A Case for Accelerating Regenerative Medicine
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abc NEWS April 19, 2012 - Early in March 2012, 77-year-old Richard Poling entered a clinic in Bonita Springs, Florida for a stem cell treatment to help with age related heart and lung conditions.

Mr. Poling, an avid golfer and family man from Indiana, had sought several conventional therapies to alleviate his suffering with unsatisfactory results and was desperate for a treatment that would allow him to enjoy his life again. Shortly after receiving his treatment, however, Mr. Poling went into cardiac arrest at the clinic and passed away. According to investigators, the alleged stem cell treatment Mr. Poling received was not approved by the FDA.

According to multiple reports, the local cardiologist who conducted the treatment removed fat cells from Mr. Poling's abdomen and sent them to a lab that claimed to process and isolate adult stem cells from a patient's own fat. A few hours later a second procedure was performed at the same clinic in which Mr. Poling had the stem cells injected back into his bloodstream for their regenerative properties. The entire process took one day, and during the hours between the procedures, Mr. Poling enjoyed lunch out with his family.

Mr. Poling was the second patient to die under the same doctor's care in the last two years after receiving his supposed stem cell therapy. The physician was already under order by the State of Florida to cease performing any further stem cell treatments pending further review, but the doctor continued performing various stem cell procedures until his license was revoked and suspended after the death of Mr. Poling.

With all the marvels of modern medicine there are still medical needs that remain unmet by our conventional healthcare system. When that happens, desperate people like Mr. Poling search for alternatives anywhere they can find them. One of these alternatives is stem cell therapy, a science that is no stranger to controversy.

The problem lies in that most stem cell therapies are not FDA-approved, and thus the market is under-regulated and consists of products that lack standardization and legitimacy. The lack of approved products has generated a gray market for stem cell therapeutics - one that is dangerous, and as we have seen, can be deadly.

Even though the United States has taken a passive approach to stem cell therapy as compared to its European and Asian counterparts, there are several US companies vying for FDA approval as they develop stem cell therapies for indications such as heart disease, neurologic disorders, and ophthalmologic diseases. While these companies spend hundreds of millions of dollars individually – billions collectively – to conduct groundbreaking research and development, rigorous safety studies, and extensive human trials to establish meaningful uses of their medical technologies, the majority of their studies occur overseas where they are sure to receive swifter review and eventual approvals.

Many patients will go to any lengths for treatment, travelling to another country for more cost-preserving procedures, or travel to receive a treatment not available in one's home

country, but medical tourism isn't practiced by just our very sick. Recently we have seen an increase in news stories of celebrity athletes who have travelled abroad to receive stem cell therapies to recover from sports injuries. This could inspire our youth and their parents to seek similar treatments locally by unproven stem cell practitioners with catastrophic results.

Problems arise when patients travel to places where regulation is not paramount and where treatment is questionable to begin with. A simple Internet search reveals that there are many companies willing to sell "stem cell therapies" for virtually any indication in the form of injections, pills, and creams without proven scientific basis or medical merit. We have seen physicians claiming that any autologous procedure, one in which the patient's own tissue are used to isolate adult stem cells, are safe to use when adequately processed.

There is no telling, however, without any studies as to the purity of the cells being hawked by today's stem cell alchemists, whose concoctions may contain useless cells, such as fat cells, which could prove deadly if injected into the bloodstream, or worse, a population of malignant transformed cells that could be cancerous.

This is when we start to see morbidity and mortality associated with these treatments. Stem cell therapy is just the latest in a slew of modalities that will cause patients harm if we, as a nation, cannot bring standardization and regulation to an entire industry.

No responsible party will advocate that the FDA regulate the stem cell industry with less scrutiny and vigor than it does for other therapeutics. However, the FDA may become more responsive after a company has established defensible safety and efficacy profiles for its stem cell therapy. Once a Phase I safety study has been inspected and the data has met the standards evaluating the chances of adverse events, the therapy should be launched into an accelerated approval process with abbreviated timelines, allowing our sickest patients swift access to safe medical technologies with extraordinary promise. The FDA could allow marketing approval for the treatment and allow remaining questions to be thoroughly answered post-market launch. This is not unlike the culture embodied in the oncology review division of the FDA which has a culture of fast-tracking treatments that show tremendous results in trials to aid physicians treating our sickest cancer patients in highly controlled environments.

The seriousness of this situation cannot be understated – there are legitimate regenerative medicine companies developing stem cell products that have real potential to create ground-breaking technology which can offer treatment for conditions that until now have had little to no options. Bear in mind these are therapies that have been investigated and validated thoroughly in trials and retrials for close to two decades in multiple animal and human studies. It would be better to have a few years of well supported products approved by the FDA that have not answered all the questions than several more years of charlatans conjuring stem cell therapies from their basements.