Unapproved Stem Cell Therapies, a Public Health Menace

By Lila Abassi — February 8, 2016

Clinics are popping up around the country pedaling stem cell therapies that are supposed to treat anything from crow’s feet to multiple sclerosis. The problem is most of these claims are based on zero percent science and 100 percent quackery.

Even if there is a grain of truth in what's being claimed, unapproved stem cell treatments threaten the progress of basic research and clinical trials that we still need to establish safe stem cell therapies for serious illnesses.

Recently, the Food and Drug Administration issued their draft guidance for tissue-based product establishments, health care providers and FDA staff that are essentially suggestions and recommendations but not legally enforceable. Additionally, stem cell therapies will not be subject to FDA regulation if said therapies expose the stem cells to minimal manipulation, ensure that the therapy is used for what it is claiming, that the therapy not be used in conjunction with any other chemical (save water), and that once used there will not be any systemic effects. If the stem cell therapy does not meet the aforementioned criteria, then the FDA will regulate the treatment as a drug, device, and/or biological product and will thus require pre-market review.

What are stem cells and why are they being used in flagrantly inappropriate treatments? Stem cells can be:

- **Totipotent**, which means they can become any cell of the body including embryonic and placental tissue
- **Pluripotent**, meaning they can still become any cell, including embryonic but not placental tissues
- **Multipotent** (i.e. mesenchymal) which means they can only become a certain set of cells
bone, cartilage, muscle and fat

- Unipotent, or that cells can only make a single type of cell

What many of these stem cell therapy clinics [4] are doing is taking adult stem cells, thought to provide the basis for tissue maintenance and response to injury, from fat tissue (for example), during a liposuction. The cells are sorted and the stem cells are isolated and injected back into the patient, most often for cosmetic procedures such as facelifts. These treatments can cost anywhere from $5,000 to $25,000.

The problem, often, is that there is no guarantee as to what is in the syringe that is being injected back into the patient from absolutely nothing to something that can theoretically be cancer promoting or infectious.

In the case of one unfortunate woman [5], who underwent a cosmetic procedure by a swanky Beverly Hills plastic surgeon, the "stem cells" were injected into her face during a face-lift. The problem was that the doctor also injected her with a filler whose main ingredient was calcium hydroxylapatite, which when mixed with mesenchymal stem cells, will be stimulated to turn into bone. Three months after the face-lift this woman had corrective surgery to remove pieces of bone from her eyelids because the plastic surgeons failed to account for this interaction.

Paul Knoepfler, a cell biologist at U.C. Davis, and frequent blogger who tracks for-profit stem cell clinics on his blog, The Niche (via Stat News) states, It’s a huge, unapproved human experiment.

In an article in Scientific American, he is quoted, Many of us are super excited about stem cells, but at the same time we have to be really careful. These aren’t your typical drugs. You can stop taking a pill and the chemicals go away. But if you get stem cells, most likely you will have some of those cells or their effects for the rest of your life. And we simply don’t know everything they are going to do.

Researchers are investigating stem cell therapy in well-controlled clinical trials for many devastating conditions such as heart failure, neurodegenerative disorders such as Parkinson’s disease and spinal cord injuries. To muddy the clinical waters with potentially harmful treatments in conjunction with negligent and predatory doctors, will serve to discredit valuable and legitimate research.

Of course, no good cosmetic story would be complete without the mention of America’s favorite family the Kardashians [6] who are culpable in spreading the false gospel of the miraculous benefits of "stem cell facials" that run people upwards of $550.

Like any organization devoted to sound science, we here at ACSH strongly advocate that while Kim Kardashian may have plenty of solid wisdom to dispense to her public, we all should resist the urge to heed any of her "medical" advice.