

2009-2010

THE PROJECT

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



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE





“Increasingly we are seeing research translate from the laboratories to the human condition.”

I am excited and enthusiastic about the incredible research and fundraising efforts that lie on the immediate horizon for our organization. Our scientists continue to push hard to gain approval from the Food and Drug Administration (FDA) for our Human Schwann Cell Clinical Trial. The final stages of the process are being accomplished and the day that we can begin this study is fast approaching. As we await approval from the FDA for the Schwann Cell Trial, I am happy to report that we are in various phases of clinical trials and studies with hypothermia (mild cooling of the body), Oxycyte (a synthetic blood that helps deliver oxygen to damaged cells) and Riluzole (a sodium channel blocker). Increasingly, we are seeing research translated from the laboratories to the human condition. Of course, our research depends heavily on the generosity of you, our friends and donors of The Miami Project and The Buoniconti Fund and for that, my family and I are extremely grateful.

I would be remiss if I didn't take this opportunity to say a special thank you to our devoted Buoniconti Fund Board Members. Year after year they raise the bar and spearhead the efforts of the Fund to creatively raise awareness and funds for The Miami Project's research programs. Without this vital support, The Miami Project would simply not be where it is today, the leader in spinal cord injury research.

With that said, The Buoniconti Fund's Board Members are organizing some unique events for 2009 and 2010. The 24th Annual Great Sports Legends Dinner on Tuesday, October 6, 2009 at the Waldorf=Astoria in New York City again will be an amazing event. We are honored to have Bob Costas as our Master of Ceremonies as we pay tribute to our Great Sports Legends and Honorees. The 2009 Legends are: Troy Aikman, Clyde Drexler, Mike Piazza, Ivan Lendl, Rusty Wallace, Brett Hull, Dara Torres, Pat Day and Chris Waddell. Our 2009 Outstanding Philanthropist Award will be presented to Stewart Rahr and The Barth A. Green Spirit Award recipient is Jack Schneider. The Buoniconti Fund Award will be presented to Adrienne Arsht and our Humanitarian Award recipient is Dr. Maya Angelou. We proudly announce the Inaugural Joseph Rahr Celebrity Golf Invitational Presented by Stewart Rahr scheduled for Friday, February 5, 2010 - Super Bowl Weekend. This is an amazing opportunity to golf with the biggest names in sports and entertainment at La Gorce Country Club on Miami Beach. Also, join Golfing Legend, Jack Nicklaus and our Celebrity Friends for the incredible 8th Annual Buoniconti Fund Celebrity Golf Invitational on Sunday, May 2nd and Monday, May 3rd, 2010, at The Bear's Club in Jupiter, Florida. In the Spring of 2010, watch out for the South Florida Golf Invitational at Indian Creek Country Club on Miami Beach hosted by our wonderful friends, Swanee and Paul DiMare.

The Buoniconti Fund Chapters, in many cities across the country, continue to amaze me with their passion and fervent dedication to our cause. Please check our website at www.thebuonicontifund.com/chapters for all chapter information and events. Until next time, thank you for everything you do to support The Miami Project and The Buoniconti Fund.

Sincerely,

A handwritten signature in black ink, appearing to read 'Marc Buoniconti'.

Marc Buoniconti, President
The Miami Project and The Buoniconti Fund

When You Believe

There can be miracles, when you believe

When my son Marc was paralyzed 24 years ago in a college football game, I searched for a medical program that I could put my trust and belief in for Marc's specialized care. It was a tedious and difficult task because 24 years ago very few physicians were experts in paralysis due to spinal cord injury. No excellent programs were readily available. My resolve did not waiver, but my belief in finding someone to help Marc absolutely did. After extensive research I found Dr. Barth A. Green, a famous neurosurgeon and, ultimately, Dr. Green, Don Misner, Beth Roscoe and I founded The Miami Project to Cure Paralysis and a whole new belief presented itself -- the belief that with hard work, cutting-edge scientific research, and financial backing, we would find a cure for paralysis.

Fast forward to 2009 -- the road to recovery has been short in terms of research, but long and agonizing for those waiting in wheelchairs, as well as for their loved ones. No one ever thought that a cure for paralysis would be found, but with the determination of Drs. Barth A. Green and Dalton Dietrich, and the expertise of their international multi-disciplinary team of more than 200 scientists, technicians and clinicians, The Miami Project is

currently presenting its research to gain FDA approval for my ultimate belief -- positive results from our Human Clinical Trials Initiative. Cellular therapies using Human Schwann Cells, with injections of the drug Rolipram and Cyclic AMP, have shown up to 70% return of walking function in laboratory animals and we are taking steps to carefully move on to human clinical trials. The initial pre-clinical safety studies already performed have shown no serious side effects and we believe we will be given the approval to proceed with human clinical trials.

We have completed an initial Hypothermia clinical study in 14 patients with acute spinal cord injury, and with traumatic brain injuries so prevalent in the Iraq and Afghanistan Wars, The Miami Project has gained U.S. Department of Defense funding to conduct a Phase 2 clinical trial on Oxycyte, a Teflon-like liquid that carries four times the oxygen levels of red blood cells to brain tissue damaged by traumatic injury.

The total cost to care for our family and friends with spinal cord injury paralysis adds up to a staggering \$20 billion annually in the U.S. (the lifetime financial costs for even one individual in the U.S. with SCI paralysis can range in the millions of dollars.)

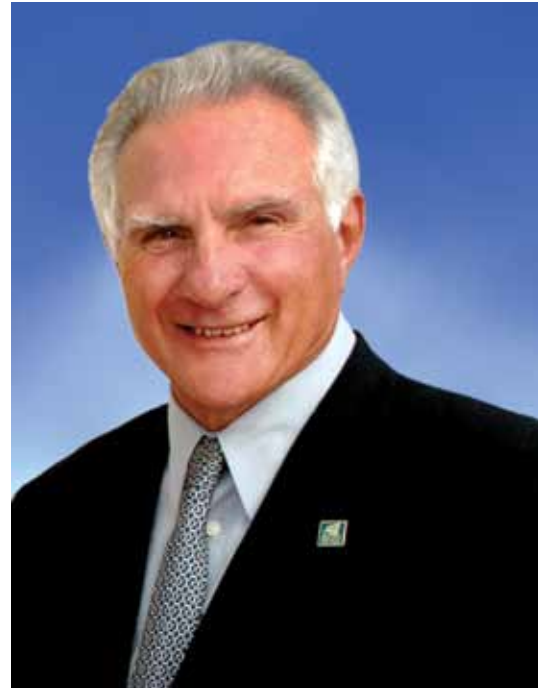
The task of reversing paralysis is challenging and expensive, but we at The Miami Project are confident we have the expertise, knowledge and drive to find a cure. **And so to all of you, THANK YOU for believing, and soon because of your support miracles will happen.**

Sincerely,



Nicholas A. Buoniconti

Co-Founder, The Buoniconti Fund and The Miami Project





www.themiamiproject.org
www.thebuonicontifund.org

Chairman and Founder, The Miami Project
Barth A. Green, M.D.

Founder, The Miami Project and The Buoniconti Fund
Nick A. Buoniconti

President, The Miami Project and The Buoniconti Fund
Marc A. Buoniconti

Scientific Director, The Miami Project
W. Dalton Dietrich, III, Ph.D.

Executive Director, The Miami Project
Buoniconti Fund Board Member
Suzie Sayfie

Managing Editor, Scott Roy
Graphic Editor, Robert Camarena
Executive Editor, Suzie Sayfie

Contributors
Maria Amador, Stephanie Sayfie Agaard, Teri Bendell, Dwayne Campbell, W. Dalton Dietrich, Edelle Field-Fote, Barth A. Green, Ian Hentall, Megan Hess, Allan Levi, Dan Liebl, Mark Nash, Francine Schoen, Jackie Tommasino, Kristin Wherry

Photographs
Robert Camarena, Gus Caballero, Scherley Busch, Manny Hernandez, Jim Mandeville, Red Eye Productions, Claude Zick, John Zillioux

Administrative Director
Diana Berning

**Director, Major Gifts, Corporate Relations,
Marketing and Events**
Stephanie Sayfie Agaard

Director, Public Relations & Communications
Scott Roy

Director, Web Services, Auction and Database Management
Teri Bendell

Director, Government Relations
Randy Medenwald

Director, Annual Giving
Megan Hess

Director, Buoniconti Fund National Chapters
Kristin Wherry

Development Director, Foundation Relations
Francine Schoen

Director, Operations
Bill Sims

Physical Address:
1095 NW 14th Terrace, R-48
Miami, FL 33136
Phone: 305-243-6001

Mailing Address:
Post Office Box 016960, R-48
Miami, FL 33101

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THE PROJECT

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

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Dear Friends,

2009 has been a year full of wonderful achievements and seemingly unlimited opportunities. Led by Dr. Dalton Dietrich, our team of basic and clinical researchers have been recognized for their extraordinary scientific accomplishments with the awarding of a historically unprecedented number of highly competitive NIH grants.

Achieving each of these prestigious awards not only adds to the credibility of our strategic research plan, but also frees up more of the funds we raised from our wonderful donors and special events for use in pursuing new opportunities in the laboratory and clinical arenas.

When The Miami Project was created almost 25 years ago, one of our most important goals was to provide our “All-Star” multidisciplinary team of basic and clinical scientists with the ability to quickly incorporate new biological and technological advances to achieve our short-term goals of improving the quality of life of patients with paralysis, as well as our long term objective of creating effective treatments and ultimately a cure for paralysis.

One might consider the concept of a police force SWAT team or a military Special Forces team that are highly trained, well equipped and funded to achieve goals previously considered impossible. To my knowledge, historically, The Miami Project has created the first such scientific SWAT team that is prepared to take advantage of any new genes or molecules that are identified, any new nano technologies or bio-engineering devices, and apply these real-time to the challenges that our physicians and spinal cord injured patients encounter in their daily lives.

What was a dream in 1985 has truly become a reality in 2009 through the extraordinarily successful efforts of The Miami Project’s development and fundraising team. At the same time that our basic and clinical researchers have scored so many home runs in the very competitive areas of federal and foundation funding, this combination has allowed us to put on a “full court press” towards our Schwann cell transplantation human trials, as well as to rapidly advance our use of hypothermia to prevent and minimize paralysis following injury.

Every day thousands of people across the world benefit from the technologies developed by our basic science and clinical researchers. The technologies include the safe monitoring of spinal column and spinal cord surgery patients in the operating room, the use of functional electrical stimulation in rehabilitation centers and clinics, the use of lowering body temperature to not only prevent damage to the spinal cord following injury and during surgery but also the extension of that technology as evidence-based medicine in the treatment of cardiac arrest on the street and in hospitals around the world.

These are but a few of the many contributions The Miami Project to Cure Paralysis has made during our 24 year journey. From birth through adolescence, and now young adulthood, we have grown not only in the number and quality of our team, but also in the breadth of our holistic approach and strategic plan to change the lives of millions of people who have experienced paralysis or are at risk to do so in the coming days, weeks, months and years.

I urge each one of our readers to do whatever they can to continue to provide the financial resources necessary to make a cure for paralysis no longer a goal but a reality. With all of my warmest regards.

Sincerely,



Barth A. Green, M.D., F.A.C.S.

Professor and Chairman, Department of Neurological Surgery
Chairman, The Miami Project to Cure Paralysis





"Recent findings indicate that Schwann cell transplantation even when initiated months after injury has significant reparative effects on the injured spinal cord and promotes functional outcome."

Dear Friends and Colleagues,

This has been an exciting and productive year for Miami Project Researchers. Important progress has been made on several fronts concerning our Clinical Trial Initiatives. New information regarding the use of human Schwann cells for the treatment of acute and chronic spinal cord injury has been obtained that continues to support this exciting cell therapy for future trials. Recent findings indicate that Schwann cell transplantation even when initiated months after injury has significant reparative effects on the injured spinal cord and promotes functional outcome. Also, two recently published clinical studies have provided encouraging data showing that therapeutic hypothermia is both safe and improves outcome in severely injured spinal cord patients. The Miami Project is therefore at the forefront of medical discoveries and advancing new strategies to both protect and promote recovery in people after spinal cord injury.

In addition to these clinical studies, investigators are continuing to conduct cutting-edge medical research to discover new compounds that promote axonal regeneration and identify novel targets for drug therapy. Using high content screening technologies targeting brain and spinal cord injury, new drugs are being identified that may one day be used in clinical trials to protect and repair the nervous system alone or in combination with cellular transplantation strategies. Deep brain stimulation techniques, previously utilized to treat patients with neurodegenerative diseases, are now showing promise in treating spinal cord and brain injury. These new approaches may provide alternative strategies to improving function in patients with paralysis. Conditioning and rehabilitation studies are continuing to make major differences in the lives of people with spinal cord injury today. Importantly, these strategies offer real hope for successful clinical trial design for the future. There has never been a more exciting time in the spinal cord injury research field, and we look forward to greater advances and discoveries in the coming year.

We thank you all for your continued support and commitment to our research program.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Dalton Dietrich, III, Ph.D.", written over a light blue horizontal line.

W. Dalton Dietrich, III, Ph.D.

Scientific Director
The Miami Project to Cure Paralysis

Professor of Neurological Surgery, Neurology and
Cell Biology and Anatomy
University of Miami Miller School of Medicine



Spinal Cord Injury Clinical Trial Surgeons Drs. Michael Wang, James Guest, Steven Vanni, Barth Green, Ryan Trombley and Allan Levi

Update

Recent Accomplishments

Completed and published in the *Journal of Neurotrauma* and *Neurosurgery* hypothermia clinical study in 14 patients with acute spinal cord injury

Gained U.S. Department of Defense funding to support a Phase 2 Oxycyte trial

Established a Clinical Trials Unit

Organized a working team to assemble an IND application for a Phase 1 trial of autologous human Schwann cell transplantation

Had a pre-pre IND discussion with the FDA that provided guidance for the design and implementation of FDA-required safety studies to assess the potential risks of Schwann cell transplantation prior to approval for human trial

UM IRB approval is pending in a safety study of a drug called Riluzole

The Department of Neurological Surgery has developed and is supporting a Clinical Trials Unit that provides the infrastructure for the conduct of current and future clinical trials in spinal cord injury.

Research That's Making A Difference

Is it luck? Or are a handful of patients treated at the University of Miami / Jackson Memorial Medical Center the beneficiaries of a new therapy for acute spinal cord injury, a therapy that's based on laboratory experiments done years before?

Therapeutic hypothermia has been the focus of much attention after Kevin Everett, National Football League player, experienced a remarkable recovery after his severe spinal cord injury. Mild hypothermia for patients who suffer certain types of heart attacks is becoming a standard treatment. In fact, the American Heart Association has published guidelines for the use of hypothermia in this patient population. Could this up-and-coming therapy also ease the degree of disability for those suffering spinal cord injury?

The Miami Project's first documented results in patients with spinal cord injury suggest this might be the case. During the last two years, clinical scientists at The Miami Project and the Department of Neurological Surgery have examined the use of therapeutic hypothermia in 14 patients with acute cervical spinal cord injury. Their results are now published in the *Journal of Neurotrauma* and *Neurosurgery*, the first of their kind relating to hypothermia in the acute SCI setting.

"We feel these results should encourage other institutions to take a closer look at the use of modest hypothermia in acute SCI cases so we can quickly and safely determine if this should be used more widely."

Of the 10 males and 4 females who participated in the study, 4 experienced improvements in neurological function. All the patients had complete AISAA injuries at the time the hypothermia treatment was administered and none worsened because of the treatment. When the participants were examined after one year, three had improved to ASIA B, which means they regained some of their sensory function. One other was classified as ASIA C, meaning he had improvements in some motor function below the level of injury.

Allan Levi, M.D., Ph.D., a neurosurgeon and lead investigator, summarized the preliminary findings by saying, "We feel these results should encourage other institutions to take a closer look at the use of modest hypothermia in acute SCI cases so we can quickly and safely determine if this should be used more widely."

The papers represented the largest modern study in the administration of mild hypothermia and demonstrated that the use of systemic intravascular cooling was safe, with a similar number of complications as the control group, and provided the much needed baseline data in terms of safety and window of opportunity for cooling acutely injured patients.

The investigators will continue evaluating the effectiveness of the treatment and are working on overcoming a challenge with the timing of the treatment. "We would like to see a major improvement in the time between the injury and the initiation of hypothermia," says Dr. Levi. It took an

average of 7 hours to begin the hypothermia treatment and another 3 hours to reach the target body temperature. "We need to do better," says Barth A. Green, M.D., who believes cooling is likely to be most effective if prehospital treatment protocols can be developed and tested. "We know early cooling is better," comments W. Dalton Dietrich, Ph.D., whose findings in preclinical studies show that cooling immediately after injury improves outcomes.

The clinical protocols were created by Miami Project / University of Miami researchers and currently The University of Miami / Jackson Memorial Hospital is the only institution in the world doing regimented hypothermia treatment and follow up for patients with spinal cord injury.

For hypothermia to become a standard treatment for acute spinal cord injury, more evidence than what this preliminary study can generate will be needed. The study included just a small number of patients whose results were not compared with a control group of newly injured patients who did not receive the treatment.

The Miami Project, under the lead of Drs. Dietrich, Levi and Wang, will likely be leading a multi-center randomized study to definitively determine the effectiveness of hypothermia for improving neurological and functional outcomes for acute cervical spinal cord injuries. Such a study will be critical for determining if this therapy should be applied broadly at trauma centers throughout the country. Dr. Wang and fellow investigators are negotiating a plan to conduct this trial with the Neurological Emergencies Treatment Trials group, a network of 17 academic medical centers with emergency personnel available to conduct large multicenter clinical trials.



Miami Project scientist in the lab examining the complexity of spinal cord injury

Better Than Blood?

With traumatic brain injuries so prevalent in the Iraq and Afghanistan wars, the U.S. Department of Defense has agreed to fund \$2.2 million of the cost of the trials on Oxycyte at the University of Miami and Virginia Commonwealth University. Oxycyte is a perfluorocarbon-based oxygen therapeutic that has shown the ability to deliver four times more oxygen than red blood cells to damaged brain tissue.

M. Ross Bullock, M.D., Ph.D., Professor of Neurological Surgery and Director of Clinical Neurotrauma and Principal Investigator of Phase II clinical trials for the therapeutic oxygen carrier, expects to begin the first trials next month in Switzerland and Israel. US trials will begin in early 2011, if FDA approval is obtained. If Oxycyte, developed by Synthetic Blood International, is successful in civilian trials, it could be used in the battlefields in 2-3 years. Beyond that, there are other potential uses. W. Dalton Dietrich, Ph.D., says he and other researchers will be taking a closer look at Oxycyte for use in spinal cord injury. Early SCI animal studies are highly promising and studies in stroke models have been completed.

The Phase II Swiss trial is expected to last two years, involving 128 patients. The US trial to follow will include the University of Miami / Jackson Memorial Hospital, the University of Pennsylvania, Virginia Commonwealth University, UC Sacramento and Fairfax Hospital in Virginia.

Clinical Trials Unit

When an experimental treatment has been approved for clinical trial, it takes a dedicated and professional team of clinical trial investigators and administrators to actually carry out that trial. The Department of Neurological Surgery has developed and is supporting a Clinical Trials Unit that provides the infrastructure for the conduct of current and future

"By establishing the Clinical Trials Unit, the infrastructure has been set in place to fuel more than just one clinical trial," says Dr. Levi. In addition to the upcoming drug trials, the Clinical Trials Unit will be ready when the development of human Schwann cell transplants is completed and we receive FDA approval to begin that trial.

clinical trials in spinal cord injury. Co-directed by neurosurgeons Allan Levi, M.D., Ph.D. and M. Ross Bullock, M.D. Ph.D., the Unit currently includes eight neurosurgeons and two clinical research coordinators with extensive experience in Neurotrauma care. These clinicians do the "hands on" work to recruit and enroll research volunteers, administer the experimental treatment and carefully collect the clinical research data. During the last two years, the Clinical Trials Unit has coordinated the clinical research for the hypothermia trial and is poised to conduct the Oxycyte and Riluzole trials when the "green light" is given by the FDA to begin enrolling volunteers.

The Clinical Trials Unit also includes administrative personnel who work behind the scenes to secure trial funding, facilitate communications with the University of Miami Institutional Review Board (IRB), and create and monitor each clinical trial budget. For the three impending drug trials, they have been responsible for negotiating with trial sponsors and have shepherded the clinical trial protocols through the UM IRB approval process.

"By establishing the Clinical Trials Unit, the infrastructure has been set in place to fuel more than just one clinical trial," says Dr. Levi. In addition to the upcoming drug trials, the Clinical Trials Unit will be ready when the development of human Schwann cell transplants is completed and we receive FDA approval to begin that trial.


Working Toward Approval for a Phase 1 Clinical Trial To Test Autologous Human Schwann Cells in People with Spinal Cord Injury

The Miami Project had a pre-pre IND discussion with the Food and Drug Administration (FDA) and received guidance on some aspects of the preclinical safety studies that need to be completed. These studies, vital for a successful IND application, are carried out under conditions that must satisfy Good Laboratory Practice (GLP) regulations. One of the goals of these studies is to establish that human Schwann cells do not form tumors or cause other toxic effects. Another goal is to generate evidence that establishes survival time of the transplanted

It's a new frontier for SCI researchers as well as FDA officials with respect to a cellular transplantation for spinal cord injury.

Schwann cells. To clearly understand the potential risks associated with Schwann cell transplantation, the FDA made it clear that the duration of the tumorigenicity study should be at least six months. Before we initiate the IND-enabling GLP studies, we need to be confident that our study specific protocols and regimen are feasible and will provide the required data. Therefore, The Miami Project is currently carrying out a feasibility study to understand how long human Schwann cells can survive when transplanted into a rat spinal cord lesion and what measures can be taken to enhance survival of the transplanted cells. This information is vital to assure the success of the large and expensive GLP safety studies that we will outsource to a Contract Research Organization.

It's a new frontier for SCI researchers as well as FDA officials with respect to a cellular transplantation for spinal cord injury. So far, only one complete Investigational New Drug (IND) application of this kind has ever been submitted, one in which the investigators sought approval for human embryonic stem cell transplantation. Other research groups, including The Miami Project, are undertaking the IND process to bring new treatments to clinical trial.

Reaching the goal of submitting a successful IND application takes a team with dedicated members responsible for the various aspects of the regulatory and therapy development process. The Miami Project scientific team that will succeed in accomplishing this goal is in place and working diligently at making this a reality. 

Human Schwann Cell Phase 1 Trial Current Development Plan (subject to change)

January - June 2009

Pre IND preparations

- Complete preclinical feasibility studies (human Schwann cell survival in nude rat, transplant procedure in minipig)
- Continue cell manufacturing development and quality assurance studies
- Finalize manufacturing and study protocols for GLP studies
- Select a Contract Research Organization and negotiate contract to complete GLP studies

July - December 2009

GLP studies and IRB submission

- Continue cell manufacturing development and quality assurance studies
- Conduct GLP pharmacology/toxicology/tumorigenicity studies (6 months)
- Address changes for preclinical and clinical protocols as recommended by FDA during pre IND meeting
- Submit clinical protocol to University of Miami Institutional Review Board

January - June 2010

IND application reports

- Compile data from GLP studies
- Conduct additional studies based on results of GLP studies
- Finalize IND application materials

July - December 2010

IND submission

- File IND
- If IND approved, begin clinical trial

Aging with Spinal Cord Injuries: Dr. Mark Nash Pursues Evidence- Based Countermeasures and Best Practice Changes



Dr. Nash oversees the training of Frank Diaz, one of many research volunteers in a federally-funded study of exercise conditioning

When Dr. Mark Nash joined the faculty of Neurological Surgery in 1984, the notion of aging with SCI was far from his mind. “Everyone was 25 years old,” remembers Nash, so he asked Dr. Barth Green what a 60-year old person with SCI would look like. “I can’t say,” he recalled Green saying, “We haven’t seen too many of them yet.” Twenty-five years later the young people have aged, and have been joined by increasing numbers of others who are sustaining injuries later in life. Together, these populations have provided an entirely new set of challenges in surgery, medical care, and health maintenance that didn’t exist in the early 1980’s.


Concern for aging with SCI was first sounded at a National Institute on Disability and Rehabilitation Research (NIDRR) sponsored conference in 1991 where Dr. Nash was a featured speaker on immune system decline and infection risks. Warning signals for every major body system were sounded. Recalls Nash, “Suddenly there was recognition that health could decline, pain could develop and personal independence could be lost, even among the most recreationally active, healthy and vital of the injured population.”

Fortunately, a pathway already existed to enhance health through exercise and diet, although it wasn’t as simple as undertaking lifestyle changes. Much of the exercise before the early 1990’s was either electrically stimulated cycling or arm ergometry, making access to equipment and long-term compliance important issues. Looking for something different and more effective, Nash set out to develop and test a resistance-training model. Many were cynical at the notion of persons with tetraplegia and paraplegia lifting weights. Nonetheless, the exercise model has proved both more effective and interesting than arm cycling and even provided an inexpensive home-based system that can be built and adapted to an individual’s exercise needs and capacities.

Unlike the exercise revolution, dietary recommendations have evolved more slowly. The first important step is to look beyond the old suggestions of eating a balanced

diet. We know that dietary intervention needs to begin in rehabilitation where people with SCI burn many fewer calories. The hypercaloric diets consumed after rehabilitation discharge are a ticket to an overweight body, and have even earned a name: obesogenic environment. Our research has also stopped focusing so much attention on the fasted states of lipids and body metabolism. “We don’t live in the fasted state,” reminds Nash. “We live in the fed states.” These studies are far more complex to perform, but also far more revealing, and have earned funding from the NIDRR and the Craig H. Neilsen Foundation. Miami Project researchers are pursuing a better understanding of nutrient and caloric balance, and how exercise can round out the picture, especially as people live longer, more active lifestyles.

The Final Frontier for Aging Related Health

Today, the health-centered research and clinical exercise activities of The Miami Project are focusing to a greater extent on persons aged 50 and older, with some still exercising regularly into their 60’s and 70’s. “They really notice the difference, not just in the way that they feel, but also in their levels of energy and life interests,” notes Nash who has long been an advocate for this type of primary prevention. “If we allow people to gain weight, establish sedentary habits and injure their shoulders, it’s an uphill battle to repair the damage and reverse the body weight gain,” he added. Despite the myriad of things that need to be taught after injury, lifestyle habits of activity and eating need to be a priority. Otherwise, a roadmap for inactivity, pain, and lost independence later in life will be set in motion. The willingness of The Miami Project to recognize and pursue this work maintains our substantial commitment to preserving health, activity, productivity and life-satisfaction across the lifespan. 

Mild Hypothermia Moving Forward in Establishing a Standard of Care For its Use in SCI

Much of the pre-clinical investigative data was pioneered by Miami Project / University of Miami researchers and has revealed the treatment is not only safe, but can be extremely neuroprotective.



Doctors have long wondered how the use of mild hypothermia could influence the outcome for someone who suffers a devastating spinal cord injury. More attention was focused on the issue in September of 2007, when then Buffalo Bills and former University of Miami tight end Kevin Everett was paralyzed following a play in the first game of that season. Luckily, he had quick medical treatment and the best care anyone in his condition could hope for, including hypothermia therapy one of his doctors learned while watching a lecture from Miami Project Scientific Director, Dr. Dalton Dietrich, one of the pioneers in the field. A few months later, he was walking again and before he was taking his first steps, the questions were swirling regarding the effects of the hypothermia on his recovery.

The medical community is always looking to research to develop and confirm hypotheses into some of the world's most complex problems and therapeutic hypothermia is no different. Now, after many years of success in the basic science laboratories, very promising results are emerging from the clinic. Dr. Allan Levi and colleagues have published two

papers which provide the first evidence that the use of mild hypothermia is both a safe and effective strategy in the acute spinal cord injury (SCI) setting. The first paper was published in the March, 2009 issue of the *Journal of Neurotrauma*, and the second is in press for *Neurosurgery*.

Most recent clinical reports have focused on the use of cooling for head injury, stroke and cardiac arrest, but until now, clinically relevant data was not available to support

This can translate into a decrease in the severity of injury and an increase in function, which can mean the difference between breathing on your own, having the use of your arms to care for yourself, or in some cases, even walking after a severe spinal cord injury.

its use for spinal cord injuries. There is still no established standard of care in the acute SCI setting for hypothermia, but because of the Everett case and others, a lot of focus has been

placed on its use in treating SCI and more importantly the need to prove its effectiveness in treating paralysis victims.

Much of the pre-clinical investigative data was pioneered by Miami Project / University of Miami researchers and has revealed the treatment is not only safe,

but can be extremely neuroprotective. This can translate into a decrease in the severity of injury and an increase in function, which can mean the difference between breathing on your own, having the use of your arms to care for yourself, or in some cases, even walking after a severe spinal cord injury.

"Our study included 14 patients and dealt with the most serious cases of cervical spinal cord injury in the acute setting and has shown that the treatment is safe and


improves outcomes dramatically compared to historical outcomes for similar injuries without cooling," said Dr. Levi. "We feel these results should encourage other institutions to take a closer look at the use of modest hypothermia in acute SCI cases so we can quickly and safely determine if this treatment should be used more widely."

Years of extensive laboratory experience under the supervision of Dr. Dietrich, and through other research

groups, provided the impetus to take the therapy to humans. The clinical protocols were created by Miami Project / University of Miami researchers and currently The University of Miami / Jackson Memorial Hospital is the only institution in the world doing regimented hypothermia treatment and follow up for patients with spinal cord injury.

The *Neurosurgery* paper was the follow-up of the earlier manuscript published by Dr. Levi and colleagues in the *Journal of Neurotrauma* that dealt with the techniques and time frames to be used in the procedure. The papers represented the largest modern study in the administration of mild hypothermia and demonstrated that the use of systemic intravascular cooling was safe, with a similar number of complications as the control group, and provided the much needed baseline data in terms of safety and window of opportunity for cooling acutely injured patients.

The compiled data strongly suggests additional trials, including multiple medical centers, should be undertaken so more information can be collected. With a multi-center trial, the ability to enroll a larger number of patients is dramatically increased and determination of the benefits of treatment is accelerated.

Dr. Levi, holding both a M.D. and Ph.D., has a perspective into the problem of spinal cord injury research and treatment that not many can boast. He spent a great deal of his career in the laboratory as a researcher obtaining his Ph.D. and his extensive experience as a neurosurgeon allows him to create and direct his research staff to conduct studies that apply to humans in real world situations. "The benefit of seeing the clinical issues faced by spinal cord injured patients and their doctors allows us to develop clinically relevant studies and ensure discoveries are directed at solving the problems associated with the SCI population," added Dr. Levi. 

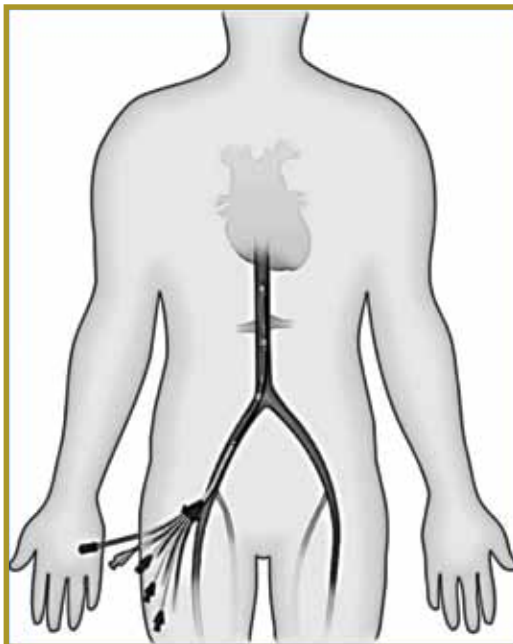


Diagram demonstrating the location of the catheter placed within the inferior vena cava after insertion within the femoral vein.

The Use of Deep Brain Stimulation in Treating Incomplete Spinal Cord Injuries

Research shows that many spinal cord injuries are incomplete and are followed by partial recovery of function over the period of several months, and in some cases years. Miami Project researchers are looking for new and innovative ways to enhance this natural recovery and based on encouraging results in Dr. Ian Hentall's lab, one of these new avenues to recovery may be found through the application of electrical stimulation in the brain, commonly referred to as deep brain stimulation.



Allison Irvine building stimulators

A team of Miami Project researchers first stimulated a brain region which releases serotonin throughout the spinal cord from highly branched nerve fibers. That same region of the brain also releases peptides that stimulate growth, such as a thyrotropin-releasing hormone. Stimulation was provided by a miniature wireless stimulator - developed by Dr. Hentall for the purposes of these studies - fixed to the skull which delivered twelve hours of intermittent stimulation daily to the

implanted electrode. The stimulation was started within a few hours of an incomplete thoracic spinal cord injury and was turned off some days later.

Several weeks after the stimulation, movement and posture control were much improved compared with untreated animals. The front paws typically have higher pain sensitivity after a thoracic injury, which was also reversed. Myelin, a substance that surrounds nerve fibers to speed electrical signaling also rose to a more normal level near the site of injury. Serotonin below the injury level, in fibers



Melissa Carballosa-Gonzalez, Ph.D., implanting a stimulator, assisted by Lizbeth Manoah, B.S., and Dr. Hentall

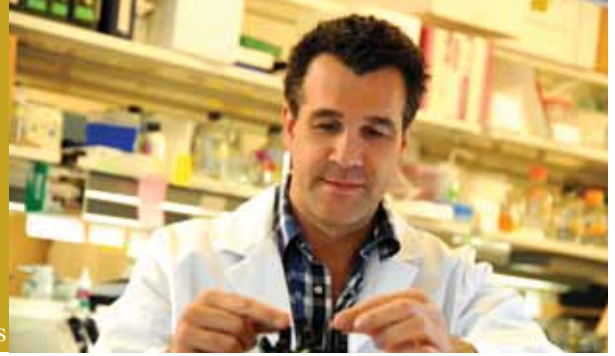
without myelin, also increased. However, the injury cavity size inside the spinal cord and numbers of surrounding nerve cells were unchanged, which suggests that the stimulation restored the tissue near the injury center without creating replacement cells.

One challenge of this treatment is the stimulated region lies deep in the hindbrain, so it is an inconvenient and risky target for neurosurgery. To try and overcome this obstacle, Dr. Hentall's team also tested alternative targets in the midbrain which strongly excites the same brain region without the inconvenience and risk. The same midbrain region has been safely stimulated before in hundreds of patients to help relieve severe pain, so it is known to be relatively safe, and, in terms of behavioral and anatomical recovery, it produced similar results as the hindbrain stimulation.

Deep brain stimulation uses proven technology that can have a low rate of adverse effects and, unlike drug effects, can be immediately stopped. Thousands of people are living with implanted brain stimulators, mostly in cases involving Parkinson's disease. Stimulation in certain brain regions affected by the disease can give immediate and dramatic relief of major symptoms such as uncontrollable tremor. For acute spinal cord trauma, an additional advantage might be that brief stimulation will give lasting restoration, so the stimulator implants do not have to be permanent as is the case in Parkinson's. Initial pre-clinical results suggest that treatment of early SCI by deep brain stimulation is worth additional study and analysis.

How Residential Stem Cells Self-Repair the Brain and Spinal Cord

Dr. Daniel Liebl studying stem cell functions



The question of whether the brain retains the capacity to regenerate has been asked by both patient and scientist alike. Most neuroscientists think of regeneration as a cellular event that is defined as the ability of a cell to regrow parts that were damaged. For example, a neuron may regenerate its axon after injury. Alternatively, regeneration can also be thought of as an ability of an organ to restore whole parts that were damaged. The brain, like many other organs, is believed to retain some capacity to regenerate through internal cellular replacement mechanisms. Dr. Daniel Liebl and colleagues have designed studies to promote this cellular replacement following traumatic brain and spinal cord injury (SCI).

More than 40 years ago, MIT researcher Joseph Altman and colleagues were the first to describe the inherent ability of the brain to generate new neurons during adult life. Now, it is widely accepted that this occurs throughout the brain and spinal cord, although predominantly in specific regions of the brain. Many studies have taken advantage of these neurogenic regions to understand the mechanisms that regulate neural stem/progenitor cell (NSPC) expansion and migration. In particular, Dr. Liebl's team believes that if we understand the mechanisms that regulate this NSPC proliferation, survival and migration, we will be better enabled to develop new and novel therapeutic strategies to enhance neurogenesis following brain and SCI. Dr. Liebl's group has identified a family of proteins, called Eph receptors that play critical roles in how NSPC's communicate with their environment to control these cellular responses.

NSPC's give rise to neuroblasts that migrate through a defined brain region to ultimately become interneurons in the olfactory bulb. Dr. Liebl has demonstrated that cells surrounding this neurogenic region express proteins that activate Eph receptors (called ephrins), which function to restrict NSPC's from expanding out of control. In mice that are deficient for ephrins or Eph receptors, NSPC's proliferate significantly faster than NSPC's of normal mice. In addition, Eph receptors can also function as death receptors to promote NSPC apoptosis when ephrins are

not present. Overall, Eph receptors function in the non-injured brains to help maintain a balance in the numbers of neurons generated throughout the normal adult life span. Following traumatic brain injury (TBI), the brain attempts to generate additional neurons by expanding the NSPC pool, however, not very efficiently. Dr. Liebl's studies show that these changes in NSPC proliferation and survival following TBI may be a direct result of a reduced Eph receptor expression by NSPC. This has led to a hypothesis that eliminating Eph receptor signals in NSPC might lead to greater improvements in NSPC numbers and a potential therapeutic strategy to restore cells lost after injury.

In addition to regulation of cell proliferation and survival, NSPC migration is also an important factor to consider since cellular replacement strategies require cells to migrate to damaged regions. Interestingly, after injury, NSPC's have some capacity to migrate to areas of damage and differentiate into a number of brain cell types, although numbers are small. For this reason, a better understanding of the mechanisms that regulate NSPC migration is essential. Dr. Liebl has shown that Eph receptors may also control some aspects of NSPC migration, and current studies in his laboratory are addressing these functions.

Ultimately, it is Dr. Liebl's hope that by limiting Eph receptor signals in adult NSPC following injury, there will be significantly larger numbers of cells to replace those that were lost. He is currently developing strategies to identify pharmacological and genetic agents to block signals in an attempt to enhance neurogenesis and he believes many of the mechanisms identified will be relevant to cellular replacement strategies in the spinal cord as well as cell transplantation studies. It is well documented that many of these same problems exist following cell transplantation, where newly transplanted cells have restricted proliferation, enhanced cell death, and limited migration. In fact, some animal studies have described greater than 90% loss of newly transplanted cells following implantation. Dr. Liebl believes this can be improved through understanding mechanisms that regulate stem/progenitor cell functions.

Dr. Edelle Field-Fote Publishes First Evidence-Based Book Covering All Aspects of Spinal Cord Injury Rehabilitation

The Miami Project's very own Edelle Field-Fote, Ph.D., P.T., who is a leading authority in spinal cord injury (SCI) rehabilitation, has written the first comprehensive evidenced-based book on the topic titled *Spinal Cord Injury Rehabilitation*. Within its pages, Dr. Field-Fote has meticulously assembled an expert team of clinicians and researchers with firsthand knowledge and experience in SCI rehabilitation and the book is expected to be both a reference and manual for clinicians and those affected by SCI.



Edelle Field-Fote, Ph.D., P.T. works with a research participant

"This exciting new book contains the most current collection of information regarding comprehensive treatment strategies for people living with SCI. Each chapter has been prepared by a leader in the field of SCI management and provides an evidence-based approach to the care and treatment of these individuals. This unique publication will be read by scientists, physicians and health related professionals from multiple specialties active in this discipline. We congratulate Dr. Field-Fote and her contributors for this very special and timely contribution to the field of SCI," said Scientific Director, Dr. W. Dalton Dietrich.

Included in her book are chapters such as an overview of spinal cord injury, maximizing mobility for those dealing with paralysis, the process of translating basic science

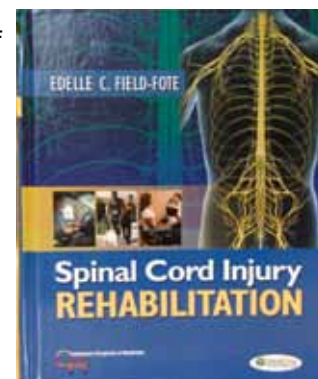
research to humans, ongoing clinical trials worldwide and quality of life issues that people with spinal cord injuries will experience throughout their lives.

"I really wanted this to be an all-inclusive book for clinicians and professionals who work with individuals who have spinal cord injury, but it is also for those living with paralysis and their loved ones so they can better understand their condition, and their potential," said Field-Fote. "In more than 20 years, I have not found any one book or reference source that explains approaches for addressing the issues that people with spinal cord injuries deal with day to day. Hopefully, this book will help fill that informational void that exists."

Dr. Field-Fote began her career in rehabilitation research working on turtle models of spinal cord injury and has become one of the foremost authorities on SCI rehabilitation. She serves as a professor and director of the Neuromotor Rehabilitation Research Laboratory at The Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine; Professor at the University of Miami's Department of Physical Therapy; Editor-in-Chief, *Journal of Neurologic Physical Therapy*; Foundation for Physical Therapy's Scientific Advisory Committee; and a member of the American Physical Therapy Association and Florida Physical Therapy Association. Dr. Field-Fote is widely published in the research arena with dozens of peer reviewed articles and consistently receives significant funding from multiple peer reviewed sources, which is a testament to the quality of her research.

"The intent was to gather the latest information from rehabilitation experts in their respective fields and put them between the covers of this book so the newest scientific discoveries, advances and treatments are at the readers' fingertips. We plan to update the text regularly to allow therapists and caregivers the ability to quickly determine the most effective rehabilitation interventions and techniques so each person can attain the best possible return of function," added Field-Fote.

The book was published in March of 2009 by F.A. Davis in Philadelphia and is available from the publisher as well as through most book vendors including Amazon and Barnes & Noble.





FACULTY notes

Dr. W. Dalton Dietrich, III, and fellow neurotrauma investigators have received exciting news that their Program Project Center Grant for Traumatic Brain Injury (TBI) will be funded for five more years. This NIH-NINDS program will move into a sixteenth year of funding with proposed studies targeting the pathophysiology of TBI using preclinical animal models and clinically relevant outcome measures. Funding over the next five years will result in approximately \$7.5 million dollars and will help support over 25 researchers including Drs. Daniel Liebl, Tom Sick, Bingren Hu, Helen Bramlett, Coleen Atkins and Pantelis Tsoulfas.

Dr. Mary Bartlett Bunge recently was honored by the University of Würzburg (Germany) by presenting the V. Hamburger Lecture at a research symposium funded by the German Research Foundation. She also served as faculty for the Ege University 5th Biennial International Neuroscience Graduate Summer School in Izmir, Turkey. Students were from Azerbaijan, Greece, Iran, Romania, Tunisia, Turkey and the Ukraine. The summer school was supported by the Scientific and Technical Research Council of Turkey, the National Academy of Sciences Committee for the International Brain Research Organization, the Society for Neuroscience and Ege University.

Dr. Barth A. Green was honored with the AXA Advisors Lifetime Achievement Award by the Greater Miami Chamber of Commerce at the 2009 Health Care Heroes® Awards for the impact he's made in the South Florida healthcare community throughout his career.

Dr. Nancy Brackett was recently an invited speaker at the American Society of Andrology meeting in Philadelphia. She presented a talk entitled: *Current Trends in the Treatment of Infertility in Men with Spinal Cord Injury*.

Dr. Edelle Field-Fote, was profiled as Researcher of the Month (April 2009) for the Foundation for Physical Therapy.

In May, 2009, **Dr. Vance Lemmon** presented his talk titled, *Testing Large Gene Sets in Neurons to Identify Genes that Promote or Inhibit Axon Growth*, at the Cambridge Centre for Brain Repair Spring School, Cambridge, UK, Wolfson Centre for Age-Related Diseases, King's College London, London, UK, and the South East Nerve Net: Keynote Address – Jacksonville, Florida.

Dr. Mark Nash is currently funded by grants from The Craig H. Neilsen Foundation to study treatments for postprandial inflammatory stress in SCI and a three-year award from the National Institute for Disability and Rehabilitation Research to examine interventions for obesity-related secondary health complications. He was keynote speaker at the 4th International State-of-the-Art Congress "Rehabilitation: Mobility, Exercise & Sports", in Amsterdam, the Netherlands, presenting on The Spectrum of All-Cause Cardiovascular Disease in Persons with SCI: Likely Causes and Focused Countermeasures.

Dr. Eva Widerström-Noga, served as a Guest Editor for a special issue on SCI-related pain for the *Journal of Rehabilitation Research and Development*, which was published in May of 2009 and the journal contains basic and clinical articles regarding the problem of pain after spinal cord injury. Drs. Jacqueline Sagen, Ian Hentall and Diana Cardenas also contributed to the issue. In addition, **Dr. Widerström-Noga** has two papers in press, *Pain Symptom Profiles in Persons with Spinal Cord Injury* in *Pain Medicine* and *Reliability and Validity of the International Spinal Cord Injury Basic Pain Dataset Items as Self-Report Measures* in *Spinal Cord*.

Dr. Roberta Brambilla, and colleagues in **Dr. John Bethea's** lab published in *The Journal of Immunology*, March 2009, a paper titled *Transgenic Inhibition of Astroglial NF- κ B Improves Functional Outcome in Experimental Autoimmune Encephalomyelitis by Suppressing Chronic Central Nervous System Inflammation*.

Dr. Lanitia Ness from **Dr. Edelle Field-Fote's** lab has had two of her three Ph.D. dissertation papers accepted for publication: *Whole-body vibration improves walking function in individuals with spinal cord injury: a pilot study*, *Gait & Posture* (2009, in press); and *Effect of whole-body vibration on quadriceps spasticity in individuals with spastic hypertonia due to spinal cord injury*, *Restorative Neurology and Neuroscience* (2009, in press).

Dr. Brian Noga, and colleagues published *Locomotor-activated neurons of the cat. I. Serotonergic innervation and co-localization of 5-HT_{7A}, 5-HT_{2A} and 5-HT_{1A} receptors in the thoraco-lumbar spinal cord*, *Journal of Neurophysiology* (2009, in press).

Dr. Daniel Liebl became the Director of the Neuroscience Graduate Program in November 2008, and published a seminal paper of the new function of Eph receptors as death receptors titled, *EphA4 receptor functions as a dependence receptor to regulate cell survival during adult neurogenesis*, *BBA-Molecular Cellular Research*, (2009), and Dr. Liebl presented his work in Brescia, Italy at the 7th International Symposium on Experimental Spinal Cord Repair and Regeneration in February, 2009.

THE 23RD ANNUAL GREAT SPORTS LEGENDS DINNER



The 2008 Sports Legends and Honorees with Nick and Marc Buoniconti, Dinner Chair Mark Dalton and Chairman of The Buoniconti Fund Board Jack Schneider



Master of Ceremonies Bob Costas



Jack Schneider, Jerry Rice, Marc and Nick Buoniconti

The 23rd Annual Great Sports Legends Dinner

Master of Ceremonies Bob Costas joined Legends and Honorees Jerry Rice, Andre Agassi, Scottie Pippen, Joe Gibbs, Helio Castroneves, Richard “Goose” Gossage, Ray “Boom Boom” Mancini, Angelo Dundee, Gabrielle Reece and Christine Lynn at this record-breaking event. NFL Hall of Famer Nick Buoniconti, his son Marc and Event Chairman Mark Dalton hosted a sold out event, the 23rd Annual Great Sports Legends Dinner, at the Waldorf=Astoria on September 22, 2008. Sports heroes, philanthropic icons and business leaders including our Buoniconti Fund Board of Directors were out in full force to support The Miami Project’s paralysis research at this grand affair. The 2008 Great Sports Legends and Honorees joined the event Master of Ceremonies, Bob Costas on stage to accept their Legend awards. Each Honoree was introduced by a stunning career highlight video produced by HBO Sports. South Florida philanthropist Christine Lynn received The Buoniconti Fund Award in front of the audience of more than 1,300 patrons. Hands were flying to bid on spectacular live auction items including a Space Adventure that consisted of a trip on a Sub-Orbital Space Flight 62 miles above Earth and a journey on nuclear-powered submarine and aircraft carriers. Another highlight was the Tiffany & Co. Chances for a Cure Wall where benefactors purchased the famous blue boxes and took home wonderful gifts while helping the cause. The evening raised more than \$7 million for the spinal cord injury research programs at The Miami Project to Cure Paralysis.



Joe Gibbs and Helio Castroneves



Dr. Barth A. Green and Andre Agassi

“...the day will soon come when they will be raised up from their wheelchairs to walk side by side with us again,”

“This dinner and the support we continue to receive from the best of the best in sports, business, entertainment and philanthropy continues to raise my spirits and that of the researchers at The Miami Project. In turn, that support fuels research and raises the spirits of the millions worldwide who live daily with paralysis because we know that, with clinical trials on the horizon, the day will soon come when they will be raised up from their wheelchairs to walk side by side with us again,” said an emotional Nick Buoniconti. 🏈

SAVE THE DATE!

Tuesday, October 6th, 2009

24TH Annual Great Sports Legends Dinner
Waldorf=Astoria, New York City

Monday, September 27th, 2010

25th Anniversary of the Great Sports Legends Dinner
Waldorf=Astoria, New York City



Jerry Rice, Richard “Goose” Gossage and
Scottie Pippen



Terry and Marc Buoniconti



Buoniconti Fund Board Member and Dinner Chairman
Mark Dalton with University of Miami President Donna Shalala



Ray “Boom Boom” Mancini and Leo Baxter



Natalie Coughlin and Janet Evans



Marc Buoniconti and Christine Lynn



Scottie Pippen, Angelo Dundee and Ray "Boom Boom" Mancini



Richard "Goose" Gossage and James Pallotta



Laird Hamilton and Gabrielle Reece



A Star-Studded Affair featuring SEAL, The Pointers Sisters and Fashion Icon Michael Kors rocked Miami to benefit The Buoniconti Fund to Cure Paralysis

More than 2,000 partygoers from the worlds of entertainment, sports and fashion descended upon Bal Harbour Shops for Destination Fashion 2009 Presented by Stewart Rahr on March 7th, 2009. Multi-platinum recording artist SEAL brought the house down with a rockin' show under the stars and The Pointer Sisters wowed the crowd with their disco beats. American iconic designer Michael Kors treated the fashionista audience to a spectacular runway fashion show presented by Saks Fifth Avenue Bal Harbour. One major highlight of the evening came when Destination Fashion Presenting Sponsor Stewart Rahr surprised guests and announced a donation of \$1 million to The Buoniconti Fund. Singing star and Buoniconti Fund Board member Gloria Estefan served as emcee and welcomed Marc Buoniconti to the stage where he then thanked Event Honorary Chairs Academy Award Winner Tommy Lee Jones and Dawn Jones for all of their help. Miami Project Founders Nick Buoniconti and Barth Green, M.D. presented *The Barth A. Green Spirit Award* to Golf Legend Jack Nicklaus and *The Buoniconti Fund Award* to Stanley Whitman of Bal Harbour Shops. The Buoniconti Fund saluted the Women of Substance & Style Honorees who were each escorted down the runway by Celebrity Presenters including Jerry Rice, Scottie Pippen, Pat Riley, Don Shula, Emilio Estefan, Ed Reed, Carl Lewis, *Friday Night Lights* television stars Kyle Chandler and Brad Leland and Romero Britto. Event chairs Nick Buoniconti, Marc Buoniconti, Barth Green, M.D., Gretchen Jordan, Suzie Sayfie and Stephanie Sayfie Aagaard were thrilled with the outcome and success of the affair.



Nick Buoniconti with Gigi, Randy and Stanley Whitman, Buoniconti Fund Award Recipient



Presenting Sponsor Stewart Rahr with Jack Nicklaus

Destination Fashion 2009 guests partied through the "Decades: 70's, 80's, 90's and Today" in the dazzling Bal Harbour Shops and enjoyed international cuisine and a seated dinner by Barton G., delicious libations, live music and interactive entertainment, which included a stunning Buy It Now Store and the Tiffany & Co. "Chances for a Cure Wall" loaded with luxury items. Many of the stores in the mall donated one-of-a-kind items including a Saks Fifth Avenue package for two to attend the Michael Kors show at New York Fashion Week with 2-night stay at The Plaza, a 100% Capri "St. Barth Without Luggage" shopping trip for two, an Audemars Piguet timepiece, a one-of-a-kind Carolina Herrera gown worn previously by actress Renee Zellweger, a one-of-a-kind white crocodile Fendi bag and more.



Honorary Event Chairs Academy Award Winner Tommy Lee Jones and Dawn Jones

Destination Fashion 2009 was presented by Stewart Rahr with other event sponsors including: Bal Harbour Shops, Bal Harbour Village and the Village Council, Barton G., Academy Award Winner Tommy Lee Jones and Dawn Jones, Carnival Cruise Lines, Eden Roc, A Renaissance Beach Resort & Spa, Continental Airlines, Kim and James Pallotta, Saks Fifth Avenue Bal Harbour, The Batchelor Foundation, Cindy Carr, Beatrice Clancy, The Cummock Family, Diane and Allen de Olazarra, Gretchen and Jay Jordan, Kandy and Jeff Kramer, Edie Laquer, Christine Lynn, Miami.com and The Miami Herald/El Nuevo Herald, The Miami HEAT Charitable Fund, Neiman Marcus Bal Harbour, Victoria Ranger Nunez, Barbara Ceuleers Salazar, Southern Wine and Spirits, Laura and Irwin Tauber, Aventura Worldwide Transportation Service and 1-2-3 Lump Sum.

The 2009 Women of Substance and Style Honorees were: Toby Ansin, Madeleine Arison, Adrienne Arsht, Patty Asseff, Dorothy Barrie, Nancy Batchelor, Bobbi Berkman, Julia Bianchi, Nora Bulnes, Cindy Carr, Beatrice Clancy, Anna May Conese, Victoria Cummock, Diane de Olazarra, Alice Fisher Edelman, Raysa Fanjul, Paula Friedland, Gladys Gelb, Andria Ares Holtz, Elsie Howard, Carol Iacovelli, Roni Jacobson, Susan Jacobson, Gretchen Jordan, Kandy Kramer, Edie Laquer, Anne McDougal, Christina Getty Maercks, Lisa Pliner, Jennifer Postrel, Christy Powell, Victoria Ranger Nunez, Loren Ridinger, Chris Riley, Mary Anne Shula, Claudine Smurfit, Jessica Goldman Srebnick, Laura Tauber, Marisa Toccin and Debra Braman Wechsler.



Toby Ansin & Rick Barry



Andria Ares Holtz & Dwight Stephenson



Raysa Fanjul & Nick Buoniconti



Madeleine Arison & Scottie Pippen



Nora Bulnes & John Footy Kross



Beatrice Clancy & Mel Renfro



Bobbi Berkman & Dick Anderson



Nancy Batchelor & Sinorice Moss



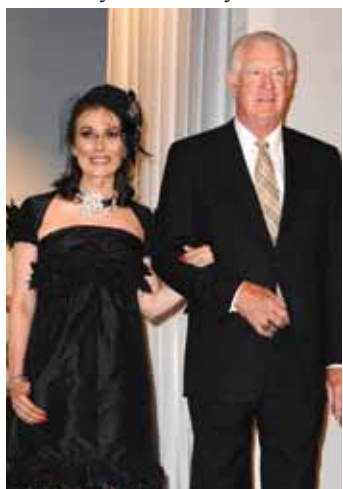
Cindy Carr & Clay Adler



Dorothy Barrie & Brad Leland



The Pointer Sisters



Victoria Cummock & John Havlicek



Adrienne Arsht & Emilio Estefan



Alice Fisher Edelman & Bob Beamon



Patty Asseff & Jeff Dellenbach



Diane De Olazarra & Brian Kelley



Gladys Gelb & Chester Pitts



Roni Jacobson & Will Allen



Elsie Howard & Tim Hardaway



Suzie Sayfie, Michael Kors, Stephanie Sayfie Aagaard and Deborah Slack



Gretchen Jordan & Kyle Chandler



Anna May Conese & Ed Reed



SEAL in concert



Kandy Kramer & Davone Bess



Susan Jacobson & Terry Kirby



Christina Getty Maercks & Maurice Jones-Drew



Anne McDougal & Earl Morrall



Chris & Pat Riley



Carol Iacovelli & Seamus Dever



Edie Laquer & Jerry Rice



Christy Powell & Asante Samuel



Michael Kors Runway Model



Lisa Pliner & Nat Moore



Victoria Ranger Nunez & Carl Lewis



Jack Nicklaus, Nick Buoniconti and Dr. Barth Green



Marc Buoniconti with Emilio and Gloria Estefan



Laura Tauber & Mark Rypien



Anna Kournikova



Julia Bianchi & Shawn Wooden



Paula Friedland & Shaun Phillips



Marisa Toccin & Leonard Marshall



Loren Ridinger & Kendall Langford



Jessica Goldman-Srebnick & Gary Hall



Claudine Smurfit & Harry Carson



Deborah Braman Wechsler & Romero Britto



Mary Anne & Don Shula




Jennifer Postrel & Gerry Cooney

STEWART RAHR

Stewart lives his life by the unforgettable words of Sir Winston Churchill, "We make a living by what we get, but we make a life by what we give".



Carol and Stewart Rahr

Stewart Rahr is the President, CEO, and sole owner of Kinray, the largest privately-held pharmaceutical/generic distributor in the world. Mr. Rahr enjoys spending time with his family and treats his employees as if they are his family as well. Mr. Rahr is also an avid golfer and golfs with Phil Mickelson, Donald Trump, Justin Timberlake and golf legends Arnold Palmer and Jack Nicklaus. A self-made man, Mr. Rahr is listed #227 in the March 2009 issue of *Forbes* Richest Americans, but has never lost touch with his roots. He knows many of his employees by first name and is always ready to offer assistance to those in need. The "overnight success" that Mr. Rahr enjoys has taken thirty-five years and dates back to the year that he took over the reins of the Kinray Pharmacy from his father, Joseph. At that time, the pharmacy had just five employees and less than \$1 million in sales. The debt free company now employs over 1,000 and the annual revenue is \$5 billion. While Mr. Rahr is known for his incredible business success, he has also made a name for himself with his loyal and generous contributions to numerous charities. His huge devotion to philanthropy and The Buoniconti Fund to Cure Paralysis is shown through his dedication to the cause and towards the goal of finding a cure for paralysis. Mr. Rahr recently donated \$1 million to The Buoniconti Fund to sponsor the necessary research to help the organization reach its goal. Mr. Rahr is hosting and is Presenting Sponsor of The Inaugural Joseph Rahr Celebrity Golf Invitational to benefit The Buoniconti Fund in honor of his father, Joseph, on Friday February 5th, 2010, during Super Bowl weekend in Miami. 

SEVENTH ANNUAL
CELEBRITY GOLF
INVITATIONAL PRESENTED
BY STEWART RAHR
HOSTED BY GOLF ICON
JACK NICKLAUS



Nick and Marc Buoniconti joined golf legend Jack Nicklaus as he opened up his home course, The Bear's Club, for the 7th Annual Buoniconti Fund Golf Invitational Presented by Stewart Rahr to benefit The Buoniconti Fund on April 26th and 27th, 2009.


The event turned out to be a sports Hall-of-Fame reunion when the likes of Lawrence Taylor, Bob Giese, John Havlicek, KC Jones, Don Shula, Ozzie Smith and Harry Carson joined the Buonicontis for this two day golf extravaganza. Now in its 7th year, Jack and our celebrity friends including the above and Nat Moore, Michael Chang, Gary Hall, Mark Rypien, Jimmy Key, Rusty Staub, Stan Bahnsen, John Vanbiesbrouck and Earl Morrall have helped raise close to \$4 million over the years for the paralysis research programs at The Miami Project.



Dr. Barth Green, Nick Buoniconti, Stewart Rahr and Jack Nicklaus stand behind Marc Buoniconti

"This year we are pressing hard with the FDA to gain approval for our first human transplantation trial, which will involve Schwann cells," said Buoniconti Fund President Marc Buoniconti. "Our amazing celebrity friends and supporters continue to help provide the fuel in the form of research funds which allows our researchers to get closer to our goal of a cure for paralysis."

The event included a Sunday night cocktail reception, a Buy-It-Now Store containing one-of-a-kind items such as a Tiger Woods autographed glove collage, Royal Caribbean Panama Canal Cruise and a Hannah Montana autographed guitar. The golfers teed off Monday morning on the immaculate Jack Nicklaus-designed golf course and enjoyed prizes including first class airline tickets thanks to Continental Airlines for longest drive and closest to the pin and a brand new Hummer H3 for a hole-in-one courtesy of Ed Williamson Hummer. The first place winners took home specially customized clubs thanks to Jack Nicklaus Equipment. Celebrities stayed at the fabulous Jupiter Beach Resort & Spa which generously donated all of the luxurious rooms to our participants and celebrity friends.

"We are in the midst of very challenging economic times, and no area has been hit any harder than charitable fundraising. But while the economy struggles to get back on its feet, the need to support those who can't rise to their feet must go on. Research and hope can't take a break just because our world has changed. I am so appreciative of those who continue to give and to support The Buoniconti Fund," said Jack Nicklaus, who has won a record 18 major championships and 118 professional tournaments worldwide. "Hopefully one of these days real soon, Marc and I are going to walk up that 18th fairway together." 

SAVE THE DATE for the 8th Annual Buoniconti Fund Celebrity Golf Invitational on Sunday, May 2nd and Monday May 3rd, 2010!

4th Annual Ameristar National Charity Golf Classic Benefits The Buoniconti Fund

Our friends at Ameristar Casinos again showed The Buoniconti Fund their generosity at the 4th Annual Ameristar National Charity Golf Classic which was hosted by the Ameristar Cares Foundation, the Company's philanthropic arm, at their St. Charles, Missouri property. The benefit was held October 6th and 7th, 2008 at the Ameristar Casino Resort Spa and the Whitmoor Country Club.




Marc and Nick Buoniconti present
an award to Gordon R. Kanofsky

Marc and Nick Buoniconti were on hand to graciously accept a very generous check from Gordon R. Kanofsky, CEO, Ameristar Casinos, Inc. to help support our research programs. Marc and Nick each took the stage and recounted their admiration for the event and company's founder, the late Craig H. Neilsen, to which the event was dedicated and discussed the important research the event and foundation supports at The Miami Project.

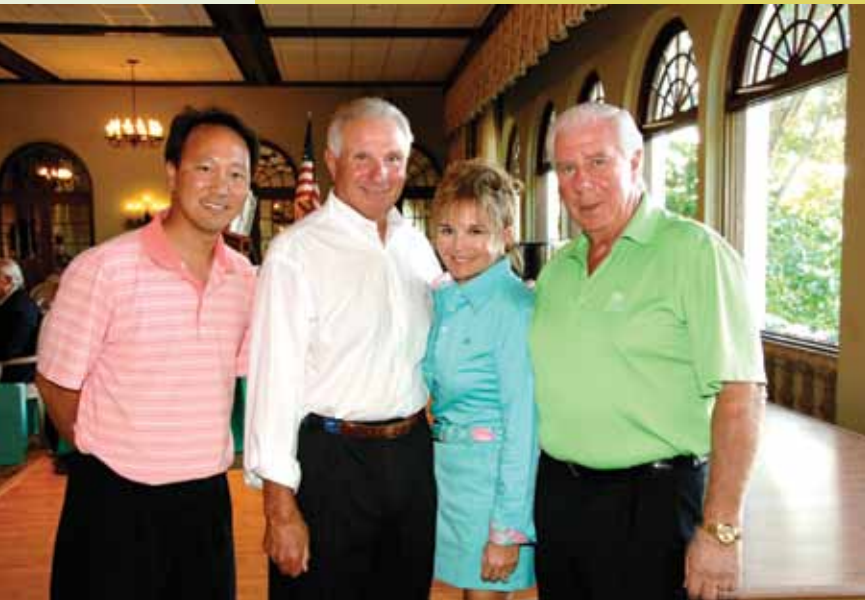


Nick Buoniconti, Troy Stremming,
Gordon R. Kanofsky and Dr. Lorne Mendell

The Craig H. Neilsen Foundation focuses on sponsoring innovative research and supporting quality-of-life programs for those living with spinal cord injuries. In recent years, the Foundation's support has been instrumental in moving our basic science and rehabilitation research forward. Past and present researchers who have benefitted from Ameristar and The Craig H. Neilsen Foundation's support are Drs. John Bethea, Nancy Brackett, Mark Nash, Damien Pearse and Christine Thomas.

Ray Neilsen, Craig Neilsen's son, and Chairman of Ameristar Casinos, Inc., and Co-Trustee of The Craig H. Neilsen Foundation said, "It means so much to me and everyone at Ameristar that my father's commitment to discovering a cure for spinal cord injuries continues in this country." The Ameristar National Charity Golf Classic has raised about \$4.6 million in its four-year history, making it one of the nation's most successful fundraising events to benefit spinal cord injury research and treatment. 

SOUTH FLORIDA GOLF INVITATIONAL PRESENTED BY SWANEE AND PAUL DIMARE AT INDIAN CREEK COUNTRY CLUB



Longtime Buoniconti Fund and Miami Project supporters Swanee and Paul DiMare, a Buoniconti Fund Board Member himself, presented The Fifth Annual South Florida Buoniconti Fund Golf Invitational. NFL Hall of Famers Don Shula, Dwight Stephenson, and Harry Carson, former Dolphins Earl Morrall and Nat Moore, Olympic Gold Medal swimmer Gary Hall, Jr. and tennis great Michael Chang teed off on the pristine course for a day full of incredible drives and contests. Lucky winners of the Longest Drive and Closest to the Pin took home roundtrip airline tickets donated by golf tournament sponsor Continental Airlines. The annual event was hosted at Indian Creek Country Club as golfers and guests mixed and mingled, buying amazing jewelry and children's items to benefit our cause! Ed Williamson Hummer donated a 2009 H3 as a hole-in-one prize and Eden Roc, a Renaissance Resort & Spa graciously donated rooms for our out of town celebrity guests and golfers. 🏌️

Top photo: Michael Chang, Nick Buoniconti, Swanee and Paul DiMare



Bottom photo: Paul DiMare, Bobby Castellano, Don Shula, Bob Brockway and Christian de Berdouare



Joseph Rahr

CELEBRITY GOLF INVITATIONAL

Presented by Stewart Rahr

To benefit The Buoniconti Fund to Cure Paralysis



SAVE THE DATE

Win Big! \$200,000 in Prize Money - Donated by Stewart Rahr.

Golf with the biggest sports and entertainment stars on the Jack Nicklaus designed private course, La Gorce Country Club on Miami Beach.

Friday, February 5, 2010 / Super Bowl Weekend

- Spectacular Celebrity Breakfast
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For sponsorship and golf information, please contact
Stephanie Sayfie Aagaard at 305-243-4656 or email saagaard@miami.edu

4th Annual Poker4Life™ Event in NYC Raises Funds for Research

The Buoniconti Fund great supporters and friends Ethan Ruby and his brother-in-law Jeremy Schwartz presented another amazing poker tournament to benefit The Buoniconti Fund in May 2009. More than 350 celebrity, professional and amateur poker players came out for the 4th Annual Poker4Life™ tournament in New York City and raised more than \$130,000. This year's event took place again at the luxurious Manhattan Auto Company. The most notable winner was Buoniconti Fund supporter from the NY Knicks, David Lee, who took home 3rd place but it's safe to say that a great time was had by all in attendance. Star athletes showing their cards and stacking their chips also included John Starks - Former NY Knick; Donald Brashier - Washington Capitals, Jeff Carter - Philadelphia Flyers and Wrestling SuperStar Jimmy "Superfly" Snuka.

Several professional poker players who battled for the final table included Bill Gazes and Olivier Busquet. Celebrity players that attended the event included Actress/Model

Sabina Gadecki, Actress/Model Amy Rutberg, Actor Chris Murney, Playboy Playmates Colleen Marie and Lindsay Vuolo, Radio Personality Goumba Johnny and Celebrity Stylist Lauren Rae Levy.

Ruby and Schwartz started Poker4Life™ with a 30-person poker tournament in a NYC bar and now host the 300-player Main Event tournament in a Manhattan showroom to benefit our cause.

Over the last four years, they have raised more than \$500,000 for The Buoniconti Fund.



David Lee, Sabina Gadecki and Ethan Ruby

UPCOMING EVENTS

Tuesday, October 6, 2009

Twenty-Fourth Annual Great Sports Legends Dinner

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

Saturday, October 17, 2009

Block Party Presented by Houston's

Benefits the Miami Chapter of The Buoniconti Fund
Coral Gables, Florida

Sunday, October 18, 2009

Detroit Free Press Marathon "Run For A Reason"

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

Thursday, November 12, 2009

Guide to Men's Style Event

Benefits The Buoniconti Fund
Nordstrom Aventura Store
Aventura, Florida

Friday, November 13, 2009

Sixth Annual Raise A Glass For A Cure

Benefits the Philadelphia Chapter of The Buoniconti Fund
The Simeone Foundation Automotive Museum
Philadelphia, Pennsylvania

Saturday, November 14, 2009

Second Annual Golf Tournament

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

Thursday, December 3, 2009

Eleventh Annual Indulgence Night

Benefits the Chicago Chapter of The Buoniconti Fund
Gibson's Steakhouse, Chicago, Illinois

Friday, February 5, 2010 - Super Bowl Weekend

Inaugural Joseph Rahr Celebrity Golf Invitational

Presented by Stewart Rahr
Benefits The Buoniconti Fund
La Gorce Country Club
Miami Beach, Florida

Sunday, May 2 and Monday, May 3, 2010

Eighth Annual Buoniconti Fund Celebrity Golf Invitational at The Bear's Club with Jack Nicklaus

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

Monday, September 27, 2010

25th Anniversary of the Great Sports Legends Dinner

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

April, 2010

Sixth Annual South Florida Golf Invitational

Benefits The Buoniconti Fund
Indian Creek Country Club, Indian Creek Village, Florida

For more information on events, please call Stephanie Sayfie Aagaard at 305-243-4656 or e-mail saagaard@miami.edu

Are you
missing
out on a
matching
gift?



One of most underutilized tools in personal philanthropy is the **matching gift**. Your gift to The Miami Project could be even more significant with a matching gift from your employer. Most employers who participate in matching gift programs match their employee's gifts dollar for dollar which means your gift could be doubled!

Matching Gifts takes 2 simple steps:

- 1) **Find out if your employer participates in a matching gift program** by contacting your HR or payroll department.
- 2) **Donate through the matching gift program**, filling out the appropriate forms to ensure that the match is donated.

That's it! Matching gifts are such an easy way to give your dollar an extra punch and, in turn, help fund the life-changing research being done here at The Miami Project. You work hard for your employer. Here's your chance to make them work for you!

The Women's Guild

This past year the Women's Guild has hosted several successful fundraising events and campaigns. On November 20th, the Guild hosted a festive Beaujolais Nouveau Release Party at Fairchild Tropical Gardens. It was truly a French dinner experience with a wine tasting by one of Miami's best wine connoisseurs, delicious French cuisine and even can-can girls! On April 22nd, the Guild hosted their annual Book Review



Terry Buoniconti and author Edna Buchanan

with author Edna Buchanan. All the attendees enjoyed a wonderful lunch followed by an interesting discussion with this renowned Miami crime reporter and novelist. On May 13th, the Membership Installation Luncheon was held and all were treated to a scientific update by W. Dalton Dietrich, Ph.D. followed by guest speaker, Dr. Eva Ritvo, co-author of *The Beauty Prescription*. After the program, the women enjoyed a lovely lunch on the 7th floor of The Miami Project's Lois Pope LIFE Center. The Women's Guild continues to promote and cultivate The Tree of Hope - a glowing sculpture in the lobby of the Lois Pope LIFE Center - and they hope to have all the leaves in the main part of the tree engraved by the end of the year. For more information on the Women's Guild or the Tree of Hope, contact Megan Hess at (305) 243-7159 or mhess@med.miami.edu.



Buoniconti Fund 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. There's no better time ~ you can help! Send an email to bfchapters@med.miami.edu or contact Kristin Wherry, Director of National Chapters, at (305) 243-3863. The Chapters raised more than \$700,000 last year in 15 cities around the country.

Chapter highlights of note include:

"Evening of the Enchanted Sea" was hosted by the Charleston, South Carolina Chapter on May 1 at Wild Dunes Resort. The event raised almost \$20,000 and featured low country-inspired cuisine, specialty cocktails by Firefly Vodka and Southern Wine & Spirits SC, live music by Permanent Vacation, and a shag



Actress Catherine Bell, Event Host Denise Mills, Donna Rosa of The Citadel

dance contest with celebrity judges, including actress Catherine Bell (formerly of JAG and currently on Army Wives), and local news WCBD's Chief Meteorologist Rob Fowler and ABC4 News Anchor Dean Stephens. Denise Mills was the Event Host and John Stephens is the Volunteer Regional Director. *Mark your Calendar for the next "Evening of the Enchanted Sea" May 14, 2010!*

Spinal Cord Injury directly impacted the Bellamy family in the summer of 2006. During a routine surgery, Kim Bellamy was stricken by a blood clot in her spine, rendering her paralyzed from the waist down. In the years since, Kim and her husband Mason have come to know the struggles associated with this chronic

condition. On May 3rd, 2009, Mason ran in the Pittsburgh Half-Marathon. Mason ran because he could, and so many cannot. The money raised by the volunteer Chapters, including the one in Nashville, TN, that Kim and Mason re-chartered in January, will help so many people living with SCI have a very real possibility of realizing their dreams. These people don't dream of being rich or famous, they dream of things you and I take for granted -- walking hand in hand with a loved one or dancing at a wedding.

Mason finished in just over 2 hours and raised more than \$4,200 for The Buoniconti Fund's Nashville Chapter.



Mason Bellamy training for the Pittsburgh Half-Marathon

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

September 9 ~ New York City Chapter's "Fall Celebration of Baseball" at Yankee Stadium

September 17 ~ Atlanta Chapter's "Casino Night" Atlanta

September 17 ~ Philadelphia Chapter's ~ "Night With the Phillies" baseball outing at Citizens Bank Park

September 25-26 ~ Charleston Chapter's "Marc A Buoniconti Weekend 2009" at Water's Edge and 314 Congress

October 17 ~ Miami Chapter's 2nd Annual Block Party presented by Houston's Coral Gables

October 18 ~ Southeast Michigan's "Run for a Reason / Detroit Marathon"

November 13 ~ Philadelphia Chapter's "6th Annual Raise A Glass" at Simeone Foundation Automotive Museum

November 14 ~ Tampa Chapter's 2nd Annual "Golf Classic hosted by Rick Hart" at Westchase


December 3 ~ Chicago Chapter's 11th Annual "Indulgence Night" at Gibson's Steakhouse

In Memoriam

The Miami Project and the spinal cord injured community recently lost a true friend, advocate and educator when Maria Amador passed away. Those who had the privilege to know and work with her will sorely miss the way she always had a smile to give or a helping hand to lend. The tremendous impact of her contributions to the cause of curing paralysis will be felt as we continue to do what she would want us to do, move forward and gather the knowledge that will soon free those who are confined to wheelchairs.

Maria's tasks at The Miami Project were immense, daunting and often very difficult, but she never shied away from trying to fully understand the complex science at hand and expertly put it into words that everyone could understand. She served as the critical bridge from the scientific team to the support staff, spinal cord injured community and their loved ones.

"Maria had the special talent of translating our science into sentences that could be understood and appreciated by the general public. Maria will always remain in our hearts and minds as we continue to work on her lifetime goal of finding a cure for paralysis."

Some of the many roles during her 18 year tenure included Editor of both The Miami Project Annual Research Review and *The Project*, the official magazine of The Miami Project and The Buoniconti Fund, research subjects recruiter, creating and managing content for The Miami Project website, and coordinating The Miami Project and the Neuroscience Center visiting lectureship series. She helped in the design of the Education Center at the Lois Pope LIFE Center, an area that she was so proud of and worked in every day. At The Miami Project, she met with thousands of people who asked questions and needed answers, hope and honesty as they or one of their family members tried to understand the complexities of their situation. The role she was most excited about was serving as the Project Coordinator for The Miami Project's Clinical Trials Initiative. She truly relished this role and looked forward to the process of taking our science to the FDA for approval. Scientific Director Dr. W. Dalton Dietrich put it best by saying, "Maria had the special talent of translating our science into sentences that could be understood and appreciated by the general public. Maria will always remain in our hearts and minds as we continue to work on her lifetime goal of finding a cure for paralysis." 



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