

# Good Players and Bad Players in Stem Cells



## Good Players and Bad Players in the World of American Stem Cells

Deborah Scott tore her meniscus. Her doctors gave her cortisone and Orthovisc injections for the next ten years, but her pain was still there. She decided she'd had enough and saw an orthopedic doctor. He said she would need bilateral total knee replacements. She got a second opinion and a third and a fourth and a fifth.

"I didn't want to go through the excruciating process for one knee replacement surgery, recover, and then do the other one. I'd subject myself to a long recovery process - with all the physical therapy and medical bills; I'd be filing for bankruptcy."

That was when she discovered a doctor using stem cells in her native Virginia. She opted to have stem cell therapy. Five months later, while on vacation in Florida, she walked on the beach and picked up shells. No surgery. But some others have not shared Ms. Scott's experience. The U.S. Food and Drug Administration (FDA) has stories with the opposite results.

### **The U.S. Food & Drug Administration - Policing the Players in the Field**

The FDA tells of one patient who became blind due to an injection of stem cells into the eye. Another patient received a spinal cord injection that caused the growth of a spinal tumor. There are enough stories that, since 2016, they've been hosting workshops to find out the depth of the stem cell story, both the positive and negative reactions.

The FDA has the authority to regulate stem cell products. They use their power to reduce the number of "unscrupulous" providers who offer dangerous procedures and open the doors for

highly skilled researchers and doctors to help those who need it.

## The Good Players

Since taking the wheel, highly skilled scientists are making an impact. One such scientist is Timothy Henry MD FACC. **Dr. Henry is Chief of Cardiology at Cedars Sinai Heart Institute** in Los Angeles, California, and a principal investigator for 1 of the 7 Clinical Cardiovascular Stem Cell Centers under the control of the National Institute of Health.

Dr. Henry studies stem cells' ability to repair the scar tissue created in a heart attack or stroke. His research shows promise that we will take cells from a young donor, culture them, and use them when needed to repair the heart cells in older patients. In a study of 1000 patients, he is finding it possible to direct stem cells to the heart muscle and improve the scar tissue.

His take? Stem cells are promising. Dr. Henry agrees that people need to know if the FDA has reviewed the treatment they seek. It is our responsibility to report scam artists. Henry supports continual enrollment in studies. Over time they will reveal more about how our bodies can genuinely heal themselves - the area of regenerative medicine.

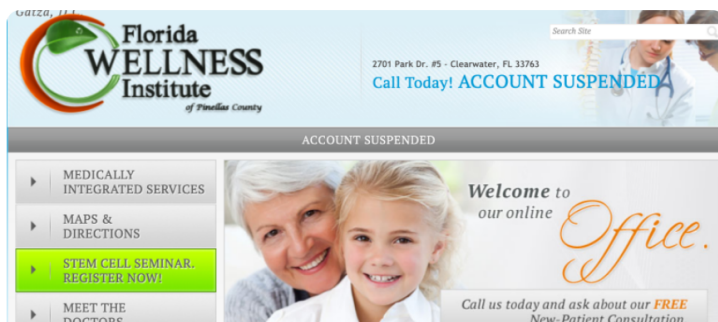
**Shane Shapiro, a Mayo Clinic orthopedic physician**, leads research in stem cells at the Mayo Clinic. Under his leadership, The Mayo Clinic completed the first-ever test of cell therapy to treat arthritis. They expect stem cells will help people with spinal cord injuries, type 1 diabetes, Parkinson's disease, amyotrophic lateral sclerosis, Alzheimer's disease, heart disease, stroke, burns, cancer, and osteoarthritis. Further, they are excited to test new drugs on stem cells instead of patients. Cardiac toxicity is a good example. The cells can be programmed to become tissue-specific targets for medication. Measurements for quality and effectiveness come from the stem cell. No humans used.

## The Bad Players

Unlike Shapiro and Henry, who work through approved NIH trials, Dr. James Gatza, is a bad player. The owner of the Florida Wellness Institute did not have FDA approval for procedures that involve the manufacturing of stem cells, nor did he tell new clients that he did not have it.

ABC News investigated Dr. Gatza, at a conference he sponsored in Tampa attended by senior citizens. The licensed holistic Florida chiropractor who claimed he spoke as the 'national spokesperson for the Stem Cell Institute of America' didn't take questions at the end of his pitch. Instead, he directed attendees to sign-up for a free consultation at his clinic - an alert that triggered a deeper investigation.

By 2016, State Senator Dana Young introduced SB 1508 "to crack down on for-profit stem-cell clinics that are preying on Florida seniors and other vulnerable Floridians." Florida suspended the Institute's account.



## How the FDA and the NIH Responds Today

The FDA and NIH advocate for stem cells. They support medical professionals researching stem cells because they learn how the cells can match and multiple other types of cells. Research opens the doors to a future where we can cure diseases where we have not succeeded - cancer, type-1 diabetes, and chronic lymphocytic leukemia.

But there is a call for public awareness. The National Institute of Health (NIH) takes a very active role in making the public aware of its benefits and drawbacks. They offer advice on how to choose a clinic that has the qualifications expected by their peers.

In February of 2018, both the FDA and the NIH joined the American Academy of Orthopaedic Surgeons at Stanford University to:

1. establish a clear, collective impact plan for improving the clinical evaluation, use, and optimization of biologics in orthopedics and
2. develop a guidance document on clinically meaningful endpoints and outcome metrics to accelerate the assessment of biologics for common orthopedic conditions.

The outcome was twofold. First, the participants created a framework for developing trials. Second, they co-wrote the recommendation for both physicians and institutions offering these therapies. They want signatories to commit to maintaining high-quality registries used for quality assessment. By January 21, 2020, full reviews were being assessed and published.

Today many practitioners heal soft tissue with adult stem cells. Knees, shoulders, wrists, and hands are typical candidates for stem cells in the emerging field of regenerative medicine.

## How To Find the Good Players.

Many tears to ligaments and tendons require surgery. But first, a skilled doctor will examine the damage in an MRI. If the tear is right, stems cells can eliminate the need for surgery. While scams are still here, and doctors vary in skill, patients can protect themselves with five easy to ask questions.

1. Who will be doing the procedure?
2. What will they be injecting?
3. Where will they be injecting it?
4. When does it work and not work?
5. How will they be performing the procedure?

The answers to these questions provide the proof needed to know if you should trust the clinic. By the time you have done your research, you should tell your friend if you know that:

- The stem cell clinic is owned and operated by an experienced stem cell physician

- A trained injection specialist performs stem cell injections.
- Spine and joint pain receive X-ray guided stem cell injections
- Fat and bone marrow, harvested from your own body, are the stem cells' source in your treatment.
- You've read several detailed case studies about the clinic's patients
- You have talked with patients who left public reviews of the clinic and staff.

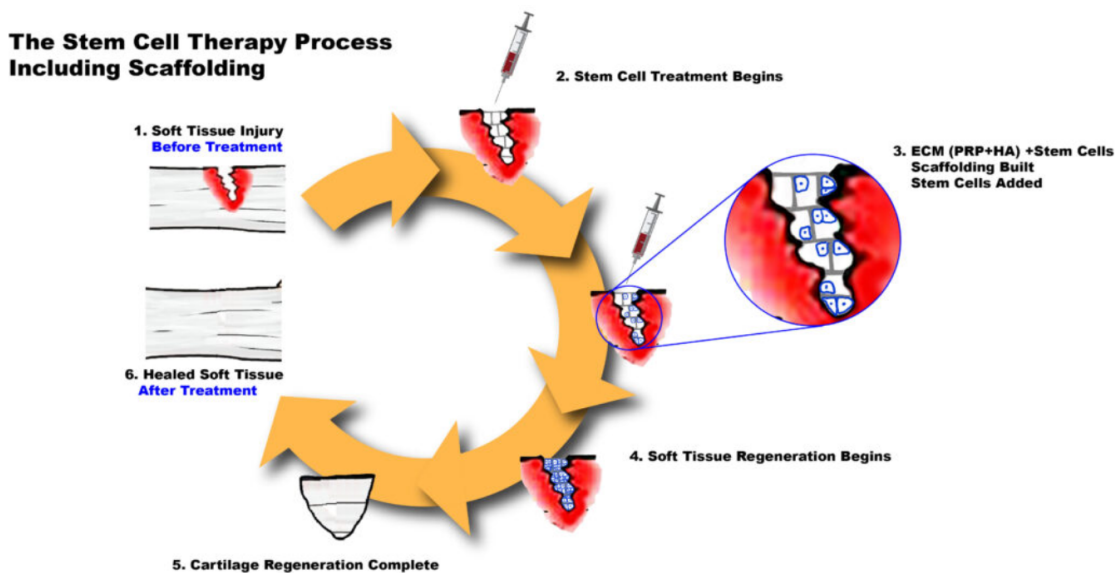
## Our Position

At the [New York Institute of Hormone Replacement](#), we see patients who respond to hormone replacement very well. So well, that they do not pace themselves and over-extend their bodies. They can tear ligaments or damaged cartilage. Common reasons include running too fast or far or trying to make up for lost treadmill time.

## How Stem Cell Therapy Heals Tissue

The following example relates to typical candidates in the process we endorse.

When a candidate meets stem cells' criteria, a medical doctor applies adult stem cells to a three-dimensional extracellular matrix ( the ECM Matrix). Then hyaluronic acid (H.A.) reproduces the tissue. Using H.A. in the matrix allows a more dense and compact cellular [environment](#).



### 1. Soft Tissue Injury

First, a magnetic resonance image (MRI) examines the injury. Completely severed cartilage requires surgery and a surgeon is recommended. But if the cartilage (tendon, ligament, or meniscus) has a "partial" tear, stem cells can regenerate the tissue.

### 2. Stem Cell Treatment Begins

When the patient qualifies as a candidate for stem cell therapy, a medical

doctor begins by injecting a combination of Extracellular Matrix (ECM), Hyaluronic Acid (H.A.), Platelet-Rich Plasma (PRP) along with stem cells into the injured joint. Ultrasound guides this procedure.

### *3. ECM (PRP+HA) + Stem Cells Scaffolding Built*

The combination of Extracellular Matrix (ECM) and Hyaluronic Acid (H.A.) builds a scaffold where stem cells can attach and begin to divide and grow.

The Platelet-Rich Plasma (PRP) contains important Growth Factors (G.F.'s) necessary for the survival, division, and growth of the stem cells.

### *4. Soft Tissue Regeneration Begins*

The stem cells begin to actively divide, grow, and differentiate along the scaffold into new cartilage (tendon, ligament or meniscus).

### *5. Regeneration Complete*

When the cells have been engineered to evolve into the new tissue they are said to have completed **differentiation** and have regenerated the damaged cartilage.

### *6. Fully Healed Soft Tissue*

The previously injured cartilage is now fully healed.

Stem cell therapy is a well tested and approved solution for patients with partial tears. Healing takes time because the stem cells regenerate soft tissue. While the patients heal, they learn to adjust to their newfound energy.

The Los Angeles office of the New York Institute of Hormone Replacement limits work to the appendicular skeleton – the shoulder, arm, hand, pelvis, leg, and foot. The institute supports stem cell therapy on the appendicular frame because the treatments are highly stable.

In the axial skeleton – the spinal cord – **NYIHR** refers patients to highly regulated clinical trials. Colleagues at Cedar Sinai and other research centers participate in approved Investigational New Drug Applications (IND) issued by the FDA.

For people like Deborah Scott, finding a good player in stem cell therapy changes life. That is the experience everyone should have. With a bit of sleuthing, everyone can.