**STEM CELL TREATMENT – ANSWER TO PRAYERS OR RISKY ALTERNATIVE?**

Most of you may have heard about “Stem Cell therapy.” This is a medical procedure using stem cells to treat or prevent a disease or condition. Body fat and bone marrow are the most widely used sources for stem-cell therapy, but there are other sources and means by which to extract stem cells. Unfortunately, this form of therapy has become controversial. On June 25, 2019, the U.S. District Court for the Southern District of Florida issued an injunction against *U.S. Stem* *Cell Clinic, LLC*, of Westin Florida, and others for manufacturing and distributing Stromal Vascular Fraction (SVF) products (adipose/fat tissue derived stem cell products) until they come into compliance with the rules and regulations of the U.S. Food and Drug Administration (FDA). The U.S. Stem Cell clinic was accused of blinding three (3) patients as a result of injecting stem cells into their eyes made from fat from the patients’ bodies.

It is human nature for patients suffering from a debilitating or life-threatening illness to seek alternative treatments and, in some cases, forego needed conventional treatments. Such is the case with stem cell therapy. While it is understandable that patients would seek unproven therapies, recent lawsuits shed light on the growing number of for-profit stem cell clinics in the U.S. selling unproven therapies directly to patients. Unproven therapies include those not approved by the FDA and, in some cases, therapies that are explicitly banned by the FDA. Most stem cell therapies are not covered by insurance and patients typically pay thousands of dollars out of pocket for such treatment.

This is not to say that stem cell therapy is without significant potential and there are specific areas where stem cell therapy has proven to have efficacy. This article, therefore, focuses on unscrupulous clinics offering stem cell treatments and products which are not proven to be beneficial. According to a July 25, 2019 letter from members of the U.S. House of Representatives to the acting Commissioner of the FDA, such treatments not only pose public health risks for patients but also harm the future promise held by the development of stem cell therapy as a field. In response, the FDA has sent 45 communications to manufacturers and providers of stem cell products and it has also filed two (2) lawsuits against clinics in California and Florida.

The case of *U.S. Stem* *Cell Clinic, LLC*, is not the only stem cell clinic to come under judicial scrutiny. In April of this year, the New York Attorney General announced a lawsuit against a stem cell clinic alleging the clinic used misleading claims and engaged in deceptive practices to attract business. Such clinics are taking advantage of patients, many in irreversible situations with chronic or terminal diseases, by leveraging the widespread belief in the eventual efficacy of these products. According to a number of recent publications, the Florida and New York clinics are but two of hundreds that have sprung up around the country offering to treat a wide variety of illnesses with products they say contain stem cells that have healing or regenerative properties. Medical experts say there is no proof that such treatments work.

Much of the controversy is due to marketing tactics. Stem cell clinics typically reach their patients through online direct-to-consumer marketing, offering what is referred to as “tokens of scientific legitimacy”, such as websites with self-serving articles and patient testimonials. To inform the public, the FDA has published a new consumer campaign warning against unapproved stem cell therapies. The head of the world’s largest association of stem cell scientists wrote a piece in *Scientific* *American* advising patients that many for-profit clinic operators are run by “people wanting to make money off of a desperate and unsuspecting and unknowing public.”

With that said, stem cells and regenerative therapies do offer opportunities for advancement in the practice of medicine. The 21st Century Cures Act was signed into law by President Obama in December, 2016, and directed the FDA to provide predictable regulatory programs through which regenerative therapies, including stem cell therapies, could be developed and approved. The problem is that rogue clinics offering such therapies are doing so outside the regulatory scheme and other efforts to insure the safety and efficacy of stem cell treatments. Some clinics have misled patients into believing that the therapies they offer are FDA-approved or that they are being offered as a part of FDA-sanctioned clinical trials.

In an effort to inform and protect the public, the Mississippi State Board of Medical Licensure, effective August 26, 2019, adopted Rules and Regulations governing the administration of “Complementary and Alternative Therapies” (Codified as Part 2635, Chapter 13). The regulation incorporates many of the recommendations of The Federation of State Medical Boards which was published in April, 2018. “Complementary, Alternative or Regenerative Medicine Therapy” is defined as those healthcare methods of diagnosis, treatment or interventions that are not acknowledged to be conventional, but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine. Examples of these therapies include but are not limited to IV infusion/hydration therapy, oriental medicine techniques and practices other than licensed acupuncture, utilization of Artificial Intelligence and stem cell therapy.

When adopting the regulation, the Board noted the growing number of physicians and patients who are both implementing and seeking alternative medicine. The Board recognizes that innovative practices could benefit patients and improve care, but notes the prevalence of consumer fraud occurring across the country and, unfortunately, not infrequently, in the practice of medicine. The Board states:

Where evidence is unavailable for a particular treatment in the form of clinical trials or case studies, Licensees [licensed physicians] must only proceed with an appropriate rationale for the proposed treatment and justification of its use, in relation to the patient’s symptoms or conditions. Novel, experimental or unproven intervention should only be proposed when traditional or accepted proven treatment modalities have been exhausted. In such instances, there must still be a basis in theory or peer acknowledged practice. The burden rests solely with the licensee [licensed physicians] in regard to the substantiation supporting the use of a particular therapy.

To reduce the potential for fraud and harm to the public, the new regulation mandates that treating physicians take and document certain steps, some of which include the following:

* Physicians who choose to utilize alternative therapies must obtain written informed consent from the patient prior to utilization of such therapies, said consent to include an accurate description of the benefits and risks of the treatment based on scientific evidence as well as an explanation of alternatives to treatment.
* The physician must conduct an appropriate medical history and physical examination, with documentation of whether the patient has already undergone conventional therapies, as well as what medical options have been offered or tried.
* Preparation of a written comprehensive treatment plan clearly establishing a favorable risk/benefit from the alternative treatment as compared to other treatments for the same condition.
* Maintain complete medical records of the therapy provided.
* The physicians must demonstrate knowledge and understanding of the medical and scientific knowledge connected with any method of the alternative medicine they choose to provide.

One of the most important aspect about the Board’s new alternative medicine regulation deals with advertising. The importance of truthful and honest advertising cannot be overemphasized, as stem cell treatments and other forms of alternative therapy attract desperate patients. Accordingly, the Board, following the recommendations of the Federation of State Medical Boards, identified twelve (12) areas of conduct which may be deemed as misleading to the public. These include, but are not limited to, certification of products or clinical practices by “international standards organizations” (not FDA), registering clinical trials whose apparent purpose is solely to attract patients willing to pay to participate in them; using the statement “ethics review” to convey a sense of legitimacy, using open-ended voluntary monitoring data rather then undertaking controlled clinical trials, and use of patient testimonials which are inherently misleading.

What does this mean for the general public? While stem cell products hold significant potential to improve human health, the potential for abuse by “for profit” clinics must be addressed. If you are considering stem cell treatment or other forms of alternative medicine, go to the Board’s website ([www.msbml.ms.gov](http://www.msbml.ms.gov)) and review the above regulation (Part 2635, Chapter 13 Complimentary and Alternative Therapies), or contact the Board by telephone and speak with one of its employees/agents (601-987-3079) or contact the FDA Consumer information line (888-463-6332). Just as important, play close attention to the clinic’s advertisements or website. The old saying, “if it’s too good to be true, it may not be true” clearly applies. Finally, do not be afraid to ask questions. Is the clinic participating in an FDA-approved clinical trial? Is the anticipated stem cell procedure covered by insurance? Does the clinic use patient testimonials (often a red flag)? Does the clinic offer conventional therapies as a precondition to alternative therapy? Were you referred to the alternative medicine (stem cell) clinic by your regular treating physician or did you find the clinic on-line or through social media? Such deliberate and careful inquiries will go a long way to protect you from harm and, most importantly, help you to receive the medical treatment you need.

Stan Ingram is a partner at Biggs, Ingram & Solop. You may reach him at 601-713-6318. www.bislawyers.com