Nebraska Coalition
FOR LIFESAVING CURES

FINDINGS

2019 FALL NEWSLETTER

Ten Undergraduate Students Awarded Holland Future Scientist Prizes

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Ten undergraduate students from five Nebraska colleges and universities recently received the 2019 Richard Holland Future Scientist Award from the Nebraska Coalition for Lifesaving Cures.

The students received cash awards totaling $5,000 at the annual INBRE (Institutional Development Award [IDeA] Networks of Biomedical Research Excellence Program) conference on Aug. 6 in Nebraska City.

The awards are named in honor of the late Richard Holland, an Omaha philanthropist and longtime supporter of research. This is the 12th year the Holland Future Scientist Awards have been given.

The students were judged for their oral and poster presentations of the research work they conducted this summer as part of the INBRE program.

The INBRE program is overseen by Paul Sorgen, Ph.D., a professor in the department of biochemistry and molecular biology at the University of Nebraska Medical Center.

Winners of the oral presentation pictured left to right are: Diego Gomez, Rebekah Rapoza, Taylor Burke, Joshua Lindenberger and Elias Smith.

Poster presentation winners pictured left to right are: Philamon Hemstreet, Wacey Gallegos, Molly Myers and Mika Caplan. Eilidh Chowanec not pictured.

Kohout Departs as Coalition Executive Director. McGill Johnson to Take Her Place

The Nebraska Coalition for Lifesaving Cures announced that its long-serving (12 years) executive director, Victoria Kohout, has left the organization effective October 4, 2019, to take the position as director of state and community relations at the University of Nebraska Omaha.

Replacing Kohout as the Coalition's new executive director will be Amanda McGill Johnson. McGill Johnson will assume her new role on November 4, 2019. McGill Johnson has served on the Coalition board of directors since 2016 and was most recently employed by the Nebraska Children's Home Society.

THE PRESIDENT'S REPORT

David Crouse, Ph.D.

Problems With Direct-to-Consumer Marketing of Stem Cell Therapies

The direct-to-consumer marketing of stem cell therapies, which has been very pronounced in the Omaha/Lincoln area recently, has come under increased scrutiny over the past few months. For example, at the end of last year 12 patients receiving stem cell treatments in Texas, Arizona and Florida were hospitalized with serious infections resulting from their treatments. Although none died, some patients were hospitalized for lengthy periods. After an FDA analysis of the sources of the cells used in the treatments, they "documented evidence of significant deviations" from standard guidelines on safe manufacture and stated that "These deviations pose a significant risk that the products may be contaminated with microorganisms or have other serious product quality defects…" They also stated that, despite repeated warnings, "many companies, clinics, and clinicians continue to market products from various sources as treatment for orthopedic, neurologic and rheumatologic conditions without FDA approval, posing serious potential risks to patients."

Very recently, the FDA has issued a sharply worded warning to potential patients about seeking unapproved therapies using unapproved sources of stem cells. This easily web-located document is accompanied by a plain English video to describe the nature of the warning. Visit FDA.gov and search "stem cells" for many more detailed documents and the video.

At about the same time the FDA was becoming more active, the September 4, 2019 blog of Scientific American released an article entitled "Don't Believe Everything You Hear About Stem Cells." This well-written article is intended for a lay audience and echoes many of the same points that are presented in the FDA documents and video. It provides straightforward advice on approaches to deal with "bad actors" in this clinical area and outlines many additional resources for patients seeking such therapy. Only a few days later, on September 6th, Google issued a ban for all ads for "…unproven or experimental medical techniques such as most stem cell therapy…" effective October 1st. They stated that such treatments can have "dangerous health outcomes" and have "no place" on its platform.

A web-based analysis of the several direct-to-consumer stem cell clinics advertising in Omaha, Lincoln and Kearney shows that more than half appear to be staffed by non-physicians, so our community reflects what is an unfortunate nationwide trend. By the way, this does not mean that direct-to-consumer stem cell clinics staffed by physicians are any better than the non-physician group!

As a final caution, a study in the August 2019 issue of Regenerative Medicine by Paul Knopfler showed a rapid change in the naming and location of direct-to-consumer stem cell clinics. About a quarter of the firms identified in 2015–16 no longer market stem cell therapies in 2019. It was not clear if they simply stopped marketing stem cells as a line of therapy, went out of business or actually changed names and appeared as a new clinic. In the Omaha area, it is clear that there have been similar shifts in the stem cell clinic population—thus, don't count on your provider of these therapies being around if you have complications!

Bottom line, do your own homework, be sure to include your primary care provider in any consideration of such direct-to-consumer therapies and know full well that it will not be covered by any insurance.

SPRING LUNCHEON
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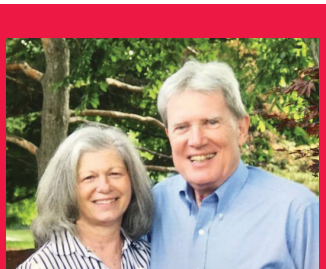
Honoring **Bob and Helen Bartee**



Transplantation of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelial Cells (MA09-hRPE) in Macular Degeneration

August 27, 2019 | From npj Regenerative Medicine

By: Tina Guanting Qiu

The use of human embryonic stem cell (hESC)-derived retinal pigment epithelium (RPE) transplants has advanced dramatically in different forms for clinical application in macular degeneration. This review focuses on the first generation of hESC-RPE cell line, named as "MA09-hRPE" by Astellas Institute of Regenerative Medicine (AIRM), and its therapeutic application in humans, which evaluated the safety and efficacy of MA09-hRPE cell line transplanted in patients with macular degeneration. This project marks the first milestone in overcoming ethical hurdles and oncogenic safety concerns associated with the use of an embryonic stem cell-derived line. Through in-depth, evidence-based analysis of the MA09-hRPE cell line, along with other hESC-RPE cell lines, this review aims to draw attention to the key technical challenges pertinent to the generation of a biologically competent hESC-RPE cell line and distill the four key prognostic factors residing in the host retina, which concurrently determines the outcomes of clinical efficacy and visual benefits. Given that the technology is still in its infancy for human use, a new clinical regulatory path could aid in cell line validation through small cohort, adaptive clinical trials to accelerate product development toward commercialization. These strategic insights will be invaluable to help both academia and industry, collaboratively shorten the steep learning curve and reduce large development expenditures spent on unnecessary, lengthy clinical trials.

Biotechs Race to Develop Stem Cell Treatments for Diabetes

Jul 15, 2019 | From The Scientist

By: Eric Bender

Each year, 40,000 people in the United States are diagnosed with type 1 diabetes, an autoimmune disease that wipes out insulin-producing pancreatic beta cells and raises blood glucose to dangerously high levels. Patients deal with the condition by self-administering insulin and managing their blood glucose levels around the clock—no easy feat, even for those who are aided by insulin pumps and continuous glucose monitors that help determine insulin dosage. A small number of patients who find it particularly difficult to control their blood glucose levels are treated successfully by beta-cell transplants from cadaver donors. But the supply of these cells is tiny, and patients have to take immunosuppressive drugs to tolerate the transplanted cells.

In recent years, advances in the lab have drawn attention to an alternative approach. Perhaps most dramatically, in 2014, a research group at Harvard University reported using insulin-producing cells derived from human embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs) to lower blood glucose levels in mice (Cell, 159:P428–39). Spurred by such successes, numerous labs now are exploiting rapid progress in human stem cell technology to develop functional equivalents of beta cells and the other pancreatic cell types. Other groups are developing novel biomaterials to encapsulate such cells and protect them against the immune system without the need for immunosuppressants.

I'm glad to see that industry is becoming involved, because that will give the push to move forward the ability to do beta-cell replacement and do it on a wide scale.

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