

SA biotech company backing fed stem cell bill to cut red tape from regulatory pathway

San Antonio-based biotech firm <u>StemBioSys</u> Inc. has put its full support behind a proposed federal law that supporters contend will break down unnecessary barriers to medical innovation and accelerate advancements in regenerative medicine.

One of the challenges in stem cell research, industry leaders contend, is that the Food and Drug Administration has yet to create a regulatory pathway for regenerative medicine that recognizes its uniqueness, impeding the delivery of potentially life-saving products. That hurdle has given companies in other countries, where the safety and efficacy of such treatments have already been acknowledged, a leg up on American entities like StemBioSys.

Senate Bill 2689, also known as the REGROW Act, was jointly introduced by U.S. Senators Mark Kirk (R-Illinois), Joe Manchin (D-West Virginia) and Susan Collins (R-Maine). Backers said if approved, it could substantially promote more stem cell innovation, requiring the FDA to work with industry stakeholders to develop standards for stem cell research that could lead to the safe delivery of more regenerative medicine products.

"Stem cells are a big frontier in medicine," said Davis, one of the industry leaders who is working to drum up support for the bill.

Davis recently participated on a national panel convened in Washington at the Bipartisan Policy Center to address the issue. He told me there has been a willingness from Texas political leaders on both sides of the aisle to weigh the merits of the proposed legislation.

The bill would create more flexibility for companies like StemBioSys engaged in stem cell research and development.

"For StemBioSys, the legislation would mean that the therapies we are beginning to look at could get to market much more quickly and efficiently than in today's process," said StemBioSys CEO Bob Hutchens.

Davis said SB 2689 would be a game changer for regenerative medicine and for StemBioSys. "This would give us an opportunity to push forward our technology," he said. "We are hopeful both sides can work together on this."

Source: http://www.bizjournals.com/sanantonio/news/2016/05/09/sa-biotech-company-backing-fed-bill-to-clear-red.html

May 9th 2016

