Ten years in, first trial treatment from California's stem cell initiative approved

At the time of its creation, the <u>California Institute for Regenerative Medicine (CIRM)</u> was a beacon of hope for people with chronic disease who thought stem cells offered a cure for their conditions.

The research institute was created after an intensive voter campaign that approved the use of embryonic stem cells for research, and funded \$3 billion in research within the state shortly after President George W. Bush pulled all federal funding for embryonic stem cells.

But in the 10 years since, many critics have suggested that the institute has fallen well short of it promises, much as the entire field of embryonic stem cell treatments has. Although scientists funded by the institute published almost 2,000 papers in the last decade, there has been a outcry for some tangible patient treatments, the cures voters say they were promised in 2014. That call has only increased ahead of plans to ask California voters for \$5 billion more in bonds in 2016.

As Christine Mummery of the Leiden University Medical Center in the Netherlands told Nature, "almost every country would be jealous of what they've got in California, but they haven't cured a patient, which is the critique."

Now, the CIRM is a lot closer on August 19 the FDA approved the first institute-partnered stem cell treatment for Phase 1-2 combination clinical trial. Developed in conjunction with the San Diego company <u>ViaCyte</u>, the treatment grows insulin-producing cells from embryonic stem cells that are then packaged in a semi-permeable pouch and implanted into type 1 diabetic patients. The permeable pouch allows insulin and other hormones to enter a patient's blood stream but prevents the immune system from attacking it.

One difficulty in stem cell transplants for type 1 diabetics is that the immunosuppresent drugs needed to prevent a patient's immune system from rejecting the transplant are considered more risky and more of a burden that continued insulin therapy. Type 1 diabetes is an autoimmune disease caused when a person's immune system acts out and destroys the insulin producing beta cells in the pancreas. There is no cure, and patients must take insulin injections for the rest of their lives.

Whether the medical device is fully approved or not, getting a treatment as far as an in-human clinical trial will be a much needed "<u>home run</u>" on the CIRM's resume as asks voters for more financing. And, it further bolsters the case that innovative ways of publicly funding science are possible given federal budget problems. In April of this year the <u>National Institutes of Medicine closed its own Center for Regenerative</u> Medicine.

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Additional Resources:

- New encapsulated beta-cell replacement therapy for type 1 Diabetes, Diabetes in Control
- Type 1 Diabetes treatment funded by California stem cell agency cleared to begin clinical trial, Sierra

Sun Times

• Shameful conflicts of interest involving California's stem cell agency, Biopolitical Times