False Promises: The Danger of Unproven Stem Cell Therapy Clinics By Shannon Clayton

Stem cells have the potential to treat a variety of medical conditions and diseases. However, to understand this potential, we must first understand stem cells. Within a growing embryo, stem cells give rise to all of the specialized cells that make up the blood, brain, bones, and organs of the organism. In an adult, stem cells divide to replenish both the stem cell population and the specialized cells that are damaged, aging, or dying. In theory, we could use stem cells to replace cells damaged due to stroke, diabetes, neurological disorders, spinal cord injuries, some birth defects, and more. The possibilities are endless!

Despite the exciting potential of stem cells and the hard work being done by researchers, science moves at a necessarily slow pace and most stem cell therapies are not yet ready for prime time. In fact, the FDA has only approved 16 products that involve cell or gene therapy⁴. Science moves at a slow pace to ensure that medical products and treatments are beneficial and safe. Unfortunately, predatory entrepreneurs recognize the hope that stem cells give and have found lucrative opportunities for money to be made. If you were to look up "stem cell therapy" or "stem cell treatment" online, you would find clinics offering treatments for a vast array of ailments, from chronic obstructive pulmonary disease to retinal disease to lyme disease. Stem cell tourism, as the name suggests, is when people travel to countries for stem cell treatments where there are few or no regulations on stem cell therapies. Although Americans are indeed travelling abroad for treatment, these clinics are present in the U.S. as well. A study by Turner and Knoepfler (2016) found over 570 U.S. clinics and recognized "hot spots", where there tend to be more than one clinic in a given area as represented by a blue star in Figure 1³.

The treatments offered by these clinics are unproven and very dangerous, catering to individuals who are vulnerable and willing to pay thousands of dollars for what sounds too good to be true—which in this case, it is. Most often, the clinics derive stem cells from patient adipose tissue, or fat, and a smaller percentage of clinics may use bone marrow or blood³. The cells are then injected back into the patient for *magic* to happen, however, this is where the danger begins. Within our bodies there are complex interactions between our cells, proteins, lipids, carbohydrates, and other molecules making it hard to predict what is going on. Without rigorous testing, there is no way to know what is going to happen once the cells are reintroduced to the patient. For example, three patients with macular degeneration had stem cells derived from adipose tissue injected into their eyes, resulting in two of the three becoming legally blind. Another patient diagnosed with lupus and experiencing renal failure had blood stem cells injected into the kidney, the stem cells later developed into tumors and eventually resulted in the kidney having to be removed completely¹.

These bogus stem cell clinics do not know whether a treatment will help or harm a patient without going through the rigorous process of a clinical trial. The only thing they know is that people are willing to pay a lot of money if convinced that it **MAY** help them. This short-cut money making scheme has many potential dangers and undermines the actual research done on stem cell therapeutics. The FDA can and should step in when stem cells are used in unapproved ways. In 2017, the FDA announced increased regulations and oversight on these clinics⁵. The FDA is currently making moves to shut down two stem cell clinics, one in California and one in

Florida, due to risky practices². These checks and balances are in place to protect individuals in need of such treatments.

If you or a member of your family is considering a clinic like these for-profit clinics, remember and share what you have read here. Steps are in place to ensure these treatments can advance as quickly as possible, with safety as the number one goal. Trust in the scientific process and the growing number of clinical trials currently ongoing for a variety of stem cell therapeutics. It's only a matter of time!

To search for clinical trials, visit this site: <u>https://clinicaltrials.gov/</u>

References

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