

Fraud Alert! Unproven Stem Cell Use Prompts International Call to Action



By Jamie Wells, M.D. — July 10, 2017



Credit: Shutterstock [1]

An international team of medical experts recently published a global call to action in [Science Translational Medicine](#) [2] in an effort to curb the unethical, unsubstantiated use of stem-cell based therapies driving medical tourism. Such ill-advised “stem cell” treatments have led to pediatric deaths in Germany, blindness in the United States, the closure of Italy’s Stamina Foundation to name a few as well as a variety of untoward effects given their lack of rigorous testing for safety and efficacy.

With high price tags, so-called “stem-cell” clinics are designing therapies without evidence that serve to do harm, be ineffective, prey on the most vulnerable—potentially curtailing their ultimate treatment choices, and threaten the legitimate work being done that holds great promise for devastating disease.

When greed trumps science, we all lose.

In [The Worst 'Healthcare': 'Stem Cell' Clinics Wrought With Red Flags, Insincerity And Blindness](#) [3], I detail the distressing accounts of three patients who endured irreparable damage to their vision after seeking treatment at the same unnamed “stem cell” clinic in Broward, Florida. Reported in the [New England Journal of Medicine \(NEJM\)](#) [4], the harrowing experiences of the women aged 72-88 years old resulted in blindness to near blindness from untested “stem cell” therapies being injected into their eyes while being fleeced \$5000 for the procedures. Promised “revolutionary” therapy, they were left with catastrophic reminders of the unfortunate and unnecessary ordeal.

Theirs is a cautionary tale of the hazards of poor and irresponsible practice at a private “stem cell” clinic, unfixable medical interventions with no scientific evidence to back claims, sales over

substance, marketing hype lacking in meaning and actions taken by seemingly complicit personnel—who may have misrepresented their credentials—that took advantage of those most in need. See [here](#) [3] for a more detailed road map of how to read between the lines of such marketing hype and to understand the timeline of this particular bad outcome.

Here's the deal with stem cells...

Stem cells are currently in use for a rather limited scope of disorders. Ones where the data is well-established and been subject to proper design, rigorous testing and clinical trials. They are also being actively studied, in general. The notion that they can cure every type of medical condition is not one based in our present reality or the near term future. The media tends to overstate where we are in stem cell-based therapeutics.

The [safety and efficacy](#) [5] of stem cell use when derived from bone marrow or your peripheral blood is well-established, but stem cells are now being increasingly derived from alternate sources like adipose (aka fatty) tissue and put in use for orthopedic to neurological disorders.

Many in the medical community are enthused about their promise and rightfully so as some advancements are already underway. In my recent article [Did Gene Therapy Cure Sickle Cell Disease?](#) [6], I discuss the hopeful work in autologous stem cell transplantation obtained from bone marrow for this and other hemoglobinopathies. This is further explored in this television appearance: [Dr. Jamie Wells On Al Jazeera TV Discussing Sickle Cell Anemia](#) [7].

Facilities offering false hope often based on the most minimal of clinical evidence are popping up all over the country and world without well-controlled clinical trials or having met any regulatory standards. In the cases of autologous use especially—since they are your own cells, advocates affirm they are safe. These [private “stem cell clinics”](#) [8] are typically patient-funded at nonacademic centers, are not based on preclinical research or sound design and lack investigational new drug application with the FDA—because, again, they are your own cells despite the fact what the facility mixes them with are unknown agents that have not been tested to confirm safety. (1)

In a [perspective written by the U.S. Food and Drug Administration](#) [5] in the NEJM, the FDA maintains: “Outside the setting of hematopoietic reconstitution and a few other well-established indications, the assertion that stem cells are intrinsically able to sense the environment into which they are introduced and address whatever functions require replacement or repair—whether injured knee cartilage or a neurologic deficit—is not based on scientific evidence.” The piece goes on to inform about misadventures of their use and the worrisome lack of evidence in particular in circumstances where therapies proved harmful or ineffective when properly studied.

Hence, why this recent global call to action by worldwide leaders in the field...

Buoyed by efforts of the scientific community to impact changes in “stem cell” facilities in Germany and Italy among others, an [international consortium of medical experts outline in their latest publication](#) ^[2] local to transnational considerations that could limit unchecked marketing claims and unfounded “science.” Appreciating the current climate of expediting lengthy approval processes, the politics of “right to try” legislation and direct-to-consumer advertising, the authors contend with respect to sham stem cell therapies under-regulation has led to substantial, reverberating harm.

Due to general regulatory resistance, the panel of fifteen urges a more coordinated approach—nationally and internationally—that emphasizes engagement, harmonization and enforcement. Highlighting prior success, the group encourages mobilization of international scientific organizations to create global standards and the utilization of traditional and social media type engagement to expand reach to the public as well as positively influence national policies.

With the main goals of eliminating harmful therapies and preserving a patient’s ability to seek effective treatment, they identify further the risk of not doing anything will worsen the big problems of destabilizing health markets and delegitimizing biomedical efforts that could genuinely benefit society.

Among their requests for proactive efforts is for groups with broad constituencies like the World Health Organization (WHO) to dispense guidelines in conjunction with national authorities for the responsible use of human cells and tissues which they maintain they already do for medical devices and medicines. They call for cross-border partnerships for compliance.

Of particular note, [the article](#) ^[2] includes a wonderful chart clarifying where inroads can be made locally, regionally and internationally to prevent the all too frequent co-opting of scientific legitimacy. It can be very difficult for patients to suss out what is fact from fiction when powerful advertising runs amok. Words like *revolutionary* and *clinical trials* and *expert* are consistently thrown around to confuse and can be a challenge for many to unpack accurately.

The authors provide in [this graphic](#) ^[2] tangible ways to cut through the nonsense. By outing deceptive tactics used throughout the commercialization of these products and spreading these protective messages, patients can become empowered and the culture of fleecing might shift. Here, they point out a number of ways scientific integrity gets diminished: the use of renting space in academic facilities as a way to appear legitimate by association, suggest by having a patent application this means the product is proven or tested as opposed to just a sign of an initiation of applying, citing preclinical and other findings to rationalize clinical use without efficacy testing etc. (3) I would argue this list is an excellent tool that could be applied well beyond the stem cell industry. Interventions starting with this list could certainly support more honesty.

In conclusion...

Though rarely a lover of regulation, in general, given the likelihood of overdoing it, creating more problems and the tendency for many policies to be one-size-fits-all and misguided, in this realm the price people are paying—as well as society—could be too great to allow the wild west ways of the stem cell industry to continue as is. The authors in this work provide some meaningful measures to compel a more honest arena.

Source(s):

1. Kuriyan, M.D., Ajay E.; Albini, M.D., Thomas A. et al. [Vision Loss after Intravitreal Injection of Autologous “Stem Cells” for AMD](#) [8]. *N Engl J Med* 2017; 376:1047-1053.
2. (& 3) Douglas Sipp, Timothy Caulfield, Jane Kaye, Jan Barfoot, Clare Blackburn, Sarah Chan, Michele De Luca, Alastair Kent, Christopher McCabe, Megan Munsie, Margaret Sleeboom-Faulkner, Jeremy Sugarman, Esther van Zimmeren, Amy Zarzeczyn, and John E. J. Rasko, [Marketing of unproven stem cell–based interventions: A call to action.](#) [2] *Science Translational Medicine*. 05 Jul 2017:Vol. 9, Issue 397, eaag0426 DOI: 10.1126/scitranslmed.aag0426.

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[1] <https://www.shutterstock.com>

[2] <http://stm.sciencemag.org/content/9/397/eaag0426>

[3] <http://www.acsh.org/news/2017/03/20/worst-healthcare-stem-cell-clinics-wrought-red-flags-insincerity-and-blindness-11015>

[4] <https://www.nejm.org/doi/full/10.1056/NEJMoa1609583>

[5] <http://www.nejm.org/doi/full/10.1056/NEJMp1613723>

[6] <http://www.acsh.org/news/2017/03/07/did-gene-therapy-cure-sickle-cell-disease-10950>

[7] <http://www.acsh.org/news/2017/03/16/dr-jamie-wells-al-jazeera-tv-discussing-sickle-cell-anemia-11007>

[8] <http://www.nejm.org/doi/full/10.1056/NEJMoa1609583>