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From the Pittsburgh Business Times:

<https://www.bizjournals.com/pittsburgh/news/2019/05/14/experts-urge-caution-despite-advances-in-stem-cell.html>

Experts urge caution despite advances in stem cell therapies

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Stem cell therapies offer tremendous promise but a panel of experts assembled by the University of Pittsburgh McGowan Institute for Regenerative Medicine say patients should also do research and think hard before embarking on many of them.

The panel, "Stem Cell Therapies: Hope vs. Hype," focused on some of the science around stem cells, which are cells that can replicate when inserted into the body and hold the possibility of repairing organs and tissues. Stem cells have been used for years to treat blood diseases like leukemia and is a longstanding standard of care. But, said McGowan Institute for Regenerative Medicine Director William R. Wagner and UPMC Hematopoietic Stem Cell Laboratories Director Albert D. Donnenberg, there's little evidence-based scientific research that proves a wide range of other stem cell therapies, including for orthopedics, are effective.

It's truly buyer beware for many stem-cell treatments that often aren't covered by insurance and have high out-of-pocket costs, they said. They advised prospective patients to know the risks, the side effects of treatment, the costs and whether the treatment is part of a formal clinical trial and whether the treatment has gotten the go-ahead from regulators.

"We want you to think about risks and benefits when you go for a treatment," Wagner said.

A New York Times article earlier this week noted some stem-cell treatments are unproven and with little regulatory oversight. Donnenberg cautioned against the unproven treatments, saying that scientific proof is so far inconclusive. But he also said that some people who have gone through the treatments are positive about their benefits.

But there are also dark sides, including cases where patient have gone blind after having stem cells injected into their eyes for treatment of macular degeneration.

Donnenberg said that while claims may have gotten ahead of the science, there is still room for optimism and opportunities. But well-controlled, well-funded clinical trials are the only way to determine efficacy, he said. He noted that bone marrow transplantation took more than a decade before it became a standard of care and it's still evolving.

Carl Kurlander, co-producer of the "Burden of Genius" documentary on the legendary transplant pioneer Dr. Thomas Starzl, said that universities have to vet the therapies to determine what's helpful and what's just hype.

"Everybody here wrestles with this ... when is it experimental and when is it ready for primetime," Kurlander said.



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Dr. William Wagner, director of McGowan Institute for Regenerative Medicine, Health Care Heroes 2016 Award Winner

Michael Hufford, CEO of the organ regenerative startup LyGenesis Inc. that got its start at the McGowan Institute, knows this well. The firm is working its way through the long process from idea to FDA approval, which takes years and lots of money.

Lygenesis, which last May raised \$3 million in Series A funding from Juvenescence Ltd., is working on technology to use lymph nodes to regrow organs and treat end-stage liver disease and other conditions. The technology could mine one donated organ to treat up to 75 patients with minor surgery instead of expensive and complex organ transplantation.

Wagner said that one potential McGowan breakthrough to regenerate skeletal muscle could be between 10 and 20 years away from being fully realized.

"This type of thing is capital and time intensive," Hufford said.

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Reporter

Pittsburgh Business Times

