

FDA Warning Not Enough To Protect Patients From Dangerous Unproven ‘Stem Cell’ Products



By Jamie Wells, M.D. — December 26, 2018



Credit: publicdomainfiles.com [1]

In an announcement of no surprise, the U.S. Food and Drug Administration (FDA) again officially [warned](#) [2] a company it previously warned in June (due to substandard safety and infection control measures on unproven treatments for unapproved indications) whose “stem cell” products actually went on to cause considerable harm in patients. Additionally at play is the agency’s grace period for “enforcement discretion” that ostensibly encourages companies to do the right thing and seek early FDA regulator contact and involvement prior to November 2020. But, these efforts designed to spur discovery while reigning in patient harms have fallen demonstrably short. Despite these formal initiatives and even a global call to action by the worldwide scientific community (see [here](#) [3]) to establish guidelines, this industry is ballooning and riddled with unsavory practices that have caused [blindness](#) [4] to [death](#) [5].

What’s the real deal with stem cells?

Stem cells have been pitched as a panacea for all ails. They are marketed as the cure for any condition, all that is needed is proper placement of such cells in close proximity to the damaged body part so that they can learn from their surrounding environment and repair everything. Such is the tale of Hollywood films not scientific rigor. In reality, there is a tiny, narrow well-established window of FDA-approved clinical uses for which there is proven benefit (eg blood cancers). For all of the remaining efforts in cartilage use to neurologic endeavors, there is little to no data to support their effectiveness let alone safety. Aside from that, a lucrative industry of private “stem cell” clinics abounds and exploits regulatory loopholes by claiming they are not subject to FDA approval.

To appreciate the wiggle room available intended to balance innovation with patient protection,

check out this *New England Journal of Medicine* piece [here](#). [6]

It is like the *Wild West* [7] these days with marketing claims for relief from an exhaustive list of conditions, ranging from orthopedic injury to Alzheimer's, pain and Parkinson's Disease. This is why the *FDA announced in November 2017* [8] the new implementation of "a comprehensive policy framework for the development and oversight of regenerative medicine products, including novel cellular therapies." This was in response to the rampant abuses of private clinics employing those of disparate expertise to inject and infuse concoctions that may or may not include stem cells along with questionable other substances that could be high risk under unknown sterile circumstances.

What happened to patients in this recent example with Genetech, Inc. of San Diego, California and its distributor Liveyon, LLC? (1)

According to the *Centers for Disease Control and Prevention* [9](CDC),

"As of December 14, CDC has received reports of infections in 12 patients from three states, including the initial Florida and Texas cases: Texas (seven), Florida (four), and Arizona (one). Infection types included bloodstream infections, joint infections, and epidural abscesses, among others...Among 11 patients for whom conditions prompting product administration were known, all had nonhematopoietic conditions such as pain or orthopedic conditions. All patients were hospitalized; none died."

The *New York Times* [10] goes on to state

"The people who became ill after receiving the Genetech products had been given injections into their knees, shoulders or spines to treat painful conditions like arthritis or injuries. They contracted infections in their bloodstreams or joints, and all were hospitalized."

One patient spent 58 days in the hospital with a bloodstream infection, a spinal abscess and other spinal problems. Another, with an infected knee, was hospitalized for 30 days. The shortest stay was four days; others lasted 12, 15 or 35 days...Eleven patients were treated at private clinics specializing in pain or orthopedics, and one — the patient who was hospitalized for 58 days — was treated at an ambulatory surgery center."

The bottom line

Placebos can be of some benefit to assuage an aspect of suffering (not cure disease) like peace of mind. If they aren't cost prohibitive or harmful, then so be it if they can provide momentary or

temporary relief. That's not what we are dealing with in this discussion. Much of the "stem cell" industry makes false promises, performs invasive procedures that can cause primary and secondary harms with untested "potions" that are accompanied by higher and higher price tags for those most vulnerable. FDA warnings no longer cut it.

Note(s):

1. Genetech, Inc is not to be confused with biotech behemoth Genentech.

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Links

- [1] http://www.publicdomainfiles.com/show_file.php?id=13933417227423
- [2] <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628918.htm>
- [3] <https://www.acsh.org/news/2017/07/10/fraud-alert-unproven-stem-cell-use-prompts-international-call-action-11526>
- [4] <https://www.acsh.org/news/2017/03/20/worst-healthcare-stem-cell-clinics-wrought-red-flags-insincerity-and-blindness-11015>
- [5] <http://www.acsh.org/news/2017/07/10/fraud-alert-unproven-stem-cell-use-prompts-international-call-action-11526>
- [6] <https://www.nejm.org/doi/full/10.1056/NEJMs1715626>
- [7] <https://www.acsh.org/news/2017/11/17/wild-west-stem-cell-therapies-coming-end-12162>
- [8] <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm585345.htm>
- [9] https://www.cdc.gov/mmwr/volumes/67/wr/mm6750a5.htm?s_cid=mm6750a5_w
- [10] <https://www.nytimes.com/2018/12/20/health/stem-cell-shots-bacteria-fda.html>