticket reservations, please contact Stephanie Sayfie Aagaard at 305-243-4656, saagaard@miami.edu or visit www.thebuonicontifund.com/fashion

BAL HARBOUR



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In 1985, Barth A. Green, M.D. and NFL Hall of Fame linebacker Nick Buoniconti helped found The Miami Project to Cure Paralysis after Nick's son, Marc, sustained a spinal cord injury during a college football game. Today, The Miami Project is the world's most comprehensive spinal cord injury research center and a designated Center of Excellence at the University of Miami Miller School of Medicine. The Miami Project's international team is housed in the Lois Pope LIFE Center and includes more than 250 scientists, researchers and clinicians who take innovative approaches to the challenge of spinal cord injury and other neurological diseases. The Buoniconti Fund is the fundraising arm of The Miami Project and is committed to seeing millions worldwide walk again. Please help us stand up for those who can't! The Buoniconti Fund is a non-profit, 501(c)(3) organization. Federal ID #65-0244316. State of Florida identification number: CH1756.

THE PROJECT
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A photograph of a person in a wheelchair, seen from the side, moving through a brightly lit hallway. The hallway has a polished floor that reflects the light, and the walls are a warm, light brown color. The person is wearing dark clothing and a black strap is visible across their lap. The wheelchair has large black wheels and smaller front wheels.

**September Is
National Spinal Cord
Injury Awareness Month**

**Will you Stand Up For
Those Who Can't?**



UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE