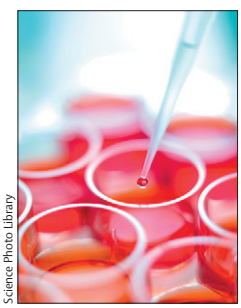
Texas stem cell rules may impede clinical research

Stem cell researchers in the USA and abroad are reeling from new laws in Texas that commercialise experimental procedures and could attract patients away from clinical trials. Carrie Arnold reports.



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New regulations on the experimental use of adult stem cells recently passed by the Texas Medical Board has returned the ethos of the Wild West to the Lone Star State. Supporters of the rules believe they offer patients seeking stem cell therapies a modicum of protection in a semi-lawless environment, but opponents believe that these regulations actually put patients at greater risk. What is more, critics say, these guidelines could actually hold back progress in stem cell research.

"I think it's outrageous", said Leigh Turner, a bioethicist from the University of Minnesota, MN, USA, who testified at the medical board's hearings. "Some of what takes place may not be credible research. It's going to be unproven interventions sold for profit with the veneer of a clinical trial."

The regulations give Texas doctors "a reasonable and responsible degree of latitude in the use of investigational agents", which allows them to offer experimental stem cell procedures without first getting formal approval from the US Food and Drug Administration (FDA). Texas doctors will have to seek approval from an Institutional Review Board (IRB) and obtain informed consent from patients about the experimental nature of the procedure before they can begin.

These regulations actually provide more protection to patients, noted Leigh Hopper, Public Information Officer for the Texas Medical Board. "These treatments are already happening in Texas. The idea was to put in place some sort of framework that would at least involve informed consent for patients and provide some external oversight", Hopper said.

Turner disagrees. He believes that the rules put corporate profits before patient safety. Clinical research trials do not charge patients to participate. Yet in Texas, it is now legal for a company to charge a patient tens of thousands of dollars to undergo a procedure that may or may not be beneficial, Turner said.

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Irv Weissman, a stem cell researcher at Stanford University, CA, USA, pointed out that the IRB process required by the new regulations only protects against patient harm; it does not require that physicians show the procedure will be beneficial. FDA regulations, on the other hand, require researchers to indicate how the trial will help patients. "Without FDA oversight, [physicians] don't have to prove efficacy", Weissman said.

The concerns of stem cell researchers and bioethicists go beyond the marketing of false hope. Patients, especially those with terminal diseases, might be especially attracted to potential stem cell clinics in Texas in part because they would not risk being randomised to a placebo group in a clinical trial. With nothing to lose, a promising treatment might be worth the investment. It might not work, true, but they could be reassured of receiving the actual procedure rather than a placebo.

The problem is that double-blind, randomised, placebo-controlled trials are crucial to understanding whether or not a particular procedure is effective, says Douglas Sipp, Science Policy and Ethics Studies Unit Leader at the RIKEN Center for Developmental Biology in Japan. Like any treatment, the administration of stem cells is subject to placebo effects, expectations, and selection bias. Without adequate controls, scientists have no way of knowing whether the stem cells are effective. Stem cell procedures in Texas—Sipp does not call them therapies—are being marketed as treatment without any evidence that they work.

Every patient who receives a commercial stem cell treatment is another patient unable to participate in a clinical trial, both due to lack of interest and their history of previous stem cell treatments. Common illnesses and injuries have a large enough pool of potential participants that clinical trial enrolment probably will not be seriously diminished. But for rarer diseases, like amyotrophic lateral sclerosis and certain orphan diseases, the availability of commercial experimental stem cells could have a much larger impact in trial enrolment, Turner said. Every patient that undergoes a commercialised and unproven stem cell procedure in Texas means that valuable data is lost to scientists trying to identify effective therapies for these diseases.

This could be the new rule's lasting irony: rather than promoting patient health, the regulations could actually impede the development of novel stem cell therapies with a proven track record. "When you introduce alternatives that have a superficial attraction to patients, it kind of undermines the system", Sipp said. "It makes it easier to conduct medical experiments in people that aren't rigorously designed, and makes people pay for the privilege."

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