



White Paper “Stem Cell”/Progenitor Cell Treatments

The Facts for Musculoskeletal Patients

CALIFORNIA
ORTHOPAEDIC
ASSOCIATION

CONTACT

PHONE:
916-454-9884

ADDRESS:
1246 P Street
Sacramento, CA 95814

WEBSITE:
www.coa.org

EMAIL:
admin@coa.org

Task Force Members

C. Thomas Vangsness, Jr., M.D., Chair
Lesley Anderson, M.D.
Ronald Navarro, M.D.
Russell Nord, M.D.
Michael Purnell, M.D.



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Some health care providers and entities marketing “stem cell therapies” offer biologic products that are both unapproved and unproven. Many injections include only a miniscule amount of stem cells. Patients are being misled as to the effectiveness of the treatments and are being charged thousands of dollars for a single injection. The FDA, FTC and state licensing boards are stepping up their efforts to protect patients from these unscrupulous health care providers and marketers who might not share with patients the lack of proven clinical effectiveness.

The Facts for Musculoskeletal Patients:

- “Stem cell”/progenitor cell based cellular treatments are being actively developed and hold tremendous hope for treating a wide variety of medical conditions from diabetes to heart disease and joint repair. But currently, the research is not there to show that they regenerate tissue. There is no evidence “stem cells” regenerate tissue in vivo.
- The term “stem cells” should not be used.
- The FDA prohibits isolation of cells for expansion or culturing unless part of an approved FDA trial. It is recommended anyone working with stem cells carefully review the Guidelines published by the FDA
- It is unlawful to advertise, market and promote (i.e. make claims) the use of any source of cells that have not been cleared or meet the FDA criteria. The AAOS Standards of Professionalism on Advertising advises that you can only tell patients your own personal experience and you must state clearly that it is only your own personal experience.

There is early evidence that several cell therapies, including expanded progenitor cells, bone marrow aspirations (BMA), Micronized Adipose Tissue, and Platelet Rich Plasma (PRP) injections have a therapeutic effect for several orthopaedic conditions. Some treatments have more evidence than others. PRP and BMA are blood products and are NOT regulated by the FDA as are Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). There are no stem cells in PRP and it should not be marketed as containing them. HCT/Ps are human cells, tissues, and cellular and tissue-based products that consist of human cells or tissues intended for implantation, transportation, infusion or transfer into a human recipient. Those using biologic treatments should be familiar with the rules for these products.

Some references include (not an exhaustive list):

- [Same Surgical Procedure Exception under 21 CFR 1271.15\(b\): Questions and Answers Regarding the Scope of the Exception](#)
- [Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use](#)
- [ODG PRP Guidelines](#)
- [Stem Cells and OA Review - January 2019: Hip Arthroplasty](#)
- [Metanalysis Stem Cells - January, 2019: AJSM](#)
- [Intra-articular Injection of Platelet-Rich Plasma Is Superior to Hyaluronic Acid or Saline Solution in the Treatment of Mild to Moderate Knee Osteoarthritis: A Randomized, Double-Blind, Triple-Parallel, Placebo-Controlled Clinical Trial - January, 2019 – Arthroscopy](#)
- [FDA Guidelines for Regenerative Medicine Therapies: The Orthobiologic Institute \(TOBI\) 2018](#)
- [Regulatory: Changes in HCT/Ps presented by Jack Farr, M.D.](#)
- [Functional Outcomes Following Microfragmented Adipose Tissue Versus Bone Marrow Aspirate Concentrate Injections for Symptomatic Knee Osteoarthritis - Stem Cell Transitional Medicine](#)

- Micronized Adipose Tissue has been 510 (K) cleared for orthopaedic surgery as a “tissue treatment,” but does not have a specific FDA clearance to treat osteoarthritis or any other specific orthopaedic uses. It is not illegal for doctors to use micronized fat for orthopaedic surgery, arthroscopic surgery and many other medical fields.
- Cell Treatments:
 - a. Autologous cells Platelet Rich Plasma (PRP) from blood have no progenitor cells/stem cells.
 - b. Bone marrow has <<1% progenitor/stem cells
 - c. Adipose tissue contains ~2% progenitor/stem cells.
 - d. Allogenic placenta products can have from 0-8% of progenitor/stem cells. Currently use of placenta products is not cleared by the FDA for any orthopaedic use.
 - e. It is the responsibility of the surgeon to ensure that they know the source of the cells they are injecting and that the cells have been properly screened and are compliant with standards from the American Association of Tissue Banks (AATB) and the American Association of Blood Banks (AABB).
- Patients seeking pain relief for osteoarthritic conditions are vulnerable to misleading marketing tactics.
- At the core of the patient-physician relationship is a sense of trust. A patient trusts that the physician is knowledgeable and provides appropriate representations of his or her abilities. A physician or other health care professional who misrepresents his or her

abilities or advertises services in a false or misleading fashion damages the patient-physician relationship of trust. In addition, the physician/health care professional who misleads through advertising may prevent a patient from making informed decisions about important health care matters.

- Currently, group health care plans and Medicare do not cover the expense of these treatments. Health care providers should have patients sign appropriate informed consent forms, as well as an Advanced Beneficiary Notice (ABN).

Conclusion

While we are excited at the hope of future biologic treatments for osteoarthritic conditions, we cannot condone misleading advertising to patients.

Physicians and other health care professionals should not rush to routinely use or suggest biologic treatments for their patients until they are confident that they are safe and efficacious. They need to be knowledgeable in the most current FDA Guidelines.

Currently, the use of biologic options requires a thorough analysis of the patient's condition prior to recommending them for treatment.

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