



October 2016 | Member Newsletter

Phil Kozera

Letter from the Executive Director



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Bioscience Week A Growing Celebration Of Our Industry

My thanks to everyone who participated and supported Bioscience Week, October 3-7. It was an eventful week dedicated to celebrating Nebraska's life sciences community and included several new activities this year. If you didn't have a chance to join, I strongly encourage you to attend next year's Bioscience Week activities.

A big thank you to our partner organizations UNeMed Corporation and NUtech Ventures. Plus, we're grateful to Baird Holm for supporting our kickoff event, along with Rep. Brad Ashford for his participation. The AgBio day was also a highlight with tours at Bayer's new wheat-breeding station, Neogen GeneSeek and a quick tour of food and crop research facilities at Nebraska Innovation Campus.

On the Nebraska Unicameral front, this is a significant election with over 50% (25 of 49) of the state's legislative seats on this year's ballot. Needless to say, there will be a lot of change in the upcoming session and big issues to tackle.

Thank you to Greg Biggs, Lyle Middendorf and Bambi Reynolds for the tour of LI-COR. The opportunity to visit our member companies is always one of the highlights of my job. It is exciting to see the activity at LI-COR and the significant investments that they are making in research and development. LI-COR is expanding its services to include synthesis and conjugation services for early phase cGMP production.

On the Nebraska Unicameral front, this is a significant election with over 50% (25 of 49) of the state's legislative seats on this year's ballot. Needless to say, there will be a lot of change in the upcoming session and big issues to tackle. Bio Nebraska is closely monitoring the races and staying current on the topics impacting our industry.

At the federal level, we are supporting national BIO in their efforts to advance a multi-year extension of the second-generation biofuel producer tax credit and the biodiesel and renewable diesel fuels credit. We believe that the financial incentives are important to foster new technologies that haven't reached commercialization. Nebraska research and industry are on the cutting edge of several new technologies.

As November rolls around, Bio Nebraska will be sending out our member renewals for 2017. As a member-driven organization, your support and participation is critical to our overall success. We are currently planning several new initiatives for next year and feel fortunate to have your continued support.

Best regards,

A handwritten signature in black ink, appearing to read "P. K. S.", followed by a horizontal line.

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Greenhouses at NU Innovation Center used for public-private research collaborations.



Visitors at Bayer's wheat breeding station hear how the company develops new varieties.



Bayer wheat varieties must pass stringent flour performance tests.



Upcoming Events



State Legislative Forum

October 26
The Nebraska Club
Lincoln, NE



Supply Chains: Advantages of a Campus

November 2
Thompson Center at UNO
Omaha, NE



Growth & Development Policy Center

November 2
Lincoln Chamber

Lincoln, NE



[UNL Research Fair](#)

November 1-2

Nebraska Union (except where indicated)

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Bioscience Leader Spotlight



Growth Is Happening Each Day at Benchmark Biolabs

Today our focus is on Mary Ann Pfannenstiel, vice president of laboratory services at Benchmark Biolabs, Inc. and that firm's remarkable progress in Lincoln

Q: Thank you for stepping into the Spotlight. Please tell us about your role at Benchmark Biolabs.

A: I began working at Benchmark Biolabs within a month of its incorporation, which was 20 years ago. I have been responsible for laboratory services for internal projects, quality control and for services provided to clients for the past thirteen years. I am currently responsible for technical training and development.

Q: Benchmark Biolabs has had an exciting year, with its merger and opening of a new manufacturing facility. What gets you excited about coming to work each day?

A: Working at Benchmark Biolabs has always been exciting because of the diversity of projects that we work on. We have a wide range of clients, from large corporations to small start-up companies. We work with many types of viruses, bacteria and parasites, so there is always something new to learn. We have had the opportunity to work on the development and USDA licensure of several unique and novel products. In 20 years, there has never been a day where I have felt my work was tedious, and I always leave work wishing I could have accomplished more that day. Each day presents new challenges and the opportunity to overcome those challenges.

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Q: Our region is developing a strong ecosystem as a hotbed of vaccine development. Do you see our area as competitive with other regions?

A: Our area is definitely competitive in vaccine development and manufacturing. One need only look at the number and competitiveness of large corporations and smaller businesses in the area. The quality of the workforce in our area has been an asset for all employers.

Q: Your background includes academia, a large pharma corporation and then work in an emerging/growing biotechnology firm. What have you enjoyed about each stint?

A: One of the most enjoyable factors in academia is the freedom to work on projects of your design and choosing. University schedules are flexible and the environment is often exciting with new students, new classes and new schedules each semester.

Working for a large-pharma corporation was interesting, because I was now applying the science I had learned in academia, and using a whole new set of operating parameters. Project management, timelines, budgets and numerous federal regulations were overlaid onto performing good science. Licensing a product under FDA for a large corporation requires a team effort, and the project has to be managed so that the numerous cogs of the machine work synchronously. There is a sense of pride when the studies are completed and approved by the FDA, and a product that offers benefits to the public is on the market.

I did not know what to expect when I began to work for a start-up company, whether the company would succeed and survive, or what my role would be. Working in a small company, you know that what you do each day has an impact on the success of the project and also the company. It has been a pleasure to be involved in the growth and success of Benchmark, and also to work with and train new employees.

Q: As you look at agriculture, there is great pressure on producers to reduce antibiotic use in food animals. Does this create opportunities for immunizing animals and thus reducing potential harm from antibiotic resistance in microbes?

A: Whenever antibiotic use is limited either through government regulations or the emergence of resistant microbes, changes are needed in agricultural practices. This may include animal husbandry and diet, but vaccination is also a key component in reducing the effects of the disease.

Q: As you look ahead at your company, you have merged with a very capable animal-health distribution company. Do you see this as growing more jobs in the Lincoln area?

A: The plan is to increase the number of employees in Lincoln, and we have begun the process with recent hires.

Q: As a training resource within Benchmark Biolabs, what advice do you have for our education leaders who are working to create our state's 21st Century workforce for companies such as yours?

A: New employees should be well trained in theory and techniques, so laboratory classes that offer hands-on training are necessary. This should include training on proper documentation, calculations and reporting of results. One of the most beneficial courses I had was a two-credit course on scientific writing. This course also discussed the ethics of reporting results. Ethics is often overlooked in curriculums, but it is necessary that employees understand and follow ethical practices in order to maintain the integrity of the scientific method.

Q: As a woman leader in science, do you feel that we are doing enough to encourage girls and young women to pursue STEM careers?

A: I am appreciative of the programs that are in place to encourage girls and young women to pursue STEM careers, because they certainly did not exist when I was a student, or even when my daughters were students. These programs can offer great benefits. I have seen the results of STEM programs when attending the KC Animal Health Corridor Annual Meeting where high-school students attend sessions. Many students expressing an interest in science are young women. We need to continue to emphasize STEM careers in school for both girls and boys, because scientific careers are not the easiest courses to pursue, and students need the encouragement for a difficult undertaking.

Thank you Mary Ann. We wish you and Benchmark Biolabs well in the coming year.

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State News

TRANSGENOMIC AND PRECIPPIO MERGING

Transgenomic and Precipio Diagnostics of New Haven, Conn., are merging to create a platform focused on cancer diagnoses. The merger, to close in 2016, awaits approval by Transgenomic shareholders. The company will be named Precipio and be run by CEO Ilan Danieli, Precipio founder. BV Advisory Partners will infuse \$7 million to provide a clean balance sheet and expansion capital. The combined company will be listed on the NASDAQ. Paul Kinnon, Transgenomic CEO, said his firm's focus on non-invasive tumor profiling using circulating DNA has made it ready to partner with Precipio and grow in cancer diagnostics.

CELERION HONORED FOR TRANSLATIONAL STUDIES

Celerion won the 2016 International Life Sciences Award in the best translational clinical pharmacology company category after a global evaluation of nominees over many parameters, including innovation, excellence in products and services, and success stories.

ZUCKER NAMED INNOVATOR OF THE YEAR

Irving Zucker landed the 2016 “Innovator of the Year” award at UNeMed’s annual research innovation awards ceremony. Collaborators Joyce Solheim and Tatiana Bronich were recognized for “Most Promising New Invention” of 2016. Drs. Solheim and Bronich developed a nanoparticle protein with potential for treating cancer.

GREEN PLAINS ACQUIRES FLEISCHMANN'S VINEGAR

Green Plains Inc., acquired Fleischmann's Vinegar Company, Inc., the world's largest manufacturer and marketer of food-grade industrial vinegar for \$250 million. Green Plains is financing the transaction with \$135 million of debt with the balance paid from cash on hand.



MIDWEST LABS GEARS UP FOOD SAFETY TRAINING

Last month 18 Midwest Laboratories staff attended formal training to enhance testing knowhow in rapidly changing markets in food, feed and pet food. Midwest Laboratories provides testing from the land to food production, waste and exporting and is adding new methods and instrumentation.

P&G RECOGNIZES NOVOZYMES

P&G, the world’s largest consumer goods company, honored Novozymes’ collaboration in household care products. “We are delighted to be recognized as P&G’s external business partner of the year,” said Anders Lund, Novozymes’ EVP of household care & technical industries. The award was presented by David Taylor, CEO of P&G.

UNMC TEAM LANDS \$20M NIH GRANT

A team of UNMC researchers headed by Matthew Rizzo, M.D., professor and chair of the department of neurological sciences, has landed the largest grant ever for UNMC -- a five-year research grant from the National Institutes of Health totaling nearly \$20 million. Funding is provided through the Institutional Development Award (IDeA) program and the NIH's National Institute of General Medical Studies. It will focus on developing early career researchers into independent scientists and increasing the infrastructure and other resources needed to support clinical/translational research (CTR) around the region.



R. Gabe Linke, 3D printing coordinator at Children's Hospital and Medical Center, shows a model of a newborn's heart.

FUTURE OF MEDICINE, 3D PRINTING EXPLORED

A panel at UNeMed's annual Innovation Week explored biomedical 3D printing applications and examined ground-breaking uses to come. The best approach to get started in 3D printing is simply to dive right in. Buy an inexpensive consumer model and start experimenting, said panelist Jorge Zuniga.

NSRI POSITIONED TO GROW DEFENSE STUDIES

After just four years, the National Strategic Research Institute is exceeding federal metrics for growth, positioning NU as a leader in national-security research. Executive director Lt. Gen. Robert Hinson (Ret.) told the NU Board of Regents that NSRI has attracted \$39 million in contract awards, with another \$5 million expected by the end of the year. The contracts support work to combat weapons of mass destruction, fight disease, defeat terrorism and protect service members. More than 40 faculty and 60 students at NU engage with NSRI.



Mark Lynas speaks about GMOs at Nebraska Innovation Campus.

ENVIRONMENTALIST CHANGES STANCE ON GMOs

British environmental writer and science advocate Mark Lynas made headlines worldwide in 2013 when he publicly reversed his stance on biotechnology and genetically modified organisms. Lynas opened the 2016-17 Heuermann Lecture series by detailing his journey from being an anti-GMO activist to today campaigning around the world for several pro-science causes. "I had made a huge mistake. I decided that I would try to do something to begin to retribute," he said.

EXPLORING VIRUS AS DELIVERY SYSTEM FOR GENE THERAPY

UNMC's Tammy Kielian, Ph.D., is exploring viral delivery of gene therapy in the search for a cure for juvenile Batten disease. Preclinical data suggests both the delivery and the therapy are working, so far, concludes a study published by Dr. Kielian and her team. The disease is an inherited, recessive, fatal neurodegenerative disorder occurring in children. First noticed from age 5 and 10, the first symptom is vision loss, followed by seizures, cognitive loss and motor decline, and eventually death. The therapy needs one more study in the animal model to prove safety and refine the optimal dose.

CHRISTENSEN RETIRING AT UNO

After 10 years as the head of UNO, John Christensen has announced that he will be stepping down from his role as Chancellor. Christensen, the first UNO alumnus to serve as chancellor, will remain on until his successor has been named by NU President Hank Bounds and the new appointee is ready to lead the campus. Christensen called it a difficult decision, but said it is important to do what is right for both his family and the university.

UNK GROWS OPPORTUNITIES IN HEALTH PROFESSIONS

More high school students are expressing interest in learning about health science programs at UNK. The Health Science Education Complex, a partnership between the University of Nebraska Medical Center and UNK, opened in August 2015. "From last fall through now, we've seen a big increase in students touring campus who are interested in learning about the health science programs," said Peggy Abels, director of health science programs.

NATUREWORKS LAUNCHING NEW COMPOSTABLE SERVICEWARE

Natur-Tec and NatureWorks introduced a jointly developed technology platform that lowers the cost of compostable service ware while increasing its performance. The new technology platform - formulations which are based on low carbon footprint Ingeo biopolymer - produces heat-resistant service ware with rigidity approaching that of injection molded polystyrene and higher toughness than either polypropylene (PP) or polystyrene (PS) cutlery.

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National News

OPINION: MANY ISSUES TO ADDRESS IN BIOSIMILARS

While biosimilars will play a large role in the future of health care, certain concerns must be addressed, writes Dr. Joshua Stolow. Improved naming conventions, monitoring and reporting, product labeling, and cost issues are all part of the learning curve, Stolow writes. Biosimilars are often described as "copycat" versions of patented biologics, but they aren't identical to the original drug. It is relatively easy to synthesize aspirin, which contains just 21 atoms. It is harder to copy biologics, which consist of more than 20,000 atoms. If an ordinary chemical drug is a small house, a biologic is like the Empire State Building in terms of size and complexity, says Dr. Janet Woodcock, who directs the FDA's Center for Drug Evaluation and Research.

MONSANTO, AHA AND NEMOURS TO PROMOTE NUTRITION

While U.S. food security improved last year, 3 million American households were unable at times to provide adequate, nutritious food for their children, according to the USDA. To address malnutrition and food insecurity impacting young children, the Monsanto Fund is supporting Healthy Food Alliance for Early Education, a joint program of the American Heart Association and Nemours, with a five-year, \$3.9 million pilot program in St. Louis.

USE OF MERCK'S HPV VACCINE EXPANDED

Merck's supplemental biologics license application for Gardasil 9, or human papillomavirus 9-valent

vaccine, has been approved by the FDA to include a two-dose regimen for children and adolescents ages 9 to 14. The agency said the firm's application fulfilled the pediatric requirement for ages 9 to below 15.

NOVARTIS REPORTS POSITIVE BREAST CANCER STUDY

Novartis' LEE011, or ribociclib, has demonstrated superiority over letrozole, the standard of care, in a pivotal late-stage study evaluating the drug as a first-line treatment for HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women. Results from the study showed that, combined with letrozole, the drug-reduced disease progression and death risk by 44% compared with letrozole alone.

FDA OKS PROTEIN SCIENCES' QUADRIVALENT INFLUENZA VACCINE

Protein Sciences' quadrivalent formulation of Flublok influenza vaccine has been approved by the FDA for active immunization against influenza A virus subtypes and an influenza B virus in adults at least 18 years old. The vaccine contains three times more active ingredient compared with other quadrivalent influenza vaccines.

BIOGENIC CO2 COALITION PUSHES REGULATORY CHANGE

A coalition of major agricultural groups, called the Biogenic CO2 Coalition, has launched a grassroots campaign to urge the Environmental Protection Agency (EPA) to remove its regulatory roadblock to development of the emerging bio-economy. The Biogenic CO2 Coalition is a working group of trade associations and companies that support American farmers and the national "bio-economy" that a USDA economic analysis estimates to be \$393 billion, provides 4.2 million American jobs, and is the leading source of domestic renewable energy.

CARLSBERG'S NEW BIO-BASED BEER BOTTLES

In 2015, Carlsberg sold 36 billion bottles of beer. That's a lot of glass bottles going to waste. Carlsberg packaging accounts for 45% of its CO2 emissions and can have a negative brand effect if disposed of in an irresponsible way. Carlsberg is looking to bio-based solutions using new bottles made from bio-based wood fibers.

TUFTS REVIEW: GMO CROPS AS SAFE AS CONVENTIONAL FOODS

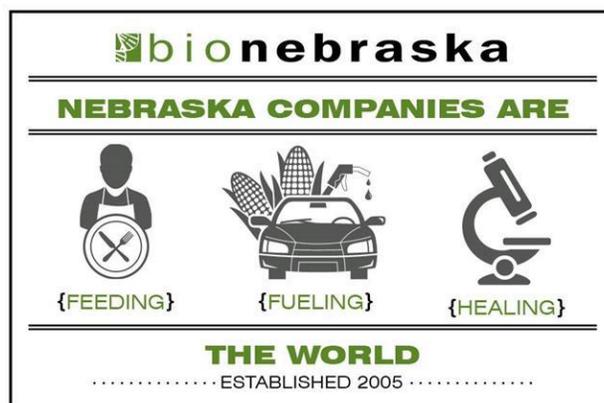
A 398-page review released by Tufts University's Friedman School of Nutrition Science and Policy concludes that biotech crops are as safe as those grown conventionally. The two-year review of 900 research publications found no evidence of environmental or health risks related to the cultivation and consumption of biotech crops.

SHELL OFFERS \$26M FOR ABENGOA BIOFUEL FACILITY

Royal Dutch Shell has made a bid to purchase Abengoa's cellulosic ethanol plant in Kansas for more than \$26 million. The oil major's initial bid aligns with its plan to develop biofuels under the Renewable Fuel Standard.

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