



February 2017 | Member Newsletter

Phil Kozera

Letter from the Executive Director



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2017 takes off with a whirlwind of activities

As I write, I'm wondering what happened to January and February. The new year has begun with several initiatives moving forward and some others are getting underway.

I'm pleased to pass on that construction has started for the incubator space at Nebraska Innovation Campus. Once complete, it will offer wet lab space as well as a maker space for biotech companies. The anticipated completion date is July.

One of our goals at Bio Nebraska is to raise the profile our industry. So, I appreciated the opportunity to join Pure Nebraska on Channel 10/11 for a discussion on ag biotechnology. Dr. Stewart Bauck and myself were interviewed about our state's ag biotech industry and reasons Nebraska is a perfect location for value-added agriculture.

If you missed it, you can see it at <http://www.1011now.com/purenebraska>.

The 2017 state legislative session passed the 30th day of its 90-day session. Bio Nebraska has been actively working on our members' behalf. One area of emphasis is working directly on Senator Morfeld and Lindstrom's Create a Bioscience Innovation Program (LB641). LB641

appropriates \$2 million to support small-enterprise formation in the bioscience sector. The hearing for LB641 is scheduled for March 6 at the Capitol.

Our pro-growth, proactive agenda addresses underlying economic disturbances that make our state's economy vulnerable. We will continue to patiently put forth a positive agenda that fostering bio tech promotes high-paying jobs. At the same time, we understand the current sense in the Legislature is focused on thrift. We also are closely monitoring issues for our members in the public sector as budget shortfalls continue to dominate the agenda in Lincoln.

“Nebraska’s emerging biotechnology sector could be an important driving force behind a new innovation-based economy that provides the state’s workers with high-wage, high-skill jobs in high-demand sectors.”

Advancing Nebraska’s Biotechnology Economy, Center for Innovation Strategy and Policy, SRI International, November 30, 2016

On the federal front, BIO has been monitoring drug importation legislation. We want to ensure patient safety and believe that no patient is served well by a drug with unknown ingredients from unlicensed middlemen who operate beyond U.S. law.

Also, several groups have filed briefs with the U.S. Court of Appeals, District of Columbia Circuit, challenging EPA's management of the renewable fuels standard. Bio Nebraska will continue to monitor the situation.

You will notice below a thought-provoking treatise on immigration provided by Lincoln attorney David Zaritzky Brown of Brown Immigration Law. While the opinions expressed don't necessarily reflect the leadership of Bio Nebraska, this viewpoint underlines the importance of speaking up for our industry and its role in our society.

I had the pleasure of visiting with Holli, Chelsea and Jennifer from Fisher Scientific. I was pleased to learn that our members saved almost \$1 million in 2016 by using the Bio Nebraska purchasing agreement. If you're interested in learning more about the program, please contact me.

Finally, please mark your calendar for the Bio Nebraska Life Sciences Association annual meeting, scheduled for April 27 from 5 to 7 pm. More details are forthcoming.

Best regards,



Phil Kozera



Governor's Ag Conference

March 14-15
Kearney, NE

Partnering for Growth

March 21–22
FFA Enrichment Center
Ankeny, IA

Ethanol Emerging Issues Forum

April 13–14
LaVista, NE

Bio Nebraska Annual Meeting

April 27, details TBD

Life Sciences on the Links

June 8
Iron Horse Golf Club, Ashland



Bioscience Leader Spotlight



Likarda Fills Unique Niche in Early Phase Research

In the Spotlight is Likarda, a contract research organization (CRO) in Kansas City. We discussed the firm with co-founder Karthik Ramachandran.

Q: Please tell us about your company and what you do.

A: Likarda CRO serves pharmaceutical and nutraceutical companies, along with health, food supplements and cosmetics. We specifically support the early phases of product development, frequently for start-ups, entrepreneurs and small businesses that are seeking data, yet do not have the large amounts of funding needed for a full research program. We utilize our 3D cell-based assay system to better predict the function of compounds on the bench, allowing teams to make better decisions as they move their projects forward. Likarda functions as a scientific team

and incorporates other services as well, including analytical chemistry, biological testing, R&D program management and ancillary services like grant writing.

Q: When did you get started and how is progress going?

A: Likarda started in 2012 as a spin-out of the University of Kansas Medical Center, primarily focused as a CRO. Our goal was to fill a need where entrepreneurs and small businesses like ourselves could access high-quality science and technologies in supporting research programs. We strive to keep costs affordable because most start-ups are running on investor funding (or in our case, reinvesting in our own pipeline of products).

Q: You do early phase research for both humans and animals. Is this an unusual model?

A: Yes, Likarda fills a unique challenge for entrepreneurs in the life sciences field. Most CROs focus on expensive tests for FDA filings. Likarda is one of the few private companies that specializes in early discovery research. Often our only competition is academic settings, but with us, the client has the advantage of working with a company that understands that data produced belongs to the client company.

Q: And what is the origin of your company name?

A: Because we created a business model unlike other CROs, we wanted a name that was equally unique. Likarda's name originates from a mix of the founder's names: LIsa, KARthik, and DADs. Another unique aspect is we are self-funded. By starting with our own money, it pushed us to become profitable as quickly as possible. That led to early innovative approaches that lowered cost, improved data reliability and helped us build a robust client portfolio.

Q: Tell us more about your 3D assays of cells. How do you use it?

A: Likarda utilizes its proprietary microplate technology to produce 3D cell clusters of nearly any cell type within the body. Traditionally, cells are grown in a 2D monolayer (or flat layer) on which drugs/therapeutics can then be tested. However, we are 3D creatures, so by testing drugs and therapies on a 3D cell cluster within a dish, we're able to better predict how these therapies will translate to humans, or your target species of interest. By providing 3D assay services, companies small and large can easily obtain the benefits of 3D without the excess costs to validate and deploy it in their lab. For the future, with some commercial partners, we are developing microplates and assays that would be available for purchase.

Q: We have many company members involved in animal health? How can you help them?

A: Our 3D cell clusters can use nearly any cell type, human or animal. We've worked on several projects where we've utilized cells from cats and dogs to test products. Likarda, itself, is developing a cell-based therapy to treat diabetes in companion animals.

Q: How can you serve our startup and emerging companies involved in human health?

A: Likarda has worked with companies small and large across the pharmaceutical, nutraceutical, health and food supplement, and cosmetic industries, all geared toward the advancement of

human health and consumer products. Frequently, we are asked for small projects to answer the first question: “Does my product work and is it worth pursuing and spending my money to develop?” We have conducted studies for companies ranging from chemotherapeutics and cancer products, to diabetes treatments, oral healthcare and food supplements. Many times, we function as the scientific division of start-ups and small companies, as they are in their initial stages of raising capital and moving a product forward, saving them on overhead costs while keeping product development focused and moving forward.

As a proud member and supporter of Bio Nebraska, Likarda offers other members a 5% discount on its services. We are all scientists at Likarda and no project is too small or too crazy to discuss with us—we love the challenge. For more information, visit www.likarda.com.



State News

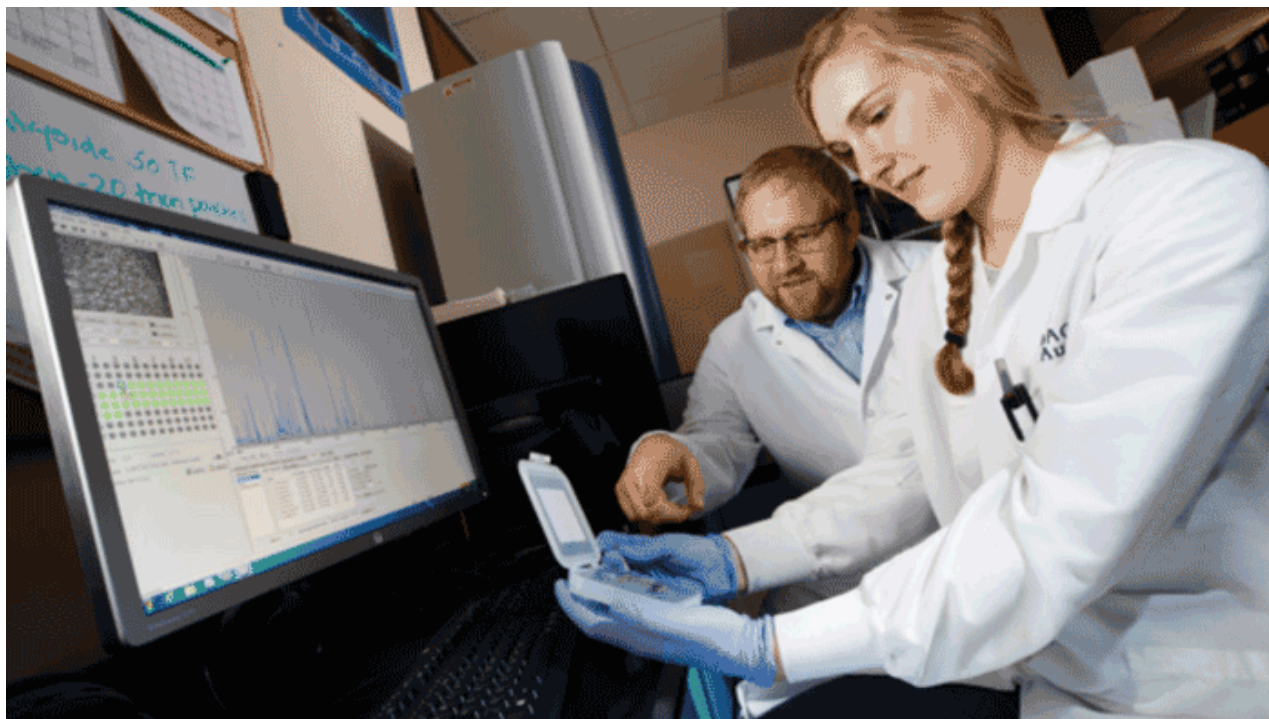


Greg Gordon, M.D., with his patented Lock-Block radiation shield from startup Radux Devices.

UNMC Valley of Death Funding Gets Good Results

UNMC’s modest use of the Nebraska Research Initiative’s proof-of-concept grants generated good results. These grants support innovation that’s too advanced for public funding but too early for commercial investment, a gap called the Valley of Death. Over five years, 17 grants totaling \$2.78 million went to UNMC and UNO. Results led to four startup companies, four new partnerships with biomedical companies, and drew in more than \$2 million in additional federal

and private research. “Without POCs, we’d have more than a dozen technologies just dying on the vine” said Michael Dixon, CEO at UNeMed.



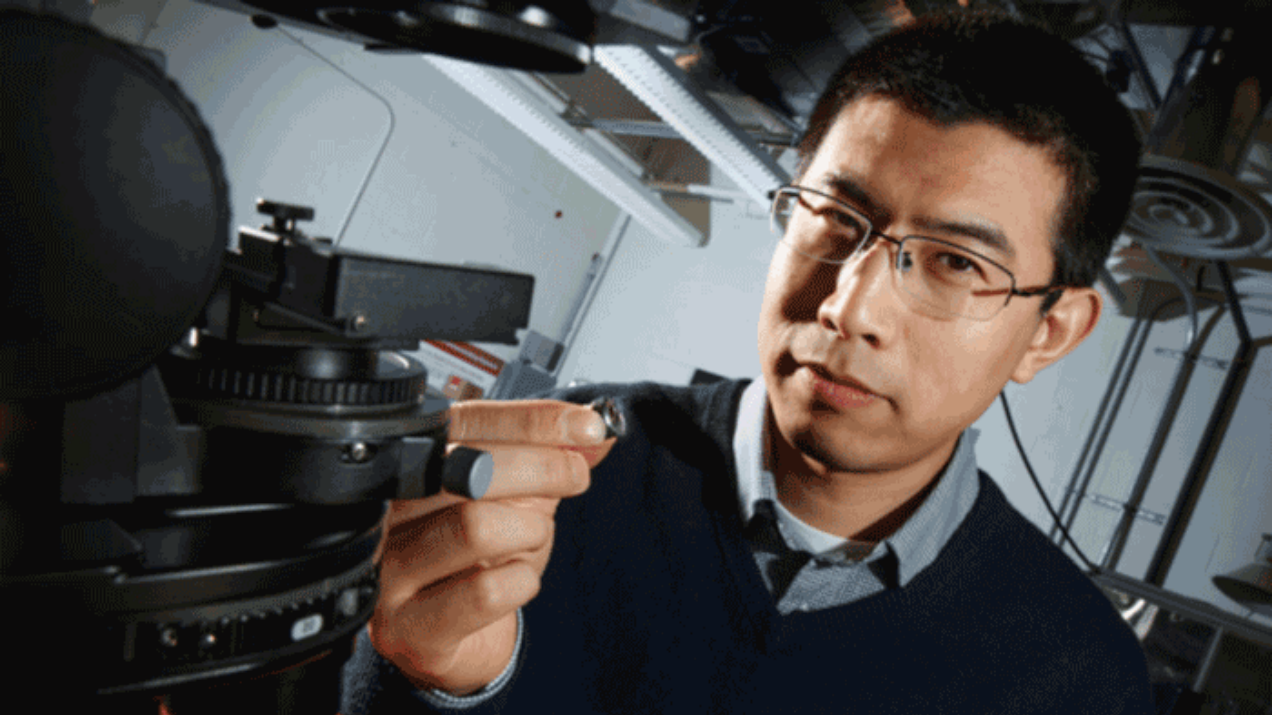
Kara Robbins and Dustin Loy inspect bacteria tests at the Vet Diagnostic Center.

New Equipment Speeds Response to Animal Diseases

A new instrument has enabled veterinarians at the UNL Veterinary Diagnostic Center identify potentially deadly bacteria in a matter of minutes -- compared to days for lab cultures. The \$250,000 MALDI-TOF mass spectrometry device is part of the new \$44.7 million veterinary lab now under construction on UNL East Campus.

State Economic Indicator Rises Sharply

Nebraska’s economic growth will improve during the second half of 2017, predicts UNL’s Bureau of Business Research. The BBR indicator, a composite of economic factors for growth six months into the future, rose by 1.97 percent in January. “The rapid increase in the indicator during January is a positive sign,” said economist Eric Thompson. “Economic growth should improve in Nebraska by mid-2017.”



Ruiguo Yang, assistant professor of mechanical and materials engineering.

Researchers Decipher Nanoscale Architecture of Beetle Shell

Beetle body armor is light and tough. Engineering similar compounds could lead to lighter, stronger materials that reduce gas-guzzling drag in vehicles or airplanes and reduce the weight of body armor.

By revealing exoskeleton architecture at the nanoscale, UNL's Ruiguo Yang, assistant professor of mechanical and materials engineering, and his colleagues undertook a difficult analysis of the fibrous nanostructure. Their work was recently featured on the cover of *Advanced Functional Materials*.

UNMC Has Massive Economic Impact

UNMC commissioned an independent third-party study to measure its economic impact in Nebraska. Overall, UNMC/Nebraska Medicine and affiliates had a \$4.2 billion impact in FY 13-14, supporting 28,927 jobs and generating \$99.1 million in state and local tax revenue. New ventures, such as those at the Fred & Pamela Buffett Cancer Center, will provide 4,657 more jobs to the metro area, infusing \$537 million into the economy on an on-going basis. See the whole story at <https://www.unmc.edu/wow/>.

College of Dentistry awarded \$4 million state contract

The UNMC College of Dentistry has been awarded a \$4 million, 10-year contract from the State of Nebraska to fund more dental graduates practicing in rural Nebraska shortage areas.



Ebola Grant Expanded From \$12 Million To \$24 Million

A \$12 million CDC grant awarded in 2015 to establish the National Ebola Training and Education Center (NETEC) has been doubled to \$24 million to expand services and research. The grant awarded to UNMC, Emory University and NYC Health + Hospitals will allow the three institutions to perform more site visits, do more education and training and build a pathogens research network at 10 regional Ebola treatment centers in the U.S.



UNMC Department of Pharmacology/Experimental Neurosciences include (left-right): Howard Gendelman, M.D., professor and chair; Divya Prakash Gnanadhas, Ph.D., post-doctoral research associate; and Santhi Gorantla, Ph.D., associate professor.

Novel pharmaceutical action for HIV/AIDS discovered

A UNMC Department of Pharmacology/Experimental Neurosciences research team is investigating how a long-acting, slow-release process for antiretroviral therapy can help HIV/AIDS patients turn daily treatments into once-a-month dosing. The work is detailed in the March *Journal of Clinical Investigation*.

Nebraska Engineering Leads Manufacturing Efficiency Initiative

A UNL engineering team has earned a \$1.4 million U.S. Department of Energy grant to help small manufacturers use energy more efficiently. Nebraska Industrial Assessment Center faculty and students will assess firms with gross annual sales below \$100 million, fewer than 500 employees and annual energy bills between \$100,000 and \$2.5 million.

Director Hired for Omaha STEM Program

Omaha's Henry Doorly Zoo and Aquarium and UNO hired Julie Sigmon as director of the Omaha STEM Ecosystem, a citywide partnership for science, technology, engineering and mathematics education.

Celerion Appoints Hoffman as CMO

Dr. Marc Hoffman has joined Celerion as chief medical officer. Dr. Hoffman will lead the global medical staff and medical oversight of early clinical research.



National News



Bill Gates and Warren Buffett.

Ten years later, Gates Investing Buffett's \$30 billion

"It was the biggest single gift anyone ever gave anybody for anything." That's how Bill and Melinda Gates describe Warren Buffett's \$30 billion donation in an open letter to the famous

investor, 10 years after his historic gift. In a report to Buffett, the Bill & Melinda Gates Foundation lays out progress preventing childhood death, ending disease and improving lives around the world.

Green Plains' Becker a Leader in Advanced Bio-economy

Todd Becker, CEO of Green Plains Renewable Energy, is listed No. 4 in the Top 100 People in the Advanced Bio-economy for 2017, as selected by readers and editors of *Biofuels Digest*.

Silicon Valley VC Firms Bet on Ag Start-Ups

Agriculture needs investment. "At least \$200 billion a year," says Rob Leclerc, AgFunder. "It's an industry hungry for capital." To bridge the gap, he founded California-based AgFunder in 2013. "We think food and agriculture is a place to literally put your money where your mouth is," Leclerc says. "We all eat. It's not going to go away, but we need to do ag smarter. To help get us there, we believe the future of agriculture is going to be driven by technology."



Minnesota Twins Cut Waste with NatureWorks

Sports concessions create a huge amount of waste each year. The Minnesota Twins sought to improve on their already impressive environmental initiatives. In 2015, they migrated to NatureWorks compostable Ingeo products to replace plastic beer cups, nacho trays, portion cups and straws. Fans dispose of packaging with leftover food in compost bins. Read more cases at: <http://www.natureworkslc.com/The-Ingeo-Journey/End-of-Life-Options/Case-Studies>

Merck: Best Practices Stem Canine influenza

When an outbreak of canine influenza H3N2 hit several large metropolitan areas in 2015 and 2016, thousands of pets were affected. Within nine months, the virus had spread to more than half the country. Examination of the outbreaks have led to new best practices. See them in February *AAHA Trends Magazine* [here](#).

Court of China Rules for Novozymes

In a rare landmark case on the validity of patents covering biotech innovations, the Supreme People's Court of China has decided for Novozymes in a patent infringement case against two Chinese companies caught producing and selling a proprietary Novozymes enzyme for ethanol.

Demi Lovato, Sunovion Launch *Be Vocal*

Sunovion Pharmaceuticals and mental health advocates launched *The Be Vocal Collection*, featuring singer Demi Lovato, Getty Images and photojournalist Shaul Schwarz and documenting 10 people living with mental illness.

Whole genome sequencing provides insight on the future of food safety

Food producers are reducing pathogens and improving public health using genomics in food safety diagnostics. Next-generation sequencing and genomics gives processors previously unavailable information on strains, sources and identity of pathogens. A local example is work done by Neogen through its NeoSeek platform in partnership with UNL specialists.

The Uncertain Future of Immigration Policy

By David Zaritzky Brown, Brown Immigration Law

The only certainty we had in immigration policy the last decade was a lack of political will to modernize an out-of-date immigration policy framework. Many forward-thinking bills were introduced to modernize our system. But ultimately the calculation that this could remain a wedge issue for future elections held sway and our elected representatives failed to act.

We are now at a moment in time when immigration policy has importance in our domestic policy agenda – defining the type of nation we hope to be and our economic future.

Many see immigration as poor border security, allowing millions to remain in the U.S. without legal status to live or work here. However, it is a much larger issue. Those in technology fields know this is a complicated problem – one that requires serious consideration.

We graduate far too few U.S.-born students with STEM degrees to build new industries and continue the pace of innovation that drives economic progress. Foreign students and entrepreneurs reinforce U.S. leadership in this area.

We also maintain a large venture capital industry that invests in all technical fields, and in recent years we are seeing increasing interest in the Midwest as an innovation opportunity.

However, capital, like immigrants, values stable markets. For years, investors have grown accustomed to founders with tenuous long-term visa status. They have learned to live in this uncomfortable situation with the belief that this was short-term. Technology companies, workers and investors have supported commonsense immigration reforms. These changes aimed to increase immigrant visas, H-1B numbers and visa classifications for innovators in new industries.

Seeking Greatness

As a nation, we have been defined by our ingenuity and industrious spirit. And this aspect of our national character thrives within open education systems, political norms and freedoms. Access to capital has attracted international talent and those who seek protection from oppression.

Attracting the best and brightest minds has been an important element in making our country the major economic and social power it is today. Despite acknowledging the importance of immigration, we are doing little to ensure it remains a benefit to our nation as administration after administration fails to modernize our system.

As immigration attorneys, we've navigated an imperfect system for some time – we have too few H-1Bs, a patchwork of visa status options that create better opportunities for certain countries and a green card system that leaves a large percentage of our immigrant population in limbo for a decade or more. As attorneys do their best to work the system, we always fear that we are reaching a tipping point – where changes to a badly outdated system could spell its doom.

Pending Debate

Unfortunately, this is our great fear as we watch the signing of new executive orders from the current administration. As a brand, America is in decline when the next generation of immigrants is afraid to make the journey.

With an as-yet unpublished executive order aimed at a review of the entire visa, parole and employment authorization system, we can review our current policies in relation to our best interests. It will fall to industry associations, businesses, economists and immigration attorneys to advocate on behalf of an expansion in these areas, or face a significant rollback. With too few U.S. born STEM graduates, our future relies heavily on foreign students.

While we get ready for the unfolding immigration debate, we will continue to use existing tools to support businesses in the state. The H-1B cap is about to open for those employers who seek a stable, longer-term status for recent F-1 graduates. New H-1 applications are due between April 3 and April 7 to be in this year's H-1B lottery.

As in the last four years, we expect to hit the cap immediately and H-1B spots will be awarded based on a lottery system. For those F-1s who are unsuccessful in getting a lottery spot, the new STEM EAD OPT extension allows an additional 24 months of work authorization.

This period allows sufficient time for many immigrants to seek a green card – an approach unheard of two years ago. As we continue using an outdated system, we will find ways around the problem – and one solution for H-1B scarcity is green card filing from non-traditional status types like F-1. While workarounds are not a long-term substitute for useful policy, for the time being the old notion “where there's a will, there's a way” holds true for business immigration practice today.

To learn more, reach the author at dbrown@brownimmigrationlaw.com, (402) 328-9899.

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