

FINDINGS

2016 SPRING NEWSLETTER

Nebraska Coalition for Lifesaving Cures
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Omaha, Ne 68114

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nebraskacures.com

UPCOMING EVENTS

14th Annual Tribute Spring Luncheon

Honoring Jim & Diny Landen

April 18
11:30 am - 1:00 pm

2016 Nebraska Science Festival

April 15-23

For more information visit
nescifest.com

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FOR LIFESAVING CURES

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NCLC to honor Jim and Diny Landen at 14th annual luncheon



The Nebraska Coalition for Lifesaving Cures will hold its fourteenth annual tribute luncheon on Monday, April 18, 2016 at Happy Hollow Club. This year's honorees are Jim and Diny Landen.

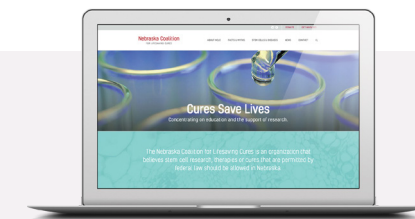
The Landens have been active in the local business and non-profit communities for more than 25 years. They both graduated from Southern Methodist University with business degrees, and returned to Omaha in 1987 to continue their business activities and raise their three sons.

Jim serves as chairman and CEO of Security National Bank, a local community bank, founded by his parents Clarence "Mickey" and Mary Landen. In 2014, Security National celebrated its 50th anniversary. Diny has also been active in the business community primarily in broadcast and communications.

Through the years, they have served on the boards of many civic, social service, arts and health organizations. Jim is currently on the boards of the Greater Omaha Chamber of Commerce, Clarkson Regional Healthcare Services, the Nature Conservancy and the Salvation Army.

He is also serving on the Comprehensive Cancer Center Building Committee. Diny sits on the board of directors of Joslyn Art Museum and Project Harmony. She also serves on the UNMC Board of Counselors.

In addition to honoring the Landens at this year's luncheon, the Coalition will also award the Chancellor Emeritus Harold M. Maurer, M.D. and Beverly Maurer Scientific Achievement award. The award recognizes the accomplishments of University of Nebraska scientists or clinicians that demonstrate promise in research topics that improve lives of Nebraskans and people around the world. The award was established in 2013 to honor the Maurers and partial funding for this award comes from a grant from Ellie Batt in memory of her brother, Larry, a long-time supporter of the efforts of medical research.



We are excited to announce our new and improved website is up and running.

Visit nebraskacures.com

World-renowned stem cell researcher guest of NCLC for Lunch and Learn



As part of Nebraska Science Festival 2016, the Nebraska Coalition is hosting a free Lunch and Learn on Friday, April 22 at the Barbara Weitz Community Engagement Center featuring Shoukhrat Mitalipov, director of the Center for Embryonic Cell and Gene Therapy at Oregon Health & Science University in Portland.

Register for this FREE event at nebraskacures.com

For more information about the luncheon, or to make a reservation go to nebraskacures.com

Author's interest in stem cell research personal

Don Reed admits he's not a scientist, and yet, he says, his life revolves around stem cell research. Reed's son, Roman, was paralyzed in a college football accident 21 years ago. In 1999, a law was passed, known as the Roman Reed Spinal Cord Injury Research Act, which raised about \$17 million in state funds and \$85 million in federal funds.

Don has recently published a book titled *Stem Cell Battles: Proposition 71 and Beyond (How Ordinary People Can Fight Back Against the Crushing Burden of Chronic Disease)*. With a posthumous foreword by Christopher Reeve, the book provides hope for individuals and families who suffer from chronic disease or disability by pointing out how they can make a difference.

Reed works closely with Robert N. Klein, sponsor of the California stem cell program, the largest source of such stem cell research funding in the world. In addition, the author is an award-winning teacher and seeks to entertain as well as educate through his writings.

The book is available for purchase through Amazon.

FDA moves to crack down on unproven stem cell therapies

*STAT | by Usha Lee McFarling
February 8, 2016*

Stem cell clinics promising everything from facelifts to treatments ranging from autism to multiple sclerosis using injections of cells are on notice – the Food and Drug Administration is coming for them.

The FDA recently issued draft guidelines clarifying that the stem cells used in most clinics are drugs and require a rigorous approval process before they

can be used in patients. At the end of December, regulators sent warning letters to a network of stem cell clinics in California, New York and Florida advising them they needed licenses and approval to sell and use stem cells. Translation – they need proof that the stem cell injections actually do what they say they do and that they are safe.

A public hearing is scheduled for April 13 in Silver Spring, Md., where patients say they will be on hand to tell the FDA they have a right to use their own cells however they see fit.

"It's a huge, unapproved human experiment," said Paul Knoepfler, a stem cell researcher at the University of California at Davis who tracks for-profit stem cell clinics on his blog *The Niche*.

Can stem cells mend a broken heart?

*The Niche | by Paul Knoepfler, Ph. D.
February 14, 2016*

The idea of the use of stem cells and regenerative medicine strategies for heart disease has taken us on a roller coaster ride over the years.

There are many controversial questions still such as whether the adult heart has meaningful populations of endogenous stem cells. Can administration of stem cells help a damaged heart?

Where do things stand today?

As Deepak Srivastava, cardiac stem cell expert, told me for a past blogpost, there are endogenous heart stem cells, but probably not in sufficient populations to be clinically significant directly.

Despite the wildness in this area of clinical research for the past one to two decades, there are reasons for hope and recent good news. For instance, the field has never had a better understanding of stem cells and the heart.

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There are also more than 600 clinical trials listed for the search "heart AND stemcells" on clinicaltrials.gov. Many of these won't work out, but I'm confident that quite a few will and could lead to safe and effective new stem cell treatments for the heart. So in the next 5-10 years, I expect we'll see stem cells mending broken hearts.

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US stem cell clinic sued for injection into patient's eyes: landmark case?

*The Niche | by Paul Knoepfler, Ph. D.
January 25, 2016*

For the first time to my knowledge, a patient has sued an American stem cell clinic alleging damage to her eyes from fat stem cell injections. Just a few months ago, there was a report of a Japanese patient who sued a fat stem cell clinic and won, but I'm not aware of a similar case in the US until now.

Elizabeth Noble, who reportedly received a stem cell injection into her eyes for macular degeneration by U.S. Stem Cell, Inc., has filed suit against the company.

Two specific individuals are named as defendants in the case: nurse practitioner Alejandro Perez, ARNP, and Dr. Shareen Greenbaum, M.D.

Dr. Greenbaum was mentioned and quoted in a press release about a stem cell trial with Bioheart from about two years ago related to macular degeneration. She is currently working at Hollywood Eye Insitute in Florida.

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How "Stem Cell Hype" leads to "Stem Cell Tourism"

*by Dr. David Crouse
President, Nebraska Coalition
for Lifesaving Cures*



Stem cells are incredibly flexible and their biology is better understood every day. Wouldn't it be wonderful if the advertisements that proclaim the many currently available, miraculous treatments and cures that stem cells may bring were all true? Indeed, you can find such ads in any "in flight" magazines, local papers and the internet. Just search "stem cell treatments" with your favorite search engine. Unfortunately, much of what you will find is not scientifically validated and the proliferation of clinics across the globe, and increasingly in the US, has become a big problem.

A fundamental concept in clinical medicine is "... do no harm." Stem cells have been successfully used to treat a wide variety of bone marrow and blood-related diseases as well as some congenitally derived diseases for quite

augmentation when that treatment is derived from your own cells? The answer is, "Quite a lot!!" There are numerous documented cases of patients being significantly harmed, even resulting in death, following treatment with an unapproved "stem cell therapy." In addition, such treatment can cost many thousands of dollars, not covered by any kind of insurance. Additionally, if you receive such a treatment, you will probably not be eligible to enter any legitimate clinical trial for a potentially valuable treatment. Plenty of harm in all three areas.

With all of these clinics proliferating around the country, it has taken a while for the US regulatory agencies to catch up. Recently, the Food and Drug Administration (FDA) has stepped in with some forcefulness. They asked the basic question, should "cells" be regulated like "drugs"? Based on one of their primary missions, protecting the public, they answered yes. It has taken a couple of years to construct a set of useable definitions and guidelines to help direct this complex area of possible treatments. Those proposed "Guidelines" have been released and can be found by searching "FDA draft guidance human cells" – there are several documents. In summary, cells and tissues that have been more than "minimally

possible harm and assure appropriate oversight. Many, many clinics that offer unproven "stem cell treatments" for a large variety of situations must now meet FDA's strict standards. Indeed, a large multi-site Stem Cell Treatment" group of clinics received a "Warning Letter" from the FDA detailing their violations. This letter was issued after numerous on-site visits and requests for corrective actions that were not followed by the clinics.

The FDA seeks detailed input from health professionals and concerned members of the public when they have questions about stem cell treatments they may see offered or are considering. Obviously, public education and awareness become important to help guide appropriate use of stem cells in clinical treatment. The Nebraska Coalition for Lifesaving Cures hopes to continue to play a role in this regard. Please contact us if you have concerns or questions about such treatments.

This growth factor and culture-based system led to the near elimination of graft versus host disease and more rapid engraftment with greatly enhanced recovery of platelets and neutrophils. He also speculated that it may be possible to "bank" the culture and growth factor modified cells as a product useful in many therapies now restricted to adult bone marrow.

All in all, the continued progress in stem cell based therapies gives great hope that more and more diseases will be successfully addressed using these approaches. The continued availability of stem cells from all sources will clearly enhance the progress of these important therapies.

For additional resources, visit News at nebraskacures.com

All in all, the continued progress in stem cell based therapies gives great hope that more and more diseases will be successfully addressed using these approaches. The continued availability of stem cells from all sources will clearly enhance the progress of these important therapies.

a number of years. UNMC is highly respected for their pioneering works in these areas. There are many additional treatments with a variety of stem cell sources (adult, embryonic, fetal, induced) currently involved in registered and legitimate clinical trials. So, what harm can come from an unapproved stem cell treatment for your bad knee, chronic back pain, erectile dysfunction or breast

manipulated" or are placed as a treatment in a "non-homologous site" fall under their jurisdiction as a drug. This means that fat tissue that has been collected and the stem cells separated out (more than minimally manipulated) and then injected into a knee to treat a knee injury or defect (non-homologous site) fall under their jurisdiction and must meet very strict standards to avoid