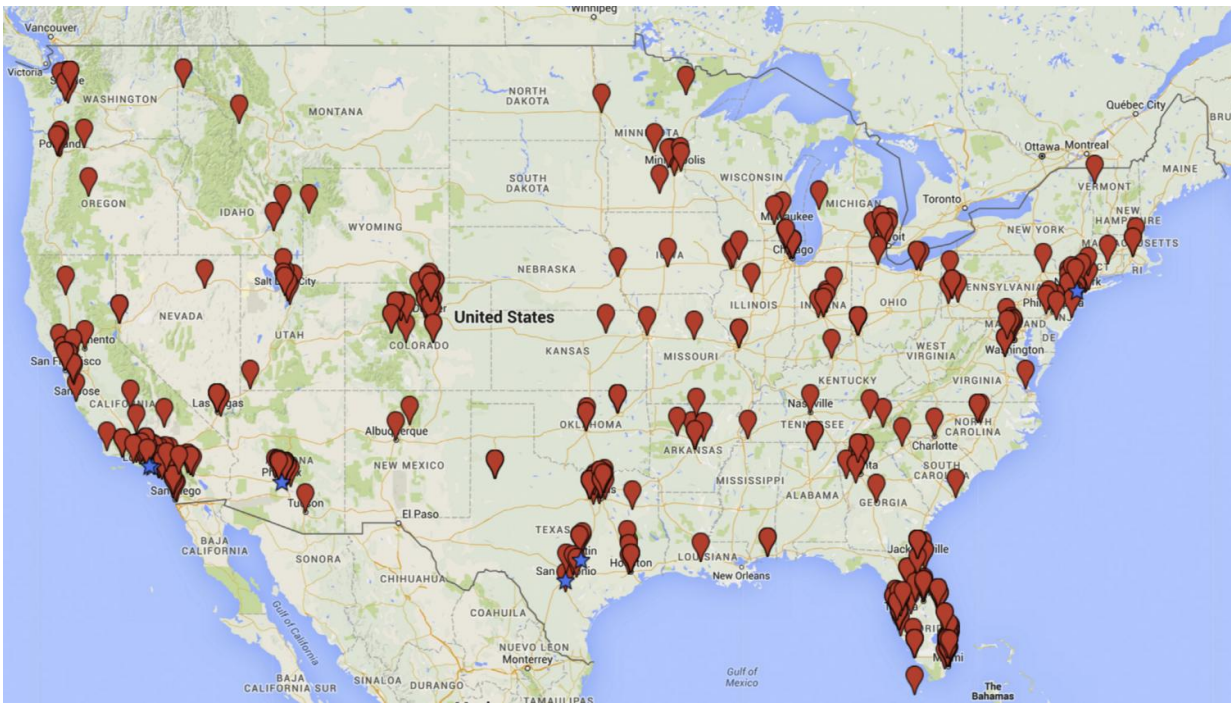


Surprising number of businesses selling unapproved stem cell 'treatments' in the US

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A map of clinics in the United States marketing unapproved stem cell procedures. "Hotspot" cities are indicated with blue stars. Credit: Leigh Turner and Paul Knoepfler

At least 351 companies across the United States are marketing unapproved stem cell procedures at 570 individual clinics. Such businesses advertise "stem cell" interventions for orthopedic injuries, neurological disorders, cardiac diseases, immunological conditions,

pulmonary disorders, injured spinal cords, and cosmetic indications. In *Cell Stem Cell* on June 30, bioethicist Leigh Turner and stem cell researcher Paul Knoepfler present an analysis of U.S. businesses engaged in "direct-to-consumer" marketing of these procedures.

"In almost every state now, people can go locally to get stem cell 'treatments,'" says Knoepfler, of the University of California, Davis, and Shriners Hospital For Children. "Many people in larger metropolitan areas can just drive 15 minutes to find a clinic offering these kinds of services instead of, say, traveling to Mexico or the Caribbean. I think this reflects a change from what we've seen documented in the past and is different from what we typically think about when we think of stem cell tourism."

Turner and Knoepfler found the businesses through Internet key word searches, text mining, and content analysis of company websites. For each business, the duo recorded the company name, location(s), website addresses, advertised stem cell types, and marketing claims concerning diseases, injuries, and conditions for which [stem cells](#) are reportedly administered. Their research should serve as a baseline for future studies of U.S. businesses engaged in direct-to-consumer advertising of purported stem cell interventions.

Key findings from the report include:

- Clinics advertising stem cell interventions cluster in particular states. They are most likely to be found in California (113 clinics), Florida (104), Texas (71), Colorado (37), Arizona (36), and New York (21).
- Beverly Hills is home to 18 clinics, more than any other city in the nation, followed by New York (14 clinics), San Antonio (13), Los Angeles (12), Austin (11), Scottsdale (11), and Phoenix (10).
- Of the stem cell procedures that are marketed, 61% of businesses

offer fat-derived stem cell interventions and 48% offer bone-marrow-based treatments. Advertisements for induced pluripotent stem cells (1 business), embryonic stem cells (1 business), and xenogeneic products (2 businesses) are rare.

- Over 300 of the businesses market interventions for orthopedic issues. Other advertised conditions include pain (150 businesses), sports injuries (90), neurological diseases (80), and immune disorders (75).

"This is a marketplace that is dramatically expanding before our eyes—we were aware early on and tracked it early on, but I don't think we knew the scope and size of the market," says Turner, of the Center for Bioethics at the University of Minnesota. "Brakes ought to exist in a marketplace like this, but where are the brakes? Where are the regulatory bodies? And how did this entire industry come into being in a country where stem cell-based interventions and the medical devices that produce them are supposed to be regulated by the FDA?"

Turner and Knoepfler, who runs the popular stem cell blog ["The Niche."](#) grew suspicious of an increase in American stem cell clinics when inquiries from readers and patients changed from Americans asking about going abroad for a stem cell treatment to Americans asking about seeking [treatment](#) in the United States. In investigating the people who run these clinics, Turner and Knoepfler found that not only were individuals such as cosmetic surgeons and naturopaths beginning to offer unapproved stem cell interventions, but the "pioneers" in the industry were training others to do the same. It is unclear whether federal authorities—particularly the Food & Drug Administration—and state medical boards missed the scope of the problem or are taking minimal action despite being aware of the spread of such businesses.

"From around 2009 to the present, businesses have been entering the marketplace on a routine basis, they've been coming in making

marketing assertions about stem cells treating 30-40 different diseases, and no one's taking meaningful regulatory action," Turner says. "Does that mean that people are getting access to safe and efficacious interventions or is there basically unapproved human experimentation taking place where people are going to these businesses and receiving experimental investigational cell-based interventions without being given a meaningful account of the lack of knowledge and evidence that they're being charged for?"

A separate downside is that patients who have unapproved and unproven stem cell interventions decrease their chances of qualifying for FDA-cleared and IRB-approved clinical trials that comply with federal regulations. This is a loss for stem cell research.

"Another serious consideration to think about is that over the years many people have begun to include these businesses in their overall impression of the stem cell field," Knoepfler says. "There is a real risk that as clinics proliferate, if we don't address it in a more proactive way, as we see negative outcomes for patients grow and people get mixed bags of information about stem cells, then this could really negatively impact the public perception of this research."

More information: *Cell Stem Cell*, Turner and Knoepfler: "Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry," [www.cell.com/cell-stem-cell/fulltext/S0092-8674\(16\)30157-6](http://www.cell.com/cell-stem-cell/fulltext/S0092-8674(16)30157-6) , DOI: [10.1016/j.stem.2016.06.007](https://doi.org/10.1016/j.stem.2016.06.007)

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