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Is The Wild West Of Stem Cell Therapies Coming To An End?

By Jamie Wells, M.D. — November 17, 2017

Credit: Wikimedia [1]

Is the *Wild West* of stem cell therapies coming to an end? Newly released guidelines [2] from the U.S. Food and Drug Administration (FDA) suggest illegitimate, unproven uses might become a thing of the past.

The latest statement [2] by the FDA announces “a comprehensive policy framework for the development and oversight of regenerative medicine products, including novel cellular therapies.”

Stem cell treatments have held great promise for a few decades now. Though specific therapies in the narrow realm of blood cancers and disorders, for example, demonstrate some realized dreams as a product of bona fide research, many private clinics and providers of a variety of professional backgrounds are touting them as a panacea for an exhaustive list of medical conditions. The untested concoctions they aggressively promote typically involve liposuction of fat from one part of the body for injection into another after some often unspecified manipulations of the material take place.

FDA Commissioner Scott Gottlieb, M.D. recognizes that “Alongside all the promise, we’ve also seen products marketed that are dangerous and have harmed people. With the policy framework the FDA is announcing today, we’re adopting a risk-based and science-based approach that builds upon existing regulations to support innovative product development while clarifying the FDA’s authorities and enforcement priorities. This will protect patients from products that pose potential significant risks, while accelerating access to safe and effective new therapies.”

This is long overdue.

In a March 2017 perspective written by the U.S. Food and Drug Administration [3] in the *New England Journal of Medicine (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.

The result of such lack of regulation has caused harm to many patients.

An issue like this is so pervasive that an international team of medical experts published a global call to action in Science Translational Medicine [4] in July 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. (See here [5] to read my article about the transnational and global coordinated proactive approach they champion).

With high price tags, so-called “stem-cell” clinics are designing therapies without evidence that serve to do harm, are 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 and serious disease.

In The Worst 'Healthcare': 'Stem Cell' Clinics Wrought With Red Flags, Insincerity And Blindness [6] , 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) [7], 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 [6] for a more detailed roadmap of how to read between the lines of such marketing hype and to understand the timeline of this particular bad outcome).

Take Home Message

With an explosion of developments in regenerative medicine, in general, regulatory bodies need walk a fine line between implementing some restrictions while still fostering innovation.

As Commissioner Gottlieb aptly puts it [2]: *“We’re at the beginning of a paradigm change in medicine with the promise of being able to facilitate regeneration of parts of the human body, where cells and tissues can be engineered to grow healthy, functional organs to replace diseased ones; new genes can be introduced into the body to combat disease; and adult stem cells can generate replacements for cells that are lost to injury or disease. This is no longer the stuff of*

science fiction. This is the practical promise of modern applications of regenerative medicine...But this field is dynamic and complex. As such, it has presented unique challenges to researchers, healthcare providers, and the FDA as we seek to provide a clear pathway for those developing new therapies in this promising field, while making sure that the FDA meets its obligation to ensure the safety and efficacy of the medical products that patients rely upon."

Whether the frontier in sham operations is truly conquered by these efforts is too soon to tell. The policy framework is evolving and includes a commentary period for some of its draft documents. Hopefully the eventual complete version will actually be enforced -- and touch upon transnational approaches as well. Only then will the short- and long-term benefits in patient safety be realized and the legitimate work already in progress stand on its own merits without being muddied by shady endeavors.
