## Stem cell therapy may enter era of “Inject and see what happens”

According to Congress, the logical way [to bring revolutionary treatments to patients sooner] is the 21st Century Cures Act, a labyrinthine bill that would make the most significant changes in decades to how medical treatments are tested and brought to market.

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Today there are close to 600 businesses in America selling stem cell solutions for everything from deafness to Alzheimer’s and autism, all without FDA approval…The 21st Century Cures Act will change that—not by reining in unproven, unregulated treatments, but by providing a direct path to medical acceptance. Under the act, the FDA would have the authority to grant accelerated approval for regenerative medicines, skipping straight from animal models and safety trials, over efficacy testing in humans, to post-market review.

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Leigh Turner, a bioethicist at the University of Minnesota, says this could be a disaster for traditional stem cell research. “If you legitimize these therapies and allow businesses to commercialize them, then it becomes difficult to recruit individuals for actual phase 3 clinical trials,” he says.

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[Paul] Knoepfler, who is a stem cell researcher at UC Davis, is worried about an even more troubling outcome: What happens once people get hurt by these therapies, either physically or financially?
**The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion, and analysis. Read full, original post:** With 21st Century Cures Act, the Future of Regenerative Medicine is “Inject and See”