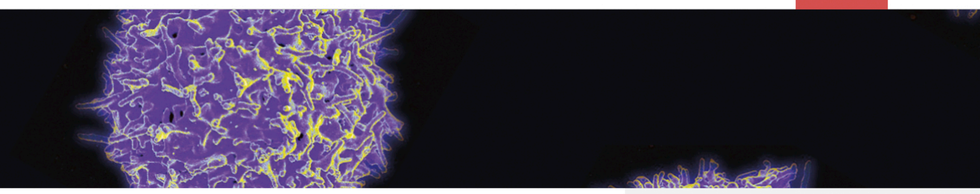

FDA Quackdown

Regulators step in to stop stem cell clinics from marketing unproven therapies

June 2018

The FDA has filed two complaints in federal court to stop two clinics from marketing stem cell products without FDA approval and for "significant deviations from current good manufacturing practice (GMP) requirements" (1).

A permanent injunction is being sought against US Stem Cell Clinic LLC of Sunrise, Florida, its Chief Scientific Officer Kristin Comella, and its co-owner and managing officer Theodore Gradel. The FDA accused the clinic of potentially putting patients at risk by failing to ensure the sterility of their products. The clinic processes adipose tissue into stem cells, which they administer (intravenously or directly) into the spinal cord of patients with a variety of serious conditions, including Parkinson's, spinal cord injuries and heart disease. The FDA issued a warning letter to the clinic in August last year, after documenting during an inspection "significant deviations from current good manufacturing practices in the manufacture of at least 256 lots of stem cell products." US Stem Cell Clinic also tried to impede the FDA's investigation during the most recent inspection by refusing entry except by appointment and by denying investigators access to employees.

The FDA is also seeking a permanent injunction to stop California Stem Cell Treatment Center Inc and Cell Surgical Network Corporation (both from California), as well as the doctors Elliot B. Lander and Mark Berman, from marketing stem cell products to patients without FDA approval. According to the FDA, Berman and Lander control the operations of approximately 100 for-profit affiliate clinics.

The move follows FDA action taken in August last year to prevent the use of a potentially dangerous and unproven treatment – a combination of excess amounts of Vaccinia Virus Vaccine (reserved for people at high risk of smallpox) and a cellular product derived from body fat – belonging to StemImmune Inc and administered to patients at the California Stem Cell Treatment Centers.

"Stem cell clinics that mislead vulnerable patients into believing they are being given safe, effective treatments that are in full compliance with the law are dangerously exploiting consumers and putting their health at risk," said FDA Commissioner Scott Gottlieb in a press release (1). He also explained how the FDA is stepping up its enforcement actions against clinics that "abuse the trust of patients and, more importantly, endanger their health with unsanitary conditions or by purporting to have treatments which may not provide any benefit."

Peter Marks, Director of the Center for Biologics Evaluation and Research at the FDA, was involved in the ISCT's Presidential Task Force Session on the Use of Unproven Cellular Therapies in May, and told The Medicine Maker, "There are so many of these clinics in the US at the moment and we can't take action against all of them at once. We, therefore, have to take a risk-based approach in which we focus on; for example, clinics injecting into the spinal canal, eye, or bloodstream – where patients can be at serious risk."

Commenting on the FDA's approach to regulating unproven therapies, Marks says the FDA will begin with the least aggressive method – untitled letters and warning letters. "But we're not afraid to escalate, if we see risk to public health," he says. "It's simply the right thing to do."

The chair of the ISCT Presidential Task Force Session on the Use of Unproven Cellular Therapies, Massimo Dominici, Professor of Oncology at the University of Modena and Reggio Emilia, Italy, says, "There are around 60 thousand people in the US who have been treated with unproven therapies, but this is a truly global problem." Dominici hopes the ISCT can collaborate with other societies to encourage the World Health Organization to take action. "We need to tackle this problem from a global perspective," he says.

Reference List 1 Reference

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About the author
James Strachan

Over the course of my Biomedical Sciences degree it dawned on me that my goal of becoming a scientist didn't quite mesh with my lack of affinity for lab work. Thinking on my decision to pursue biology rather than English at age 15 – despite an aptitude for the latter – I realized that science writing was a way to combine what I loved with what I was good at.

From there I set out to gather as much freelancing experience as I could, spending 2 years developing scientific content for International Innovation, before completing an MSc in Science Communication. After gaining invaluable experience in supporting the communications efforts of CERN and IN-PART, I joined Texere – where I am focused on producing consistently engaging, cutting-edge and innovative content for our specialist audiences around the world.

About this Article
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"Welcome to the June issue. Upfront investigates an FDA crackdown on unproven stem cell clinics and concerns that post-Brexit border delays could turn the UK into a "second tier state for pharmaceutical imports." Phil Morton makes the argument for Albumin in "In My View," while our cover feature looks at the three frontrunners of The Medicine Maker 2017 Innovation Awards. In Best Practice, we explore plastic recycling in biopharma manufacturing and the upcoming serialization deadlines; and in Profession, Valarie Higgins from Almac discusses how clinical trials have evolved over the years. We also Sit Down With Ajaz Hussain, President, National Institute for Pharmaceutical Technology and Education, Minnesota, USA.

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