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July 2018 | Member Newsletter

Phil Kozera

Letter from the Executive Director



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July full of learning, networking and promoting Nebraska

Nebraska was well represented at the BIO World Congress of Industrial Biotech in Philadelphia. The tradeshow was an opportunity to learn about advances in renewable chemicals, synthetic biology, enzymes, food ingredients and biofuels. I had the good fortune to speak at the conference on why Nebraska is the perfect location to build your industrial biotech company.

Thank you to Joe Fox, Jason Guernsey, Ben Kuspa and the Nebraska Department of Economic Development for supporting our efforts to grow Nebraska's renewable fuels and biomaterials industry.

Bio Nebraska was a sponsor of the Governor's Summit on Economic Development on July 12. Attendees from across Nebraska focused on innovation, workforce and housing. I was pleased to see biotechnology members Evan Luxon of Centese and Abe Oommen of MatMa Corp featured during the business and innovation panel.



Taylor Wahlberg (Iowa Bio), Melissa Moyer (Iowa Bio), Greg Ibach, USDA undersecretary, Phil Kozera, Joe Hrdlicka (Iowa Bio)

Bio Nebraska also hosted, with the Iowa Biotech Association, the ***Animal Health in the Heartland*** Symposium at Nebraska Innovation Campus. The event highlighted the importance of animal-health innovation with a keynote from Greg Ibach, Under Secretary for the U.S. Department of Agriculture. There were attendees from throughout the country.

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On the federal legislative front, Bio Nebraska is asking our members of Congress to support the Senate's version of the Farm Bill's energy title programs as they reconcile House and Senate bills. Biofuels and renewable chemicals are a tremendous opportunity for Nebraska and our rural communities.

Also, on the federal front, we've been monitoring the repeal of the Medical Device Tax. The excise tax of 2.3% was included in the Affordable Care Act. We believe this tax limits investment in new technologies and treatments. The House of Representatives passed stand-alone legislation to repeal the medical device tax (H.R. 184) by vote of 283-132.

Regarding Nebraska legislation, I was pleased to read the report by Dr. Eric Thompson that highlights the success of the Business and Innovation Act (BIA). The BIA was signed into law

in 2011 to grow our state's entrepreneurial firms. The analysis finds that companies raise \$4.46 in capital for every \$1 in state funding.

In closing, please mark your calendar for the next Bio & Beers scheduled for September 20th at Lazlos in the Lincoln Haymarket.

Best regards,



Phil



Upcoming Events

Midwest US-Japan Conference

September 9-11

Omaha, NE

Bio & Beers

September 20

Lincoln, NE

Bio, Renewables, and Brew

September 27

Kearney, NE

Midwest Drug Development Conference

October 1-2

Omaha, NE



Bioscience Leader Spotlight

Animal Health In The Heartland Conference



In the spotlight this month is the issue of animal health and food security, topic of the recent Animal Health in the Heartland.

Q: Why is this issue important for our region?

A: State veterinary officials from Iowa, Missouri and Nebraska cited statistics showing that Iowa is No. 1 in pig production, Missouri is No. 1 in cow-calf production and Nebraska is No. 1 in beef cattle. Poultry is important in these states, too. The 2015 avian flu epidemic, which caused widespread losses, showed how an animal disease outbreak – caused by accident or bio-terrorism – could kill millions of animals in these states. The state veterinarians described their front-line work on animal inspections, investigations and emergency preparedness. All cited resource shortages due to funding cutbacks and their fears of epidemics. The speakers also discussed the challenges of closing borders to pinpoint farm sources of diseases while not destroying the industry they are trying to protect. For example, two counties in Missouri were impacted by high-pathogenic avian flu but all chickens were barred from border crossings. Livestock need to move to processing on a daily basis, or losses occur. High-through-put diagnostic labs running 24/7 are needed in these situations. The state officials participate in monthly calls, attend conferences and work with their USDA counterparts on emergency readiness.

Q: Will advances in vaccine approvals improve animal health?

A: USDA has streamlined approval processes for “platform” vaccine products, said Amy Gill, USDA APHIS. A production platform is a manufacturing process that relies on a single vector or expression system (“backbone”) and a standard process for inserting a gene or genes of interest (GOI) into the system. Once the platform is licensed, genes of interest can be dropped into the product. The process speeds updating of vaccines for new variants.

Q: What is the role national diagnostic labs play in monitoring disease outbreaks?

A: The National Veterinary Services Laboratories are using whole-genomic sequencing to detect disease sources, said Suelee Robbee-Austerman. She described several cases where an initial disease diagnosis in humans was tracked back to its source. In one case a disease in a human was thought to come from local-area swine. Genomic testing showed that the bio-variant of the disease was not from local hogs, which thus were not destroyed. In another situation, a skin infection among fish workers in New York was thought to come from fish farms. Analysis showed that this was not the case. In another case, a tuberculosis diagnosis on a cattle operation was problematic due to mixed up animal IDs. Using genomics, the source of the animals of concern was identified using genomics. The panel with Gill and Robbe-Austerman was moderated by Bryon Rippke, USDA Center for Veterinary Biologics.

Q: How can a foreign animal disease get into this country?

A: The mysterious appearance of Porcine Epidemic Diarrhea (PED) in the U.S was addressed by Scott Dee, Pipeline Veterinary Services. His company questioned whether feed sourced from China was the culprit. PED is widespread in China and the variant in the U.S. closely resembles the virus in China. Dee said grain in China is spread and dried on road surfaces, exposing it to traffic by people, vehicles, livestock and wildlife. Pipeline modeled a study to mimic shipping conditions for grains and other feed ingredients. This initial study showed that viral pathogens can survive transit and suggests feed may be a potential transmission source of viral disease, especially imported soybeans. Dee said that further study is needed but he felt that there was reason for caution about these grains and the feed industry should consider ways to mitigate these concerns.

Q: What is the interaction of regulation and innovation play in animal health trends?

A: This panel, composed of Aaron Gilbertie, Aptimmune, Ron White, Zoetis, Pete Thomas, Iowa Select Farms, and moderated by Tom Overbay, Expedite Animal Health, reviewed the considerations companies make in determining if a new disease in animals is temporary or a significant threat. This judgement call drives the response of the collective manufacturing base of drug companies. It can take years to develop a new vaccine. The panel discussed the many challenges faced in scale up of manufacturing capacity. The experts also discussed the potential market for vaccines in animals that could reduce transmission of sickness to humans, such as e-coli or other food pathogens. The consensus was, if the public wants this as a mass market, retailers will specify the practices within the food distribution system and producers will use these kinds of vaccines.

Q: What role does gene editing play in animal health?

A: The final panel spoke about novel gene editing techniques like CRISPR and TALEN, which take gene sequences naturally existing within a species and transfer them to breeding animals, speeding genetic improvement. Mitch Abrahamsen, Recombinetics, said his firm is focusing its applications for livestock on animal welfare and animal disease resistance. Traditionally, new traits are bred into animals using in-breeding. This, however, may have other negative effects, he said. Using gene-editing speeds such applications as dairy cows without horns, pigs that do not require castration, naturally sterile stocks in fish farms and

resistance to porcine reproductive and respiratory syndrome (PRRS), a devastating swine disease. Terry O'Neel, Friend, Nebraska, pork producer and former National Pork Board president spoke about his industry's aim to address consumer interests in safe food, animal welfare and sustainable production. He indicated that the industry has needs that gene editing can deliver on and was disappointed about a recent EU decision to regulate gene editing like it does GMOs. Benny Mote, UNL extension swine researcher, reviewed the rapid progress of genetic and genomic sciences in livestock production and its beneficial uses in human health.



LJS: Nebraska Innovation Grant Program Successful

A UNL study showed the Nebraska Business Innovation Act grant program provided about \$22.5 million to early stage companies in 2016 and 2017. Those companies raised \$100.3 million in capital, generated \$100.6 million in revenue, grew 630 new jobs, paid annual wages of \$32.6 million and created \$328 million in economic impact.

OWH: Ag Tech Reshaping Agriculture

In 2017 \$4.2 billion in venture capital flowed into ag software, big data and automation, with Nebraska home to several firms exploring these new opportunities.

LJS: Economic Indicator Drops

UNL's monthly economic index fell sharply in June, suggesting sluggish 4Q growth. The leading economic indicator report fell 0.40 percent during June and had not been negative since last October.

LJS: Millennials Can Do Well in Omaha

Omaha is No. 7 in a top-25 list of millennial income. Millennials — with student debt, rising housing costs, and the aftermath of the 2008 recession — are in a tough spot financially. Average adjusted income for Omaha millennials was \$38,534.



Channabasavaiah Gurusurthy, D.V.M., Ph.D., associate professor of developmental neuroscience at the Munroe-Meyer Institute (left), and Rolan Quadros, transgenic researcher in the mouse genome engineering core facility, played key roles in a cancer breakthrough.

Collaboration Edits Mouse T-Cell Expression

Two UNMC scientists used their novel Easi-CRISPR in a cancer breakthrough. Channabasavaiah Gurusurthy and Rolan Quadros worked with other researchers to reprogram T cells to destroy cancer cells in mice. The discovery may lead to new and safer treatments for cancer and other disorders. ([See the paper](#))

UNMC College of Pharmacy Cracks Top 10

UNMC finished 10th among U.S. pharmacy schools in NIH research dollars with more than \$10.5 million in funding. With 40 full-time faculty, the college is one of the nation's smallest among the 138 accredited U.S. pharmacy schools.

UNL Helping Lead Antimicrobial Resistance Institute

UNL is partnering with Iowa State University, UNMC and the University of Iowa to create a national anti-microbial institute. Infections from drug-resistant “superbugs” result in an estimated \$20 billion per year in direct health care costs and up to \$35 billion in lost productivity.

Fischer Bill To Help Entrepreneurs

The U.S. Senate approved bipartisan legislation sponsored by Sen. Deb Fischer to help entrepreneurs with SBA microloans. The bill, known as the Microloan Modernization Act, would improve the program and increase accountability.



Center for Plant Science Innovation Is Transforming Agriculture

Director Edgar Cahoon says the UNL Center for Plant Science Innovation (PSI) is making discoveries in metabolic biochemistry, stress biology, genetics and epigenetics that will improve stress tolerance, create more nutritious crops, increase bioenergy qualities and enhance yields.

Tyler Martin Joins Ceva Animal Health

Tyler Martin, previously head of Adjuvance Technologies, joined Ceva Animal Health as chief operating officer and will run Ceva biology operations. Ceva, in Lenexa, Kansas, ships vaccines to over 70 countries and employs 400.

UNeMED Licenses Cancer Nomenclature

UNMC researchers Scott Campbell and Jim Campbell developed a way to codify and cancer gene testing into terms a doctor could quickly understand. UNeMed negotiated the licensing agreement for the system with GenomOncology, which provides an end-to-end solution for data coming out of the sequencer to the oncologists making treatment decisions.



[Breakthrough Enzyme Heats Up Biomass Conversion](#)

London's Imperial College developed a technique they say enhances bio-process products like fuel, plastic, and cosmetics by breaking down plant-based biomass 30 times faster than current technology.

[EU Gene-Editing Rule A Threat](#)

Plants traits introduced by CRISPR gene editing will be subject to the same lengthy regulatory process as 1980s-style genetically modified organisms containing genes from other species, said Europe's highest court.

[Trump Administration May Boost Ethanol](#)

President Trump said his administration is very close to allowing fuel stations to sell gasoline with 15 percent ethanol during summer, now prevented by EPA due to concerns about air pollution.

[FDA Drafts Guidance on Single Enzyme Defects](#)

The FDA drafted guidance to help drug companies measure enzyme levels in treatments for slowly progressive, rare diseases due to single-enzyme defects, rather than waiting decades for other treatment endpoints. ([See draft here](#)) –

[New Hope for Head and Neck Cancer](#)

Merck announced that its phase 3 KEYNOTE-048 trial on Keytruda for head and neck squamous cell carcinoma met a primary endpoint of increasing overall survival compared to the current standard of care for first-line treatment.

[Pfizer's Biosimilar Nivestym Approved](#)

A biosimilar white blood cell stimulator from Pfizer was approved by FDA and will compete with Amgen's Neupogen to help reduce infection in cancer treatments.

[FDA Exploring Drug Imports](#)

The FDA is looking at ways to safely import certain drugs from foreign countries as part of an effort to lower the price of prescription medicine.

[KC Life Sciences Institute Rebrands](#)

The Kansas City Area Life Sciences Institute (KCALSI) announced it is rebranding as BioNexus KC to highlight the organization's work in both animal and human health.

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