April 2014

Stem for Life Foundation

LifeLines

www.stemforlife.org

Contents

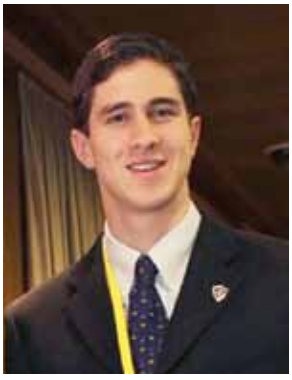
Student Ambassador Update

SFLF STUDENT AMBASSADOR PROGRAM

Bringing the Inspiration Home

Humberto Mestre Payne

Humberto is a medical student, class of 2014, Universidad Anáhuac, and a member of the inaugural class of the Stem for Life Foundation's Student Ambassadors for the Cellular Age program.



Humberto M. Payne, Universidad Anáhuac

Last year when I sat in the Aula del Sinodo in the Vatican I really began, for the first time, to comprehend the vast universe of adult stem cells and their tangible therapeutic potential. The conference *Regenerative Medicine: A Fundamental Shift in Science and Culture* took what I knew about stem cell science and amplified it to a whole new level. As I marveled at concepts ranging from good manufacturing protocols to randomized controlled clinical trials, I realized that I had been imbued with a new level of scientific professionalism and knowledge. I couldn't wait to use my new excitement to help spread the message about adult stem cell therapies and the field of cellular therapeutics. But upon my return home to Mexico, several issues began to temper my enthusiasm.

First, is Mexico's internationally recognized, yet infamous reputation as a destination for stem cell therapy medical tourism. In these clinics (most of them in U.S. border cities, i.e. Tijuana) patients from all over the world come to receive autologous stem cell transplants for a steep price. Many of these clinics have filed for clinical trial status and have been listed on the Clinical Trial Registry of U.S. National Institutes of Health–a U.S. federally-funded medical research institute.

What troubles me, and should trouble anyone looking for these treatments, is the fact that none of these clinical trials (many of which have been registered since 2011), have ever published any results. There are, however, countless stories of patients receiving stem cell treatments with dismal outcomes, and who demand reimbursement for their squandered investment. These poorly controlled studies steal away potential patients from legitimate, well-

Continued on page 7

Welcome

Dr. Robin L. Smith

Hello and Happy Spring from the Stem for Life Foundation.

It's hard to believe that it's been a year since we gathered in Rome for the Second International Adult Stem Cell Conference: *Regenerative Medicine: A Fundamental Shift in Science and Culture*. When we left the Vatican last April, we were all riding high on the momentum we generated from the inspiring speakers, presentations and programming. Thankfully today, that momentum is still going strong. For a great example read the remarkable reflection of Humberto Mestre "Bringing the Inspiration Home," on the front page of this issue. Humberto, a member of our inaugural class of Student Ambassadors, was so inspired by his experience at the Conference that he returned home to his University and organized a Symposium on adult stem cell policy and regulation in Mexico. You can read more in this issue about Humberto's inspiration, and see some photos from the Symposium on page 6. Humberto is just one of our many inspired Student Ambassadors who are accomplishing great things around the world.

In this issue, you will also meet Dr. Alex Vasquez, a cardiologist and an expert in clinical trials based at The Heart Center in Huntsville, Alabama. Dr. Vasquez shares some advice on how to get patients involved in clinical trials and how we can help change static attitudes in the medical profession towards stem cell therapies. I am also excited to share with you some writings from Richard M. Cohen, the prolific author and blogger. Richard shares his feelings as he undergoes a stem cell treatment for his multiple sclerosis. We thank him for sharing his intense personal experience with us. We also are pleased to present an educational feature on apheresis, a medical procedure that separates the components of your blood. Many apheresis professionals are hard at work in the field furthering the use of apheresis procedures as treatments or as part of a treatment for disease.

Last but not least, have you visited out our newly redesigned SFLF website (www.stemforlife.org)? I hope that the website's sleek new look and feel will help you to better educate yourself and share information about the exciting potential of adult stem cells. I also hope that you will take the time to stay up-to-date on all the latest adult stem cell news and events happening at SFLF, in your community and around the world.

Thank you again for your interest in our cause. ■

Dr. Robin L. Smith
President and Trustee

Adult Stem Cell News Highlights

SFLF is pleased to share some recent developments happening around the world in the field of regenerative medicine:

- Mayo Clinic researchers reported in a scientific poster that a stem cell transplant was viable and effective in halting or reversing degenerative disc disease of the spine. A meta-analysis of animal studies showed this result, and accordingly is expected to open up research in humans.
  (Source: American Academy of Pain Medicine Press Release 03/07/14)
- Researchers have found that sutures embedded with stem cells led to quicker and stronger healing of Achilles tendon tears than traditional sutures, according to a new study published in the March 2014 issue of Foot & Ankle International. Researchers compared traditional surgery, surgery with stem cells injected in the injury area, and surgery with special sutures embedded with stem cells in rats. The group receiving the stem cell sutures healed better.
  (Source: Science Codex 03/12/14)
- The Alliance for Regenerative Medicine (ARM) has introduced a bill into the Senate entitled Regenerative Medicine Promotion Act of 2014. Major provisions of the bill include creation of a multi-agency Regenerative Medicine Coordinating Council within the Department of Health & Human Services (HHS); and calling for a detailed assessment of federal activities in regenerative medicine as well as progress compared to national programs in other countries.
  (Source: ARM Press Release 03/13/14)
- The Alabama Institute of Medicine (AIM) received a generous donation of $1 million from an anonymous Birmingham resident to fund stem cell research, ensuring that stem cell research moves forward and thrives in Alabama.
  (Source: AIM Press Release 03/16/14)
- Scientists at UC Davis Medical Center have succeeded in coaxing laboratory cultures of human stem cells to develop into the specialized cells needed to repair a patient's defective or diseased bladder. This research, published in Stem Cells Translational Medicine scientific journal, is important as researchers can now potentially use bladder cells that they created to make a new bladder. This discovery could someday help children born with spina bifida, and adults with a diseased bladder or bladder cancer.
  (Source: UC Davis Health System Press Release 03/21/14)
- Researchers in Galway, Ireland predict that stem cells could be used to treat osteoarthritis within five years, following successful phase 1 clinical trials involving the injection of adult stem cells, derived from adipose tissue or fat, into cartilage to stimulate its regeneration. Osteoarthritis affects some 70 million people across the EU, and current treatment is limited to surgery or pain management.
  (Source: *The Irish Times* 03/26/14) ■

Investigator Spotlight

Meet Dr. Alex Vasquez

Dr. Alex Vasquez is a leading interventional cardiologist at The Heart Center in Huntsville, Alabama and a primary investigator on numerous clinical trials. He is one of the many distinguished physicians that have committed their time and resources to the pursuit of information and research gathered from clinical trials. In this interview, he explains why he chooses to participate in clinical trials; his advice on how we can change the mindset of medical professionals, and how his patients view the exciting promise of adult stem cell therapies.

How did you choose a career in medicine, and ultimately cardiology?

I come from a family of physicians, so it made sense that I would end up in a career in medicine. I am originally from Guatemala and received my medical degree there, but then came to the U.S. to complete my training. I chose cardiology first for its complexity, but also partly because of its simplicity: cardiologists can make an immediate impact on people's lives.

In the cardiac field we have a plethora of diagnostic tools at our disposal and multiple therapeutic options that can deliver immediate results. But despite these advances there is no single therapy directed at reversing cellular and tissue damage post AMI (acute myocardial infarction or heart attack). That is why I am excited about the potential contribution of adult stem cell therapies.

Tell us about the clinical trial work you are performing in Huntsville.

In addition to our clinical practice, we have a large, cardiologist-led research facility that allows us to run anywhere from 35-45 clinical research trials. As part of every patient encounter, I try to answer the question: "Does this patient qualify for any of our available research projects?" One of my mentors loves to say that every patient deserves to be involved in a clinical research trial.

Primary Investigators in clinical trials are responsible for personally conducting or supervising the conduct of human-subjects research and for protecting the rights and safety of the patients.

How do we get more people excited about adult stem cells?

The preliminary data on autologous stems cells is as innovative as it is promising. I am confident that as more data becomes available from ongoing and future clinical trials in humans, more people will be lining up to learn about possible treatments and cures using adult stem cells.

Most patients are excited about clinical trials, especially those who have limited options. Sure, I get the guinea pig comment a lot. But the more you can educate patients and families about the science and the rationale behind the clinical trials, the more you can change people's perceptions about them. And of course, as a physician you have to believe that the treatment you are recommending is beneficial and the best option for your patient.

How do we change static attitudes in the medical profession towards adult stem cells?

Education, education, education!! Stem cell biology and therapies are becoming part of today's medical school curriculum and, interestingly enough, the curriculum of allied professions as well. More widespread acceptance will come in the next few years as physicians and the general population begin to understand the process and access the data from research trials.

The stigma of embryonic stems cells lingers and is ever present, even among health care professionals. Those of us in the practice need to take the time to address questions and misinformation with thorough research and sound scientific data. Rarely does basic scientific information fail to overcome reactionary and contradicting attitudes.

Dr. Alex Vasquez
The Heart Center, Huntsville, AL

The deeper we get into a trial, the more physicians and patients hear about it through word of mouth, which is important to build excitement and support for these trials. We also have champions in the news arena that we need to leverage. We can't underestimate the need for influential press and objective media coverage for our data results.

How do your patients react when you explain that an adult stem cell therapy is leveraging your body's own cells?

Patients are incredibly receptive to the idea of using their own stem cells as a therapeutic alternative. Many patients are excited and hopeful that there is something new on the horizon, particularly when dealing with a potentially life threatening diagnosis.

When it comes to treating inheritable disorders, altruism never fails to show up. Many a patient has agreed to participate in a trial based on the potential benefit this could offer to future generations.

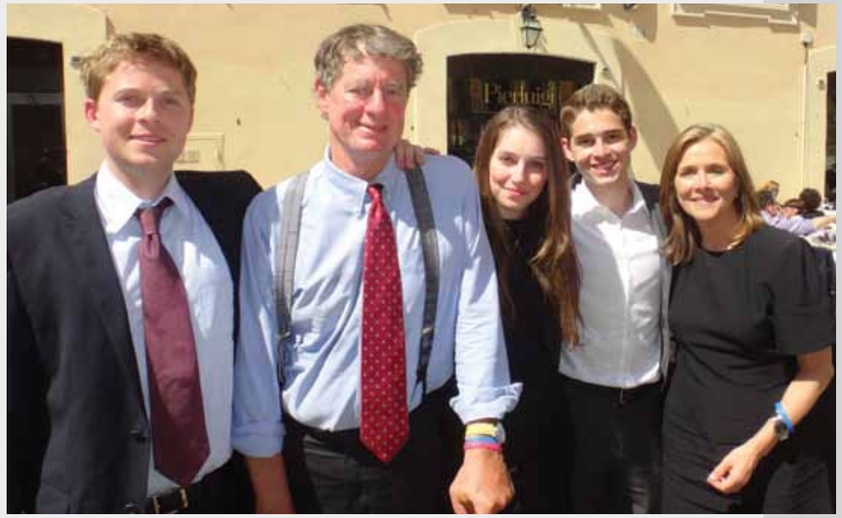
What can ordinary people do to inspire others to learn more about adult stem cell therapies?

Never before have patients and their families had access to such a wealth of information and means to share that information with others. People can participate in clinical trials, then share their experiences in forums, support groups and blogs. I often talk to people who ask about a clinical trial based on what they have read on the internet. In the era of social media, the sky is the limit! ■

***Dr. Vasquez** graduated from Francisco Marroquin University and completed his internship and residency at the State University of New York in Syracuse. He completed fellowships at the University of Arizona (Cardiology), and at the University of Minnesota (Interventional Cardiology). He is a fellow of the American College of Cardiology and is board certified in Cardiovascular Diseases as well as Interventional Cardiology.*

Richard M. Cohen

Richard M. Cohen, well-known journalist, author and blogger, is currently undergoing a stem cell treatment for multiple sclerosis. He shares some of his experience below.



Richard M. Cohen and Meredith Vieira with their family in Rome, 2013.

Stem cell therapy no longer is the stuff of science fiction. We are not just discussing the future anymore. Reputable medical centers all over America are raising money and some beginning the long, expensive process of holding clinical trials. Such trials mark the beginning of the journey to beating serious sicknesses.

The drumbeat for access to stem cell therapy can be heard across the land. This is the new weapon that will slay the dragon: debilitating, chronic illnesses. My fight is with multiple sclerosis. I live with the remnants of two firefights with colon cancer. Pick a disease and get in line.

The day of the passive patient has to end. Let me share a secret. We have to get involved. We need to stay on top of developments. We are our best advocates. We have to be prepared to lead the horse to water. Stem cell therapy is real and approaching fast. In fact, in some places, it is here.

My prediction for 2014 is that the large pharmaceuticals are going to invest heavily in cell therapy. That process has begun. Eventually, they may control our health futures. Drug companies have the resources. Big pharma sees the handwriting on the wall and actually can read it. Stay ahead of them. Pursue and learn about these alternative therapies. Invest in them. They may be your futures.

I am lucky enough to be included in an FDA approved trial of mesenchymal stem cells in treating MS. I am lucky, for I am a body in motion, even as others only sit in wheelchairs, impatiently waiting for their turn.

Results? I will believe anything when I see it. Yes, I am skeptical. How can I not be? But for the first time in four decades, I know hope. It is new to me. I am reasonably hopeful but counting on nothing. I will be overjoyed if the MS is halted in its tracks. I want to hear the sound of progressive deterioration grinding to a halt like the iron wheels of a steam engine on steel tracks. We cannot assume anything, but we can hope.

All of us have to get real. Stem cell therapy is the grand medical experiment of our time. Medicine is changing. I do believe cell therapy is the future. But finding the future is a long trek across uncertain terrain. Any patient with a serious problem must not just take a number and passively wait in line. Help raise funds for stem cell clinical trials. Push the medical establishment.

Doctors and patients are learning together as we go, and there is a large sky above us. All of us need to know more than we do now. The land is shifting under our feet, and we need to keep our balance. I, for one, am trying to get smart. All of us are in this together. A stranger's victory today can be ours tomorrow. We need to better know what our self-interest is. I believe cell therapy will push us across the finish line.

You can read more about Richard's experiences on his Journey Man blog www.richardmcohen.com. ■

***Richard M. Cohen,** in his words, is a "journalist turned television producer turned patient advocate turned writer turned author turned blogger." He was diagnosed with multiple sclerosis in 1973 and has battled with the disease ever since. He is the author of Blindsided (2004), Strong at the Broken Places (2009), and I Want to Kill the Dog (2012). Richard is married to journalist, Meredith Vieira, with whom he has three grown children.*

Did You Know? Apheresis can play an important role in treating serious illness.

What is apheresis?

Apheresis, derived from the Greek word meaning "to separate," is a medical technology used to separate a donor or patient's blood into different components. The donor or patient is connected to an apheresis instrument via one or two intravenous lines and their blood is funneled into a centrifuge to be separated into these components. Once separated, the specified component is collected or replaced, and then the rest of the blood is returned to the donor or patient's body.

A single apheresis instrument in a donor center or hospital can perform several different cell collection procedures. For example, in a donor center, plateletpheresis (see below box) can be performed on qualified donors to collect platelets to be donated to patients who have low platelet counts. Using this same procedure, plasma and red blood cells can be collected from qualified donors to be used in transfusions to patients during surgeries or hospitalizations.

Collecting stem cells using apheresis

Volunteer donors or patients can also donate stem cells using the apheresis instrument that can then be then used for stem cell transplants. If the patient donates their own stem cells for their transplant, this is called an autologous transplant. If a patient receives stem cells from a matching donor (based on Human Leukocyte Antigens (HLA), the genetic markers of the immune system), this is called an allogeneic stem cell transplant.

Prior to the stem cell collection, the patient or donor is given a medication to increase the number of stem cells circulating in the blood stream. The collection of stem cells can take 4-6 hours and if a larger amount of stem cells are required for the specified treatment, may be repeated over 2-3 days.

There are other methods that can be used to collect stem cells, including bone marrow aspiration or removal from fat tissue, but apheresis is the least invasive option.

Why is apheresis important?

Stem cell collections by apheresis are most commonly used for cancers of the blood system, including lymphomas, leukemias and multiple myeloma. As cancer patients require intensive chemotherapy that can destroy their bone marrow and prevent them from creating enough blood cells, the collected stem cells can then be used to restore the normal cells of the bone marrow.

Similarly, some diseases are caused by excessive numbers of certain cells and by abnormalities of the proteins and other substances dissolved in the plasma. In these cases, plasmapheresis (see below box) might be used to temporarily separate the blood into its components and remove the plasma from the body.

A donor undergoing an apheresis procedure.

The unwanted plasma can be collected and replaced with donated plasma or albumen while the other components are returned to the body. Although only a small volume of blood is removed from the body at any one time, large quantities of blood can be processed in this way, leading to a significant reduction in the level of cells or substances responsible for the disease.

The apheresis field

Apheresis specialists can be nurses or medical technologists and must be specially trained to perform apheresis procedures. These specialists work in hospitals, clinics and private offices. They may perform the apheresis procedures as part of the patient's routine treatment or as part of the many clinical trials being performed all over the United States and other countries that are working to provide proof that apheresis procedures are viable treatments and/or cures for specified diseases.

The apheresis field is rapidly growing and is becoming one of the most evidence-based medical fields. Besides performing collections, many apheresis professionals are also collecting data on how to perform apheresis; the outcomes of all types of apheresis procedures to document the most efficient way to perform apheresis; and if apheresis works as the treatment, or as part of the treatment, for a specified disease. Many physicians and nurses are also working to promote apheresis-related education, research, and advocacy initiatives on behalf of donors and patients. ■

If a patient …	apheresis procedure performed	goal of the proceedure
has malaria, sickle cell anemia or thalassemia	erythrocytapheresis	Remove red blood cells which would then be exchanged with donated red blood cells.
has thrombotic thombocytapenia purpura or is about to undergo a liver transplant	plasmapheresis	Remove the patient's plasma and replace it with donated plasma or albumen.
has a very high platelet count that is causing neurological changes	plateletpheresis	Remove the excess platelets to return to a normal platelet count.
has a very high white blood cell count from a specific cancer	leukapheresis	Remove the excessive white blood cells so chemotherapy treatment could be started.

Symposium at Universidad Anáhuac in Mexico City Explores Stem Cell Regulation and Policy in Mexico

On March 13, 2014, Universidad Anáhuac in Mexico City hosted a symposium entitled "Simposio sobre el uso clínico de células troncales adultas en humanos" translated as, "Symposium on the Clinical Use of Adult Stem Cells in Humans." The Symposium brought faculty and students together with government leaders and policy-makers to discuss important issues of stem cell regulation and policy in Mexico. The Symposium took place as part of the university's larger 50th anniversary celebration. SFLF Trustee Dr. Max Gomez, was a featured speaker at the symposium, addressing an audience of medical students on the topic of cellular therapies for cardiovascular disease. The symposium was organized, in part, by Humberto Mestre Payne, a member of our Student Ambassador program, and the author of this issue's cover story. ■

Humberto Mestre Payne, Dr. Max Gomez, and Dr. Arnulfo L'Gamiz on Radio Anáhuac, 1670 AM
?Que ondo con tu salud? or What's up with your health?

Policymakers, speakers and organizers of the Symposium, including Dr. Max Gomez (second from right).

The auditorium at Universidad Anáhuac was filled for the symposium.

Bringing the Inspiration Home

Humberto Mestre Payne - Continued from page 1

structured clinical trials in both the U.S. and Mexico. More importantly, the purity and the safety of the stem cells that these laboratories procure are also questionable. It's disappointing how the dismal results of these "backroom" clinical procedures obscure the real restorative power of authentic stem cells.

I couldn't imagine how Mexico could permit these institutions to pursue research ventures without even insisting on minimal compliance to good clinical practices or manufacturing protocols. As I delved deeper into the matter, I realized that Mexico's legislature is decades behind on regulating stem cell research. Deficient laws cripple the authority of COFEPRIS, the Mexican equivalent of the U.S. FDA. The lack of even basic oversight on stem cell research in Mexico allows these clinics to easily access sanitary licenses, culture adult stem cells and transplant them with no regulation; and they do not require periodic monitorization and safety studies as are required in legitimate clinical trials. There are laws that pertain to hematopoietic progenitor cells and bone marrow transplants, but this leaves a big area of stem cell research open for exploitation.

As a Student Ambassador to the Stem for Life Foundation, I felt compelled to bring this issue to the forefront of discussion. Fortunately, I was not alone; several investigators from the most prestigious research institutions in Mexico are dealing with similar issues. In an attempt to raise awareness I met with the General Director of the National Center for Blood Transfusions in Mexico City, the governmental organization responsible for stem cell legislation. During this meeting, it was clear that the administrators at the National Center were unaware of the damage that these unregulated trials have on Mexican stem cell research and public health.

The National Center is responsible for drafting the norms that dictate the use of cell therapies in Mexico. Unfortunately, these guidelines are about 20 years behind where research stands today. Mexico needs to generate the necessary legislation using functional models like the International Society of Stem Cell Research's guidelines for the clinical translation of stem cells.

The best way for me to bring this issue to the forefront of discussion was to organize a symposium with the key players in Mexican stem cell research. The symposium was held on March 13, 2014 at Universidad Anáhuac in Mexico City, and you can read more about the symposium in this issue. We convened leading authorities on stem cells in Mexico and leading physicians that have completed accurately designed and executed clinical trials. We stressed the fact that Mexico is several years behind in biotechnology and cellular therapeutics, and highlighted successful models such as the U.S. The participation and excitement for the event was inspiring, and hopefully will incite the necessary change in Mexico's regulatory system.

As a result of our efforts and together with the Secretary of the General Council of Health–one of our country's most important advisors on matters of health policy–a working group known as the Committee for Regenerative Medicine and Advanced Cellular Therapeutics has been developed for this precise purpose. This committee will have the daunting task of evaluating the needs of my country in matters pertaining to policymaking on stem cell research. I am proud to have been invited to be a part of the Committee's activities.

All of this was inspired by a week in Rome with the Stem for Life Foundation. I hope that you too will somehow find the inspiration to advance the cause. ■

Student Ambassador Enrollment is open

Now enrolling students for our 2014 Student Ambassadors for the Cellular Age class.

Please visit www.stemforlife.org/studentambassadors to learn more.

A Trip to Remember!

It's hard to believe it's already been a year since we gathered in Rome for an enlightening few days of science and hope. To mark this anniversary we want to say thank you again for believing in our cause and helping to spread the word about adult stem cells.

JOIN US

We invite you to join our dedicated and exceptional association of scientists, physicians, advocates, educators, philanthropists, public servants, and clergy as we stride forward in unlocking the healing powers that are already inside our own bodies.

To learn more:

Call 212.584.4176 or visit **www.stemforlife.org**

To make a contribution:

Visit **www.stemforlife.org/donate**

or send a check to:

The Stem for Life Foundation
420 Lexington Avenue, Suite 350
New York, NY 10170

To learn more about becoming a Student Ambassador:

Email **studentambassadorprogram@stemforlife.org**

The mission of The Stem for Life Foundation is to raise public awareness about adult stem cells and their therapeutic promise and to support the advancement of adult stem cell research and development.

Stem for Life Foundation

420 Lexington Ave., Suite 350, New York, NY 10170

Item No.: SFLNL-2014-04