

# Exploring Stem Cell Therapy Potentials

A Q&A with Anthony G. Payne, Ph.D.

**Julia Schopick**

*EDITOR'S NOTE: Researchers and clinicians throughout the world are exploring the promise of stem cell transplants for patients with debilitating diseases and degenerative conditions. Reports of these transplants causing remarkable recoveries from conditions that have long been regarded as untreatable have come from around the world from places such as Mexico, Costa Rica, China, Korea, Russia, the Barbados, the Grand Bahamas, Argentina, and Portugal. Stem cell treatments for some conditions are not legal in the United States, however. Therefore, American patients with intractable conditions, and their health care practitioners, want more information about access to treatment outside of the United States.*

*For the past 3 years, The Steenblock Research Institute (SRI) in San Clemente, California, has been gathering information on stem cell procedures and providing technical support and data analysis to practitioners in countries where stem cell therapy is performed. David Alan Steenblock, M.S., D.O., director of the SRI, does not perform stem cell therapy nor does he refer patients to overseas physicians who do. He does, however, refer patients to SRI's stem cell therapy educator, Anthony G. Payne, Ph.D., who advises clients on what conditions can be treated with stem cells, and suggests the most appropriate overseas clinics for particular procedures.*

*In this Q&A, Dr. Payne discusses various forms of stem cell therapy, focusing on human umbilical cord stem cell (hUCSC) infusions and implants. He also talks about the SRI's role in providing foreign clinics and research centers with technical support, patient pre- and post-stem cell treatment protocols, and patient-response data and analysis.*

**Julia Schopick:** Let's start at the beginning. What are stem cells and why should stem cell research be of interest to alternative and complementary medicine practitioners?

**Anthony G. Payne:** A stem cell is a cell that is capable of both self-renewal and differentiation. The original stem cell of an embryo is "totipotent"—capable of producing all the cells of the body. A stem cell can divide to produce another stem cell [self-renewal] or divide to produce a cell more committed to a specific

purpose. Stem cells are attracted to areas of injury and disease, and have the ability to multiply and then divide into the cells needed to repair the damage. Stem cells have revolutionary clinical potential because they can be used as a therapeutic intervention for treating many injuries and diseases, including brain repair and regeneration, in many instances.

Many alternative practitioners don't understand stem cells and they don't want to know about them because they think this is "high-tech" biomedicine. But alternative practitioners should know that this treatment augments a natural mechanism. I spoke a while back with the editor of a British natural medicine journal who stated that stem cells are as far removed from natural medicine as one can get. I explained to this chap that I couldn't think of anything more natural than the use of adult stem cells, including hUCSCs to augment the stem cells we all mobilize from our bone marrow when disease or injury strikes.

When you lose blood, you get a blood transfusion. Is that unnatural? Of course not. If a person's own stem cells can't be marshaled to address, say, stroke-related brain damage, umbilical-cord stem cells can be introduced to help repair it. That's augmenting nature.

I am committed to teaching holistic practitioners about umbilical-cord stem cells so they, in turn, can teach their patients. Some of the conditions practitioners treat—strokes, cerebral palsy, amyotrophic lateral sclerosis [ALS] and multiple sclerosis [MS], for example—are not especially responsive to conventional or alternative treatments. In some cases, alternative treatments are effective at first, but prove to be of limited utility as the disease progresses. My hope is that, after learning about stem cells, practitioners will recommend that patients who would be most likely to benefit from their use consult with scientists who are doing this leading-edge work.

**JS:** What are the biologic sources of stem cells?

**AGP:** There are four main sources of stem cells: (1) fertilized eggs [embryonic stem cells]; (2) aborted human fetuses [a human fetus up to 2 months of age, an embryo, is the source of fetal stem cells], (3) umbilical-cord blood; and (4) adult bone marrow and other adult tissues [adipose, skin, et cetera].

Stem cells can be characterized as embryonic or adult. In the first group are the embryonic and fetal stem cells. Embryonic cells are from the earliest stage of human development; fetal cells are a little further along. When you remove an embryonic stem cell, you are removing it from an early stage embryo. Fetal cells can also be removed from an embryo (usually from an aborted baby). Umbilical-cord stem cells are actually considered to be one kind of adult stem cell. At the SRI, we tend to think of umbilical cells as occupying a unique niche of their own.

**JS: American scientists are concentrating their research on embryonic stem cells. Do you consider this the most effective source?**

**AGP:** We think a great deal of American research is on the wrong track. Many scientists argue that while embryonic stem cells are pluripotent (i.e., can give rise to any cell or tissue and thus be used to treat a whole host of diseases), umbilical-cord stem cells are far less so and are only useful for treating blood diseases. This restrictive position has been challenged by findings reported in mainstream peer-reviewed journals and elsewhere, and broader therapeutic applications for umbilical-cord stem cells are steadily gaining acceptance.

Embryonic stem cells, which our politicians and scientists are so interested in, are also the cells that present the greatest challenge in terms of control, as they are very unstable outside of a growing embryo. It will be years before clinicians will be able to put embryonic stem cells into humans with any assurance these cells will function both safely and effectively.

Most alarming is the fact that embryonic stem cells can cause cancer. This is because, like other early stage cells in an embryo, they divide rapidly and have a tendency to be unstable outside their native environment. Indeed, once outside the embryo, they no longer proliferate normally, since they no longer have the matrix of biologic material around them that gives them epigenetic signals to slow down, shut down, and change.

In some instances this results in a state of affairs not unlike taking one's foot off the brake in a car headed downhill. These embryonic stem cells are very unstable and they can form teratomas. In many settings, these are "tumors waiting to happen." These are really powerful cells, so we must be very careful when it comes to introducing them into patients.

**JS: Which stem cells do you feel offer the most promise for the treatment of neurologic conditions?**

**AGP:** Umbilical-cord stem cells. Two researchers here in the United States, Kathy Mitchell [Ph.D., assistant professor, department of pharmacology & toxicology, University of Kansas-Lawrence] and Paul Sanberg [Ph.D., D.Sc., distinguished university professor, director of the Center of Excellence for Aging and Brain Repair, and associate vice president/associate dean for biotechnology development at the University of South Florida College of Medicine] are doing animal studies with umbilical-cord stem cells. Dr. Sanberg induced stroke in rats, then gave them cord-blood stem cells. He found that these stem cells went in and repaired about 40 percent of the stroke damage.

## Richard Jaffe, J.D., on Legal Dimensions of Stem Cell Therapy Referrals

Richard Jaffe, J.D., of Houston, Texas, is a health care litigator with a primary focus on cutting-edge medical/legal cases. Mr. Jaffe has defended many high-profile alternative health practitioners—most notably Stanislaw Burzynski, M.D., of the Burzynski Research Institute, Houston, Texas.

**Q:** What are the potential legal problems for a practitioner who refers a patient for a treatment that has not been approved in the United States?

**A:** There are usually no problems for the referring physician in cases like those described in this article. Doctors usually have the opposite problem, that is, not referring a patient who should be referred out to another health care practitioner. In the case of the Steenblock Research Institute, we are talking about two kinds of referrals. Dr. Steenblock sends patients to Dr. Payne, who functions as an educator or as someone who provides people with treatment options. I don't see this as a problem because I believe that Dr. Steenblock, or any other physician who would send a patient to someone who has general information about treatment options, is acting responsibly, and the medical boards should not have a problem with this type of conduct.

I also don't think there is a problem for physicians to refer patients to Dr. Steenblock or to some of the non-U.S. doctors like Drs. Ramirez or Huang. In general, I don't think there is a significant risk of board problems for a physician who refers a patient to a physician or health care facility outside the United States, so long as the facility is operated by an appropriately licensed practitioner.

Ultimately, the patient has a right to decide whether or not to undergo the treatment. The referring doctor is not making any decision; he or she is only providing options.

In the case of diseases like amyotrophic lateral sclerosis, cerebral palsy, or any other disease for which there is no known curative treatment, I cannot imagine there could be any problem for a referring physician, even if the referral is to a facility that uses an unconventional treatment.

I have seen problems arise when a doctor is using unconventional treatments on patients with a so-called "curable diseases." Even if a patient consents to the treatment, there could be licensing issues.

One of the simplest examples is stage I breast cancer, or better still, carcinoma *in situ*. The conventional treatment for that condition is surgery. A doctor who does not advise the patient to get the tumor removed, and provides some kind of alternative therapy instead of surgery, is going to have board problems. And the doctor will have these problems even if the patient gave informed consent to the alternative treatment.

Here is where even a referring doctor could run into problems. If presented with such a patient, the referral should be to a surgeon. If there's also a referral to some other type of practitioner for some adjuvant therapy, then the referral note should clearly indicate that the referral is for a limited purpose. The doctor should document that a referral was made to a surgeon for the removal of the tumor.

Of course, not every case might be as clearcut. But then, some cases are. A doctor has to use his or her best medical judgment, and there are some cases, when it is clear that the best and only safe course of action is the tried and true conventional care. Failing to make the proper referral in this type of case could quite possibly lead to problems down the road.

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And, in terms of human patients, we at the SRI have seen some amazing results in patients treated by overseas practitioners with human umbilical-cord stem cells, especially in patients with cerebral palsy, certain eye diseases, and recent strokes.

Our website [www.stemcelltherapies.org](http://www.stemcelltherapies.org) provides a great deal of information on umbilical-cord stem cells with reference to neurologic conditions.

#### JS: Are umbilical-cord stem cells a new form of treatment?

AGP: They are, in terms of treating neurologic conditions. But cord blood has been used safely and effectively over many years for specific conditions like leukemia. The problem is that most of the scientific community denies that these cells are good for anything but treating diseases of blood-cell origin. These scientists think that these cells are great for treating a blood disease like leukemia but otherwise the scientists believe umbilical-cord stem cells are useless or nearly so. We are convinced that this is just not the case.

#### JS: Is treatment with umbilical-cord stem cells safe?

AGP: Absolutely. We make people aware of the work being done by Fernando Ramirez [M.D., at the International Spinal Cord Regeneration Center in Tijuana, Mexico]. Dr. Ramirez has a license issued by the Mexican Ministry of Health allowing him to use human umbilical-cord stem cells in human patients for both research and therapeutic application.

The umbilical-cord stem cells Dr. Ramirez uses are processed utilizing the very highest standards and state-of-the-art technology. The cord blood is collected from healthy mothers who have given birth to full-term, normal, healthy babies; it is then screened for all major communicable diseases. Blood that passes muster at this level is then sent to the lab, where technicians separate out CD34+/CD133 cells, the cells that are "primed" to become neurons of various kinds.

These progenitor cells are then expanded in number in a cell-culture medium. After peak expansion is reached, the stem cells are treated with a cryoprotectant and frozen in liquid nitrogen and stored. Certificates of analysis are furnished to researchers by the lab where the umbilical-cord blood stem cells were produced.

#### JS: Isn't actual treatment with umbilical-cord stem cells illegal in the United States?

AGP: Cord-blood and many other forms of adult stem cells are approved for use in treating a number of diseases and conditions, including leukemia, in the United States. While cord blood and cord-blood stem cells for neurologic conditions are not actually illegal here, our government makes it very difficult to provide patients with these cells without an FDA [Food and Drug Administration]-approved IND [Investigational New Drug Application]. Therefore, to treat a patient with stem cells outside of a clinical trial would be a violation of the FDA [regulations] and hence, illegal. An IND, I might add, requires reams of paperwork and several hundreds of thousands of dollars, well outside the means of all but the largest of institutions.

#### JS: How does your arrangement with Dr. Ramirez work?

AGP: Dr. Steenblock [who also is director of The Brain Therapeutics Medical Clinic, Mission Viejo, California], in his capacity as a physician, does not refer patients for treatment with umbilical-cord stem cells. If he feels someone might benefit from this therapy, he has the person call me. I look at each case individually and endeavor to make patients aware of the most appropriate research center for their particular conditions. I match the patient to the program. I work in this regard essentially as an educator.

The SRI has developed protocols that are geared to enhance umbilical-cord stem cell activity in the body and thus improve patient response. These proprietary protocols are licensed to doctors, including Dr. Ramirez, in countries where stem cell therapies are accepted.

#### JS: Other than Mexico, where do you send patients?

AGP: Depending on their individual conditions, I've given people contact information on disease-specific research and treatment programs in Portugal, China, Germany, and Korea. In short, we strive to help people seeking stem cell therapy find clinics, hospitals, and research centers where the treatment offered appears most likely to be of greatest benefit.

For example, patients with ALS are routinely directed to contact Hongyun Huang [M.D., chair and professor, Second Department of Neurosurgery, Beijing Chaoyang Hospital, Affiliated Capital University of Medical Science, in Beijing, China], who has had success in treating this horrendous condition with trans-

planted olfactory ensheathing glial cells [OEGs]. Dr. Huang has transplanted fetal OEGs into more than 400 people, including people with ALS or spinal-cord injuries.

Patients with spinal-cord injuries are often directed to contact Antonio Carlos Viana Lima [M.D., department of neurology, Hospital de Egas Moniz, in Lisbon, Portugal]. Dr. Lima is reportedly getting notable clinical responses in patients with these injuries using OEG-cell transplants.

**JS: With which patients has Dr. Ramirez had the best results?**

**AGP:** Without a doubt, the best results have been in children with cerebral palsy. Umbilical-cord stem cells used in these children have wrought phenomenal results in many instances. Many of these children have undergone 200 or more hours of alternative treatments, such as hyperbaric oxygen, and have essentially reached a plateau in terms of improvements. Parents on a quest to push their children further toward normalcy have found us, and through us, Dr. Ramirez. With umbilical-cord stem cells, many of these children have gone further than with any other treatment. They are not yet completely normal but some of them can now do things they could never do before.

**JS: Can you tell us about some of Dr. Ramirez's successes with patients who have cerebral palsy?**

**AGP:** Emily Pike, whose family lives near Palm Beach, Florida, is now 13. She had her first stem cell treatment at the age of 9 and will soon have her fourth treatment. When she came to us, she was unable to walk, feed herself, or communicate effectively. She couldn't even count numbers. Now she can do all these things. Emily had suffered birth trauma that had deprived her of oxygen for more than 20 minutes and had left her severely brain damaged. Some of Emily's doctors actually compared her to a "stick of furniture" and advised her parents to warehouse her. Her conventional doctors have acknowledged Emily's dramatic improvement to her family.

Then there's Adam Susser [Boynton, Florida], a 4-year-old boy with cerebral palsy who went into a pilot study in Mexico last year involving 7 other children with this condition. Dr. Ramirez carried out this study with technical support from the SRI. Adam entered the study unable to see, talk, or walk effectively. His umbilical-cord stem cell treatment was successful and now he can see, talk, and get about. He and his parents have gone on national television telling about the positive changes Adam has achieved and his pediatrician, like Emily's, credits the stem cell treatment for his improvement.

**JS: Dr. Steenblock is known for his work with people who have had strokes.\* In fact, his website is [www.strokedoctor.com](http://www.strokedoctor.com). Has he had success treating patients who have had strokes with stem cells?**

**AGP:** People with recent strokes have gotten a great deal of benefit from umbilical-cord stem cell therapy. Four (4), 6, or 8 years after the original stroke, the results are not as good.

## Informational Websites

[www.clinicaltrials.gov/](http://www.clinicaltrials.gov/)

<http://stemcells.nih.gov/info/faqs.asp>

[www.stemcelltherapies.org](http://www.stemcelltherapies.org)

**JS: Why don't "old strokes" respond as well as more recent strokes to umbilical-cord stem cells?**

**AGP:** In a patient who had a stroke, or any other injury, in the distant past, the old injury heals over, like a wound on a hand that scars over and is no longer red and inflamed. If there is no inflammation at the site of the injury, the stem cells won't find the injury because inflammation generates chemical signals such as stromal-derived factor- $\alpha$ , which attracts stem cells. In other words, the inflammation sends out signals that draw stem cells into the brain, to the signal-emitting source. We try to tweak the old healed-over quiescent wound in the brain to get it to emit signals that attract stem cells.

**JS: How does Dr. Steenblock improve the response of patients with "old strokes" to the stem cell treatment?**

**AGP:** Dr. Steenblock is refining a number of technologies that help the brain emit signals that attract stem cells, even to old injuries. One method is to induce intermittent hypoxia, which slowly reduces oxygen in the body's tissues to about the level of someone who has ascended Pike's Peak. This stimulates the production of growth factors and chemoattractants like vascular endothelial growth factor.

We are now evaluating whether, using this and other techniques, he can get someone who has had a stroke, say, 8 years ago, to produce the signals needed to rally introduced umbilical-cord stem cells. Dr. Steenblock has been exploring several techniques over the past 3 years or so and is getting closer to tweaking these old injuries to get them to reliably emit signals. In addition to intermittent hypoxia, he uses external counterpulsation and specific hormones. As far as I know, Dr. Steenblock stands alone in having taken so many pioneering steps in this area of clinical research.

**JS: Are you doing something else at the SRI that makes the stem cells more effective for neurologic conditions?**

**AGP:** We've found that the body needs to be as free as possible of conditions that might compromise stem cell function. So we provide input to treating physicians to help them in creating a tissue environment in these patients that encourages stem cell activity. This doesn't apply so much to children, because their tissue environment is young, almost pristine, in many cases.

Toxic levels of heavy metals such as lead, which we see in some children with cerebral palsy, must be recognized and treated. But the tissue matrix of an older person is typically a more challenging biologic environment for transplanted stem cells. The older person's tissue matrix has been exposed to damage, mutations, heavy metals, and toxic chemicals, which compromise the tissue environment in terms of stem cell engraftment and proliferation.

\*See: Mason R. Reversing nerve damage: The Brain Therapeutics Medical Clinic [clinic profile]. *Altern Complement Ther* 2001;7(5):277-283.

### Recommended Reading

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#### **JS: What approaches do you take at the SRI to clean up a patient's tissue environment?**

**AGP:** We advise patients to have such laboratory tests as heavy metal testing. For instance, with MS we often suggest that patients have the Great Smokies Diagnostic Laboratory [Asheville, North Carolina] urine organic-acid test done. This gives us a good idea as to whether or not they have gut dysbiosis. Most of them do, and many have yeast overgrowth and a gut replete with more health-eroding than health-sustaining bacteria.

We recommend that these patients change their diets and have their doctors consider prescribing things that help eliminate yeast and nurture the good bacteria, including probiotics, the antifungal drug ketoconazole, and acidophilus supplements. In some instances, we suggest that the physicians give these patients glutamine, which is very good for healing the intestinal lining and thereby lowering permeability and leakiness.

We also recommend that people contemplating having umbilical-cord stem cell therapy deal with secondary infections in the body. For instance, since the target is the nervous system in patients who have MS, you don't want the umbilical-cord stem cells heading for an abscessed tooth! Remember, stem cells are attracted by signals from damaged, inflamed, or diseased tissue. We want the stem cells to zero in on the brain and nervous system only. We don't want them to be decoyed to an infected lung, abscessed tooth, or leaky gut. So, you clean up all these secondary infections first.

#### **JS: Is there a special dietary protocol patients should follow prior to stem cell treatment?**

**AGP:** Yes. We put these patients on a specific diet, which is part of a U.S. patent pending regimen. We have an entire protocol that is followed by patients prior to going overseas. For instance, we advise them to consume no red meat, heat-processed foods, or alcohol for specific amounts of time before and after treatment. And, of course, tobacco in any form is to be eschewed.

#### **JS: Is this way of preparing the body to accept stem cells new?**

**AGP:** Yes, it is. As far as I know, other doctors don't clean up their patients' bodies in such a way that the stem cells will work better. The SRI has developed a systematic approach for doing so that is part of a patent-pending regimen. Dr. Steenblock, in fact, trains doctors in this method in countries where it is legal to treat patients with umbilical-cord stem cells for neurologic challenges. He has worked with several doctors already: Fabio Solano [M.D. at the CIMA Hospital in Costa Rica], John Clement [M.D. in Freeport, in the Bahamas], and Frank Morales [M.D. who runs the Rio Valley Medical Center in Matamoros, Mexico].

Dr. Steenblock's clinic is the only one that has the technology and know-how in place to help comprehensively prepare patients for umbilical-cord stem cell treatment abroad. People choose to come to his Mission Viejo office for that reason.

#### **JS: How much do these treatments cost?**

**AGP:** A 2004 survey by the SRI of foreign clinics that perform stem cell therapy revealed that they charge between \$10,000 and \$30,000 for the first stem cell transplant, and \$6,000 or more for subsequent treatments. In addition, pre- and post-treatment care, such as Dr. Steenblock provides, may last anywhere from 1 week to 5 weeks, depending on the particulars of the patient's situation and typically costs about \$1,000 per week. None of these estimates include such expenses as transportation to the respective clinics, lodging, or food.

#### **JS: Where can practitioners find out about different clinical trials now being done in the United States using stem cells?**

**AGP:** Go to the National Institutes of Health [NIH] website, and look up clinical trials [[www.clinicaltrials.gov/](http://www.clinicaltrials.gov/) and <http://stemcells.nih.gov/info/faqs.asp>]. You'll see what they're doing with bone marrow and other adult stem cells. That's all well and good, and should certainly continue, but we feel that umbilical-cord stem cells have more plasticity and more flexibility than a lot of other adult stem cells, for neurologic conditions, and for this reason should receive funding.

#### **JS: Do you feel that umbilical-cord stem cells should be the first treatment for some conditions?**

**AGP:** Based on 2 years of collecting and analyzing the responses children with cerebral palsy who have had hUCSC therapy, I feel strongly that umbilical-cord stem cells confer benefits that will one day compel their recognition as a first-line treatment. These cells should also be included in the treatment repertoire for

some ocular diseases and acute strokes—possibly most diseases that involve conditions that generate signals that act as homing beacons for umbilical-cord stem cells. Stem cells could also possibly be an important factor in delaying, slowing, and in some instances, halting, deterioration, even reversing the course of a sudden acute injury or acute onset crisis situation.

**JS: Do you feel that the United States will change its policies toward stem cells in the near future?**

**AGP:** I certainly hope so. I feel that the time is right for people to know that umbilical-cord stem cell treatment works so well in treating certain neurologic conditions. The public is

angry over many of the FDA's arcane policies, as well as at this country's lack of progress with regard to stem cells in general. There has been lots of press about the COX-2 inhibitors, and NIH doctors taking consultancy money from drug companies. The mood in America is one of anger—anger with the FDA and NIH. It's time for change. I hope that umbilical-cord stem cell therapy will emerge at the forefront of such change. □

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