

US clinics avoiding government oversight of 'stem cell' treatments

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Clinics across the United States are advertising stem cell treatments that attempt to take advantage of what they perceive as exceptions in FDA regulations, according to bioethicist Leigh G. Turner, PhD, Associate Professor, University of Minnesota Center for Bioethics and School of Public Health.

The therapies in question are adipose-derived autologous stem cell treatments, in which fat cells are removed from a patient, broken down to separate components that purportedly contain [stem cells](#), and are then reinjected into the same patient. Proponents of these treatments advertise both cosmetic uses, such as "stem cell facelifts" and "stem cell breast augmentation," as well as "therapies" for amyotrophic lateral sclerosis, [spinal cord injuries](#), Parkinson's disease, multiple sclerosis, Alzheimer's disease, muscular dystrophy, and other diseases and injuries. Clinics charge thousands or even tens of thousands of dollars for their so-called stem cell therapies.

"When researchers study ethical and legal issues related to businesses selling unproven stem cell interventions, they often write about so-called 'stem cell tourism' to such countries as China, India, Mexico, and Panama," Dr. Turner said. "However, U.S. residents need no longer leave the United States to find clinics marketing a wide range of purported [stem cell therapies](#). They can find such businesses in Arizona, California, Florida, and other domestic locations."

The clinics claim that they are following exceptions delineated in 21

CFR 1271, the federal regulation governing human cells, tissues, and cellular-and-tissue-based products. This has prompted the FDA to issue draft guidance documents to clarify the exceptions.

According to Dr. Turner, U.S. stem cell clinics often make very persuasive claims about how they are complying with federal regulations. While these assertions might seem compelling, they aren't necessarily true. On the contrary, his review of federal regulations, warning letters, letters written by the FDA's Tissue Reference Group in response to questions about how the FDA interprets 21 CFR 1271, and new draft guidance documents all indicate that the claims many of these businesses make about regulatory compliance are incorrect.

If the claims that the clinics are relying on are wrong, then many of these businesses ought to have submitted Investigational New Drug or Investigational Device Exemption applications to the FDA. Clinics marketing biological drugs requiring premarketing approval by the FDA are prohibited from advertising and profiting from the sale of investigational agents until safety and efficacy trials are conducted and they have the licenses they require to market such medical products.

"These clinics aren't going to stop making these marketing claims and performing procedures just because the FDA has issued three new draft guidance documents," Dr. Turner cautioned. "It is going to take a substantial effort by the FDA to address the rapid spread of U.S. businesses marketing unapproved stem cell interventions. Whether the FDA will make that effort is at present unclear. The last five years of relative regulatory inaction is cause for concern. Perhaps these new draft guidance documents are a harbinger of the FDA providing more effective oversight of such businesses. If not, more patients are going to pay thousands or tens of thousands of dollars for so-called adipose-derived 'stem cell interventions' even though there is little or no evidence that they are safe and efficacious for [amyotrophic lateral sclerosis](#),

Parkinson's disease, Alzheimer's disease, multiple sclerosis, spinal cord injuries, and many other diseases and injuries."

More information: "Federal Regulatory Oversight of U.S. Clinics Marketing Adipose-Derived Autologous Stem Cell Interventions: Insights From Three New FDA Draft Guidance Documents," by Leigh G. Turner, PhD (DOI: dx.doi.org/10.1016/j.mayocp.2015.02.003), published in *Mayo Clinic Proceedings*, Volume 90, Issue 5 (May 2015)

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