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Taking a new approach to stem cell regulation

Policing clinics isn't the right move; instead, the FDA needs to consider the concerns of key stakeholders

By Kirstin Matthews and Ana Iltis

A stem cell clinic brochure in full color with beautiful before-and-after photos of formerly afflicted patients walking with ease after receiving stem cells contrasts starkly with a scientific journal's black-and-white print articles with graphs and text explaining why a particular intervention actually makes no significant difference.

Advertising for stem cell clinics focuses on patients who have few to no other options, often claiming that the clinics have miracle cures. It is estimated that there are dozens of these clinics in Texas alone. Many clinics have no rigorous clinical trial data to back these claims. As a result, the U.S. Food and Drug Administration is policing clinics to cease their activities. In response, these clinics either move abroad and patients follow; offer a modified version of the interventions; or reopen under a new name.

It's unclear whether the patients and the results featured in these brochures are real, but there are testimonials that at times suggest the stem cell interventions offered are beneficial. The FDA's policing to stop clinics is not the right method; rather, a compromise policy that engages the needs and concerns of key stakeholders would be more beneficial.

When stem cell research first captured the media and medical researchers' attention in 2004, patients and scientists worked together to increase federal funding for research. But after a decade with limited proven stem cell therapies, patients now are seeking treatments in the U.S. and abroad that use unproven stem cell-based interventions instead of waiting for clinical trial data.

The central problems with unproven stem cell-based interventions, particularly when delivered abroad, include lack of protection of patients, U.S. liability standards, regulation of clinical sites and clinician licensing. These interventions have insufficient evidence of safety and efficacy. Patients may be wasting money and time, and they may forgo other clinical opportunities, instead choosing an intervention that has not been shown to be safe and effective. Current practices do not contribute to scientific progress because the information from patients is not suitable for follow-up research to measure outcomes. In addition, there is no assurance for patients that they are receiving the intervention promised or the appropriate dosage.

What's missing in addressing this problem is an understanding and acknowledgement of valid claims from both the FDA and advocates of experimental stem cell-based interventions. In the past, we've seen similar disconnects with patients pushing the FDA and eventually gaining early access to experimental therapies still in clinical trials for HIV and breast cancer. More recently, patient advocates successfully pressured state legislatures around the country to pass "Right to Try" laws, including Texas' recently passed "Right to Try Act," House Bill 21, which allow for patients to gain access to experimental interventions after Phase 1 clinical trials and physician approval. But these laws are limited and work around the FDA instead of with the regulatory agency.

Public policy, more specifically a revision of FDA policy and regulation, should be re-evaluated to correct the current situation with clinics pushing unproven stem cell-based interventions. Stakeholders, including scientists, clinicians, regulators and patient advocates, need to work together to find a compromise to keep patients from seeking unproven interventions abroad, to ensure that safe experimental interventions are offered within the clinical trial process, and to promote research. Bringing these stakeholders together will allow the creation of a policy that protects patients from undue risk, while still allowing them access to experimental stem cell-based interventions. Furthermore, it can help fill the research gap, allowing physicians to determine which interventions are truly safe and effective.

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This is really the ultimate goal of medical regulation — providing patients with therapies that work and preventing harm.

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