

**THE FUTURE OF BIOTECHNOLOGY:
SOLUTIONS FOR ENERGY,
AGRICULTURE AND MANUFACTURING**

HEARING

BEFORE THE

SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY
COMMITTEE ON SCIENCE, SPACE, AND
TECHNOLOGY

HOUSE OF REPRESENTATIVES

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**THE FUTURE OF BIOTECHNOLOGY:
SOLUTIONS FOR ENERGY,
AGRICULTURE AND MANUFACTURING**

TUESDAY, DECEMBER 8, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittee met, pursuant to call, at 10:09 a.m., in Room 2318, Rayburn House Office Building, Hon. Barbara Comstock [Chairwoman of the Subcommittee] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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Subcommittee on Research and Technology

***The Future of Biotechnology: Solutions for Energy,
Agriculture and Manufacturing***

Tuesday, December 8, 2015

10:00 a.m. to 12:00 p.m.

2318 Rayburn House Office Building

Witnesses

Dr. Mary Maxon, Biosciences Principal Deputy, Lawrence Berkeley National Laboratory

Dr. Steve Evans, Fellow, Advanced Technology Development, Dow Agro Sciences

Dr. Reshma Shetty, Co-Founder, Grinkgo Bioworks

***Dr. Martin Dickman, Distinguished Professor and Director, Institute for Plant Genomics and
Biotechnology, Texas A&M University***

Dr. Zach Serber, Co-Founder and Vice President of Development, Zymergen

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

HEARING CHARTER

The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing

Tuesday, December 8, 2015
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Purpose

On Tuesday, December 8, 2015, the Research & Technology Subcommittee will hold a hearing titled *The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing*. The purpose of the hearing is to examine new and emerging biotechnologies for applications in the energy, agriculture, and industrial manufacturing sectors. The witnesses will provide an overview of these new and emerging technologies, discuss their current and potential practical applications and economic benefits for the United States, and address the role of the federal government in funding as well as regulating biological science and biotechnology.

Witness List

- **Dr. Mary Maxon**, Biosciences Principal Deputy, Lawrence Berkeley National Laboratory
- **Dr. Steve Evans**, Fellow, Advanced Technology Development, Dow AgroSciences
- **Dr. Reshma Shetty**, Co-Founder, Ginkgo Bioworks
- **Dr. Martin Dickman**, Distinguished Professor and Director, Institute for Plant Genomics and Biotechnology, Texas A&M University
- **Dr. Zach Serber**, Co-Founder and Vice President of Development, Zymergen

Background

Biotechnology is the manipulation, through genetic engineering, of living organisms or their components to produce useful products. Humans have used biotechnology or bioengineered products since the dawn of civilization by crossbreeding to modify plants and animals with desirable traits through hybridization, and other methods. In the mid-1800's, scientists discovered the underpinnings of internal units of information that account for observable traits (genes), which are passed from one generation to the next. This discovery led to a new wave of biotechnology for plants and organisms.

In 1973, the modern age of biotechnology began when American scientists Stanley Cohen and Herbert Boyer devised recombinant DNA technology, the deliberate introduction of DNA from one organism into another. Their work made possible the production of genetically engineered human insulin, the first such product approved for sale in the United States in 1982.

Today, the biotechnology industry is a large and growing sector of the U.S. economy, employing over 1.62 million Americans across more than 73,000 companies.¹ According to one estimate, U.S. revenues from bioengineered products are over \$350 billion, approximately 2.4 percent of U.S. gross domestic product.² The Biotechnology Industry Organization currently estimates over 4,200 innovative research and discovery biotechnology projects in the industry's product pipeline.³

Biotechnology Innovations

A number of recent advancements in biotechnology due to research and development are beginning to affect the growth and expansion of biotechnology in many sectors of the economy. These advancements include:

Gene Editing

Gene or genome editing is a type of genetic engineering in which DNA is inserted, replaced, or removed from a genome using molecular "scissors."⁴ The CRISPR technique, discovered by scientists in 2005, has quickly become one of the most popular ways to do genome engineering. Utilizing a modified bacterial protein and an RNA that guides it to a specific DNA sequence, the CRISPR system provides a simple and fast way to control genes in many species. On June 16, the Subcommittee held a hearing titled *The Science and Ethics of Genetically Engineered Human DNA*. The hearing examined the research and issues surrounding the application of new gene editing technologies for human health.⁵

Synthetic Biology

Synthetic biology is an emerging interdisciplinary field that uses advances in chemistry, biology, computer science, and engineering to make or re-design living organisms, such as bacteria, so that they can carry out specific functions. Synthetic biology involves making new genetic code, or DNA, which does not already exist in nature.⁶ The Woodrow Wilson Center's Project on Synthetic Biology has identified over 50 synthetic biology-based products on the market, or close to market, including new solvents, polymers, and food ingredients.⁷ On July

¹ "Battelle/BIO State Bioscience Jobs, Investments and Innovation Report 2014," Available at: <http://www.bio.org/articles/battellebio-state-bioscience-jobs-investments-and-innovation-2014>

² "The U.S. Bioeconomy in 2012," Available at: <http://www.synthesis.cc/2014/01/the-us-bioeconomy-in-2012.html>

³ BIO Testimony, "U.S. Senate Committee on Appropriations FY15 Hearing: Driving Innovation through Federal Investments," Available at: <http://www.bio.org/advocacy/letters/us-senate-committee-appropriations-fy15-hearing-driving-innovation-through-federal-investments>

⁴ "The CRISPR Revolution," Science Magazine Special Collection, Available at: <http://www.sciencemag.org/site/extra/crispr/?intcmp=HP-COLLECTION-PROMO-crispr>

⁵ <https://science.house.gov/legislation/hearings/subcommittee-research-and-technology-hearing-science-and-ethics-genetically-engineered-human-dna>

⁶ Woodrow Wilson Center Synthetic Biology Project, Available at: <http://www.synbioproject.org/>

⁷ Synthetic Biology Products and Applications Inventory, Woodrow Wilson Center, Available at: <http://www.synbioproject.org/cpi/>

17, 2014, the Subcommittee held a hearing titled *Policies to Spur Innovative Medical Breakthrough from Laboratories to Patients*, which in part examined synthetic biology research for human health.⁸

DNA Sequencing

DNA sequencing is a process used to determine the sequence of individual genes, larger genetic regions or an entire genome. Technological improvements and automation have continued to increase speed and lower costs to the point where individual genes can be sequenced routinely and an entire human genome can be sequenced for about one thousand dollars.⁹ Beyond humans, DNA sequencing has become a valuable tool across many fields, including agricultural biology based on its ability to reveal information regarding crop and livestock genome variation that is critical for predicting traits in progeny, screening for diseases, monitoring the results of experiments involving transgenic plants and animals, and testing crop quality and purity.

Biotechnology Applications

The process of biological engineering has many applications in sectors outside of human health, primarily energy, agriculture, and industrial manufacturing.

Energy

There is increasingly robust research and development for using biotechnology to address a number of energy challenges such as enhanced oil recovery, environmental remediation, carbon sequestration, new materials, and large-scale sustainable biomass utilization for economic production of chemicals and fuels. More than 50 bio-refineries are currently being built across North America to test and refine technologies to produce biofuels and chemicals from renewable biomass.¹⁰

Agriculture

The application of modern biotechnology to agriculture in the United States was established in the 1990s with the first successful commercialization of a biotechnology-derived crop. Many new crop varieties have been developed and made available to farmers. In 2012, 88 percent of the corn, 94 percent of the cotton, and 93 percent of the soybeans planted in the U.S. were varieties produced through genetic engineering.¹¹ Biotechnology methods are being used to protect crops from environmental threats, such as pests and drought, to improve the quality of

⁸ <https://science.house.gov/legislation/hearings/subcommittee-research-and-technology-hearing-policies-spur-innovative-medical>

⁹ NIH Genome Project Fact Sheet, Available at: <https://www.genome.gov/10001177>

¹⁰ "Healing, Fueling, Feeding: How Biotechnology is Enriching your Life," Available at: <http://www.bio.org/sites/default/files/ValueofBiotech.pdf>

¹¹ "Agriculture Biotechnology," Available at: <http://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH>

crops (nutritional content) as well as its quantity or yield. On November 19, 2015, the U.S. Food and Drug Administration approved the first genetically engineered animal intended for food, the AquAdvantage Salmon.¹²

Industrial Manufacturing

Industrial biotechnology is the application of biotechnology for industrial purposes, including using cells such as microorganisms, or components of cells like enzymes, to generate industrially useful products in sectors such as chemicals, detergents, paper and pulp and textiles. Companies are investing in industrial biotechnology to reduce costs and create new sustainable products.¹³ Scientists have identified thousands of naturally occurring chemicals, forming the basis of creating new and synthetic materials. These materials have the potential to be cheaper in order to lower operating costs and reduce capital expenditures when compared to traditional manufacturing methods.¹⁴

Coordinated Framework for the Regulation of Biotechnology

In the United States, the Coordinated Framework for the Regulation of Biotechnology, first established in 1986, sets basic federal policy for regulating the development and introduction of products derived from biotechnology. The Framework was last updated in 1992. Last July, the White House Office of Science and Technology Policy, Office of Management and Budget, Council on Environmental Quality, and U.S. Trade Representative issued a memorandum¹⁵ directing the three Federal agencies that have oversight responsibilities for bio-based products—EPA, FDA, and USDA—to “develop a long-term strategy to ensure that the system is prepared for the future products of biotechnology, and commission an expert analysis of the future landscape of biotechnology products to support this effort.”¹⁶ The update to the Framework is expected to be finalized in 2016.

¹² <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473249.htm>

¹³ “What is Industrial Biotechnology,” Available at: <https://www.bio.org/articles/what-industrial-biotechnology>

¹⁴ <http://www.zymergen.com/what-we-do/product-development.php>

¹⁵ https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

¹⁶ <https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology>

Chairwoman COMSTOCK. The Subcommittee on Research and Technology will come to order. Without objection, the gentleman from Texas, Mr. Weber, is authorized to participate in today's hearing.

And without objection, the Chair is authorized to declare recesses of the Subcommittee at any time.

Good morning, and welcome to today's hearing entitled "The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing."

In front of you are packets containing the written testimony, biographies, and truth-in-testimony disclosures for today's witnesses. I now recognize myself for five minutes for an opening statement.

Humans have used biotechnology since the dawn of civilization, manipulating biology to improve plants and animals through hybridization and other methods.

Rapid advancements in science—scientific knowledge and technology throughout the 20th century gave rise to the field of modern biotechnology, making useful products to meet human needs and demands. Biotechnology has become part of our everyday lives, from producing the insulin used by diabetics, to the corn we eat and use to produce fuel, to the detergent that cleans our clothes.

Today, we are here to discuss what the future of biotechnology will look like in this century, specifically for solving some of our greatest 21st century challenges in energy, agriculture, and manufacturing.

In June, the Subcommittee held a hearing on "The Science and Ethics of Genetically Engineered Human DNA." The hearing looked at the research and issues surrounding the application of new gene editing technologies for human health. I hope that today's hearing will build upon that fascinating discussion, and help inform a research and regulatory framework that continues to ensure safety without stifling innovation.

The biotechnology and biological science industry is a sizable and growing economic driver in our country. In Virginia, the industry employs over 26,000 people across 1,500 companies and institutions, including the George Washington University Ashburn Campus Computational Biology Institute located in my district. Here, they apply technology tools to a variety of funded research in pediatric medicine, coronary heart disease, cancer, Alzheimer's disease, and schizophrenia, just to name a few.

Those are good-paying jobs, and I want to find ways to keep those jobs in the United States and encourage young people to study the STEM subjects needed to fill these jobs and create new ones. But more importantly, these are jobs and an industry that is going to improve our way of life and improve our health and save lives.

So I appreciate and look forward to learning more about these new and emerging technologies and their applications, understand better the role of the federal government in funding and regulating biotechnology, and hear from the witnesses about the economic benefits to the United States and how we can stay on the cutting edge of innovation.

[The prepared statement of Chairwoman Comstock follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY
CHAIRWOMAN BARBARA COMSTOCK

Humans have used biotechnology since the dawn of civilization, manipulating biology to improve plants and animals through hybridization and other methods.

Rapid advancements in scientific knowledge and technology throughout the 20th Century, gave rise to the field of modern biotechnology- making useful products to meet human needs and demands. Biotechnology has become part of our everyday lives, from producing the insulin used by diabetics, to the corn we eat and use to produce fuel, to the detergent that cleans our clothes.

Today, we are here to discuss what the future of biotechnology will look like in this century, specifically for solving some of our greatest challenges in energy, agriculture and manufacturing.

In June, the Subcommittee held a hearing on the Science and Ethics of Genetically Engineered Human DNA. The hearing looked at the research and issues surrounding the application of new gene editing technologies for human health. I hope that today's hearing will build upon that fascinating discussion, and help inform a research and regulatory framework that continues to ensure safety without stifling innovation.

The biotechnology and biological science industry is a sizable and growing economic driver in the United States. In Virginia, the industry employs over 26,000 people a cross 1,500 companies and institutions. Including the George Washington University Ashburn Campus Computational Biology Institute, located in my district. Here they apply technology tools to a variety of funded research in pediatric medicine, coronary heart disease, cancer, Alzheimer's disease, and schizophrenia, to name a few.

These are good paying jobs—and I want to find ways to keep those jobs in the United States and encourage young people to study the STEM subjects needed to fill those jobs and create new ones.

I look forward to learning more about these new and emerging technologies and their applications, understand better the role of the federal government in funding and regulating biotechnology, and hear from the witnesses about the economic benefits to the United States.

Chairwoman COMSTOCK. I now recognize—I guess our Ranking Member is not with us yet this morning but will be joining us shortly. I know he does have a little bit of a flight delay but will be with us shortly. And I appreciate Mr. Lipinski joining us, and we will recognize him at that time.

But, let me see, we will—if there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

Chairwoman COMSTOCK. Now, at this time I would like to introduce our witnesses: Dr. Mary Maxon is the Biosciences Principal Deputy at Lawrence Berkeley National Laboratory. She has previous experience as Assistant Director for Biological Research at the White House Office of Science and Technology Policy, or OSTP, and has worked for a variety of biotech organizations. Dr. Maxon earned her Ph.D. in molecular cell biology from the University of California, Berkeley and did postdoctoral research in biochemistry and genetics at the University of California, San Francisco.

Our second witness today is Dr. Steve Evans. Dr. Evans is a Fellow for Advanced Technology Development at Dow AgroSciences. Dr. Evans is the past Chair of the Industrial Advisory Board of the Synberc Synthetic Biology Consortium funded by the National Science Foundation. Dr. Evans earned his bachelor's degrees in chemistry and microbiology from the University of Mississippi and his Ph.D. in microphysiology from the University of Mississippi Medical Center.

Today's third witness is Dr. Reshma Shetty, Cofounder of Ginkgo Bioworks. Dr. Shetty served as an advisor to the International Genetically Engineered Machines competition, where she was best known for engineering bacteria to smell like bananas and mint, and was named by Forbes as one of the eight people "inventing the future" in 2008. Dr. Shetty earned her bachelor's in computer science from the University of Utah and a Ph.D. in biological engineering from MIT.

Testifying next is Dr. Martin Dickman, Distinguished Professor and Director of the Institute for Plant Genomics and Biotechnology at Texas A&M. Dr. Dickman's research focuses on the genetics and molecular biology of fungal-plant interactions, and he established that parallels exist between plant and animal systems, disease, and infection strategies. Dr. Dickman earned his Ph.D. from the University of Hawaii.

Our final witness is Dr. Zach Serber, Cofounder and Vice President of Development for Zymergen. Dr. Serber previously worked as Director of Biology at Amyris, and as a Research Fellow at Stanford University Medical School. Dr. Serber earned his bachelor's degree from Columbia University, his master's in neuroscience from the University of Edinburgh, and his Ph.D. in biophysics from the University of California San Francisco.

As always, we are so honored to have such distinguished and accomplished witnesses joining us here today.

And I now recognize Dr. Maxon for five minutes to present her testimony.

**TESTIMONY OF DR. MARY MAXON,
BIOSCIENCES PRINCIPAL DEPUTY,
LAWRENCE BERKELEY NATIONAL LABORATORY**

Dr. MAXON. Chairwoman Comstock, Members of the Committee, thank you for holding this very important meeting and for inviting me to participate. I applaud the committee for exploring the great potential that advanced biology has to address the Nation's grand challenges and to stimulate innovation. I believe a federally coordinated strategic program that leverages the national labs and other existing federal capabilities would greatly accelerate this.

I am the Biosciences Principal Deputy at Lawrence Berkeley National lab and have enjoyed a 30-year career as a biologist. Recently, I served as Assistant Director for Biological Research at the Office of Science and Technology Policy, where I was the principal author of the National Bioeconomy Blueprint.

Although my testimony represents my own views, I would be remiss not to recognize the leadership of the Department of Energy and Berkeley Lab in driving the Nation's engineering biology capabilities forward. In particular, DOE's Office of Biological and Environmental Research supports some of the Nation's most foundational resources in this field.

DNA can be viewed as a programming language where, instead of the 1's and 0's that are used to program computers, A's and C's and G's and T's, the building blocks of DNA, are used to program biology for useful purposes. While DNA can improve agricultural yields, increased nutrients in soil, reduce the need for water and fertilizers, it can be used to create bio-solutions to reduce the demand for livestock-based protein sources such as beef and poultry and for a planet with more people and fewer resources. It can convert non-food biomass into fuel and chemicals, and in the process, replace fossil fuels. It can convert microbes into low-cost producers of drugs and alter microbiomes to improve human and animal health.

Although DNA sequencing—that is, reading DNA—thanks in large part to the Human Genome Project, is fast, cheap, and democratic, meaning that researchers everywhere can now sequence DNA themselves, engineering biology—that is, writing DNA—remains slow and expensive.

National labs can help change this dynamic. They can play important roles in harnessing biology to meet national-scale challenges and, in doing so, democratize engineering biology to enable researchers everywhere to drive advancements across fields of science and industrial applications. But currently missing from this collection of high-throughput open—high-throughput—sorry, currently missing from the collection of national laboratory user facilities is a bio-foundry, a high-throughput, open engineering biology facility powered by capabilities in physical sciences and supercomputing to develop freely available tools, technologies, and knowledge needed to accelerate engineering biology and drive a sustainable national bioeconomy.

Such a facility could accelerate scientific discovery, reduce cost and time to market for new bioproducts that are needed to transform manufacturing processes for both human and environmental

benefit. It would build on and capture a greater return on DOE's existing investments in genome sequencing, synthetic biology, and other engineering research capabilities.

Berkeley Lab has made an initial investment to launch an open bio-foundry and has undertaken early proof-of-concept work aimed at establishing a robust democratic platform technology for the engineering of biology to provide fundamental advances needed to transform manufacturing to reduce energy intensity and negative environmental impacts of traditional manufacturing.

Recent industry listening sessions held by Berkeley Lab indicate that, in addition to user facilities, national labs can serve at least four unique and important functions for industry: 1) meet vital research needs that are considered off-mission by the company investors; 2) validate technologies from the academic sector for companies, which is currently a cost—a time-consuming and frequently unproductive endeavor for industry, and provide for the transfer of technical expertise and capacity-building directly by embedding industry researchers in the bio-foundry; and lastly, by providing access to flexible pilot-scale production facilities to enable research advances in understanding how to predict large-scale production of bioproducts, currently something of a holy grail.

I applaud the Committee for its interest in the topic of engineering biology and believe that a vision for a strong, long-term research and development program, including research in the ethical, environmental, and social aspects of engineering biology, is needed for the United States to lay a solid foundation on which to build a robust and responsible biomanufacturing future, create new markets and jobs, and drive the U.S. bioeconomy.

Thank you.

[The prepared statement of Dr. Maxon follows:]

Testimony

Dr. Mary Maxon
Principal Deputy for Biosciences
Lawrence Berkeley National Laboratory

The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing

Subcommittee on Research and Technology
Committee on Science, Space and Technology
U.S. House of Representatives

December 8, 2015

Chairwoman Comstock, Ranking Member Lipinski and Members of the Committee, thank you for holding this very important hearing and for inviting me to participate. I applaud the committee for exploring the great potential that advanced biology has to address the nation's grand challenges and to stimulate innovation and economic growth.

As the Biosciences Principal Deputy at Lawrence Berkeley National Laboratory (Berkeley Lab), I am privileged to enjoy a front row seat as some of the world's best scientists push the boundaries of engineering biology. Over the course of a 30-year career as a biologist, I have been employed in industrial and drug discovery biotechnology. Most recently, I served as Assistant Director for Biological Research at the Office of Science and Technology Policy in the Executive Office of the President where I was the principal author of the National Bioeconomy Blueprint. Although my testimony represents my personal views and does not necessarily represent the views of Berkeley Lab or those of the Department of Energy (DOE), I do want to take a second to recognize the leadership role of both in driving the nation's engineering biology capabilities forward. Funding from the DOE Office of Science's Office of Biological and Environmental Research (BER) has nurtured world-class scientists and supported the creation of cutting edge tools at Berkeley Lab and throughout the DOE national laboratories that are internationally unique and extremely productive. Leveraging BER's investments in new and dynamic ways is a key feature of my testimony.

By 2050, the global population is expected to exceed 9 billion people. To feed all of those people, the world will need to increase agricultural productivity by 60 percent. Further challenging our ability to feed the planet is a predicted 40 percent decrease in

crop yields by 2050 – as much as 80 percent by the turn of the next century. An ever-growing population is also expected to increase worldwide demand for energy by over 50 percent within the next 30 years. Creating an unvirtuous cycle, growing energy consumption will increase the production of carbon dioxide and cause climate changes, such as decreased rainfall, that challenge food production and contribute to disease. Another growing threat is posed by pathogens resistant to existing pharmaceuticals. With more than 25 percent of drugs used today derived from plants, competition for land to grow food and plants for medicines create the potential for shortages. These challenges are great, and biology can be harnessed to address them in sustainable and more efficient ways.

Biology can improve agricultural yields, increase nutrients in the soil, and reduce the need for water and for fertilizers. It can be used to create bio-solutions to reduce the demand for livestock-based protein sources such as beef and poultry for a planet with more people and fewer resources. It can convert non-food biomass into fuel, electricity, and commodity and high-value chemicals and, in the process, replace fossil fuels. It can convert microbes into low-cost producers of drugs and alter microbiomes, which are beneficial microbial communities, to improve human and animal health. It may even be able to produce novel biomaterials with desired properties that do not yet exist – such as shatter-proof bio-glass – having an array of uses and potential to create new markets in the way that the discovery of the novel material Kevlar did in the 1960s to revolutionize everything from tires to racing sails to body armor.

How is this happening? What about biology today leads my colleagues and I to have such great optimism about the future and about the value proposition for the nation and the world of investing in advanced biology? In a sentence, biology has reached an important inflection point. Similar to the advances made in information technology decades ago with the advent of programmable electronics, biology can now be programmed to more efficiently and effectively address challenges and opportunities.

Although engineering biology is an extremely sophisticated and complicated effort that brings together many fields of scientific and technological research, it is not over generalizing to describe its underlying foundation as the ability to program DNA. Where computer coding languages use ones and zeros to program computers, DNA is a coding language that uses As, Cs, Gs, and Ts, the four building blocks of DNA, to program biology. Farmers and botanists have been “programming” DNA for centuries in the quest for better food and material sources. And, scientists have been programming biology using genetic engineering for decades, applying it to a vast array of useful purposes - therapeutics, food, and consumer products.

Today, biology is poised to exponentially expand its application across broad areas of science and technology. Genome sequencing is fast, cheap, and has revealed a staggering array of biological diversity and metabolic potential that scientists have only scratched the surface of being able to understand. Synthetic biology tools and methods, advances in biological imaging technologies, and high performance computing-aided analysis have opened doors to new discoveries regarded as impossible only a generation ago. The promise is great, but the process of programming biology is still slow, expensive, and lacks tools, facilities and other platforms that are publicly available to researchers broadly. My testimony will focus on the opportunity and challenge of democratizing engineering biology in a way that will unleash the power of America's research biologists at universities, national laboratories and in industry.

Although genome sequencing has accelerated at an impressive pace as a consequence of the Human Genome Sequencing Project, advances in genetic engineering have not kept pace in allowing scientists to concomitantly benefit from this wealth of genome sequence information to create public benefit. As I mentioned, biological engineering is still relatively slow. It can take years to engineer simple microbes to produce desired products and even longer to engineer plants to be more productive, resilient crops. And because of the competitive landscape, I know from firsthand experience having worked in industry, that when a company makes a significant advance and creates new products through engineering biology it is often reticent to share the tools and technologies it has developed – naturally, it wants to maintain its competitive advantage. This means that those who follow often must spend time and money solving problems that have already been solved by others.

However, new emerging technologies such as synthetic biology and gene-editing, combined with powerful computation capabilities, promise to advance scientists' ability to engineer biology. As you will hear from other members of this panel, researchers now have the capability to create novel applications that were previously unimaginable across a broad variety of national and societal needs. The challenge is to create an ecosystem in which these new capabilities (expertise, tools, facilities, methods, knowledge) are widely available, easy to access, and domain neutral, meaning they can be used for a wide variety of desired purposes.

New engineering-biology research platforms promise to greatly accelerate the discovery of solutions to national and global needs, and in the process democratize engineering biology to enable researchers everywhere to drive advancement across fields and industrial applications. An excellent model for such democratic research platforms exists in the national laboratories, where national user facilities allow any researcher in academia, government, and industry to competitively apply to utilize and

benefit from a broad range of world leading scientific instrumentation and expertise, from genome sequencing, to high performance supercomputing, to the world's most powerful electron microscopes, provided through support from the federal government.

Currently missing from the collection of national laboratory user facilities is a biofoundry: a high-throughput, open, public engineering-biology facility powered by capabilities in physical sciences and supercomputing to develop freely available tools, technologies, and knowledge needed to drive a sustainable national bioeconomy. Such a facility could accelerate scientific discovery, reduce costs, and cut the time to market for new bioproducts needed to transform energy, agricultural and industrial manufacturing processes for human and environmental benefit. It would build on and capture a greater return on DOE's existing investments in genome sequencing, synthetic biology, and other engineering biology research capabilities. A major asset of such an effort would be an open and public knowledge repository available to all research sectors interested in effectively engineering biology for useful purposes.

Berkeley Lab has made an initial investment to launch a prototype of an open biofoundry to address this unmet need, and has undertaken early proof-of-concept work to create bio-based products using novel technologies. The effort is aimed at establishing a robust, democratic platform technology for the engineering of biology for a wide variety of desired purposes. This effort will also create a public knowledgebase envisioned to provide the fundamental advances needed to transform manufacturing to accelerate the creation of biological solutions to national needs such as reducing energy intensity and negative environmental impacts of traditional manufacturing.

Ensuring that the nation has a well-trained workforce in engineering-biology is another critical reason to democratize all aspects of the field – including education and workforce training. To address this need, Berkeley Lab has also launched a workforce initiative to collaborate with individual community colleges and national organizations to further incorporate biological engineering and biomanufacturing into community college curricula and programs, and to promote undergraduate research for making renewable fuels and chemicals. Approximately 75 community colleges across the country have biomanufacturing programs and are engaged in conversations now with Berkeley Lab, and in the near future, the Berkeley Lab will make biological tools available for students to manufacture renewable fuels and chemicals and create new industrial production organisms. These efforts provide opportunities for community college students to do exciting cutting-edge research with advanced technologies, and valuable experience to enhance employment and career prospects.

In addition to technological and workforce challenges, economic challenges have inhibited the acceleration of biomanufacturing for both large and small companies. The so-called production organism is regarded as the most important determinant of the economics of the biological production process, and bioprocessing facilities represent the largest capital expense for a company. A 2015 National Research Council report, entitled *Industrialization of Biology*, recognized that the biomanufacturing of products is poised to greatly expand in scale and scope if future advances in feedstocks, production organisms, and fermentation and processing are realized. A federally-coordinated and strategic engineering biology initiative perhaps like the National Nanotechnology Initiative, could not only help solve several of the fundamental research challenges that impede the expansion of biomanufacturing but also address some of the significant economic challenges in the process.

How can the national laboratories help? Recent industry listening sessions held by Berkeley Lab indicate that in addition to user facilities, national laboratories can serve at least four unique and important functions for industry. First, many companies currently involved in biomanufacturing have expressed concerns that they face specific research challenges, such as the lack of suitable production organisms or readily available software solutions, that are considered "off-mission" by investors yet are likely to greatly accelerate the success of "on-mission" efforts. National laboratories could address such industry needs by creating and curating a diverse array of novel "domesticated" production organisms and freely available software solutions to greatly expand industry opportunities for engineering biology toward biomanufacturing.

Second, possible applications of published research from the academic sector must be carefully validated by companies before they can be usefully integrated into standard operating procedures, a process that is often time-consuming for companies and frequently unproductive. National laboratories could establish biological engineering validation platforms with standardized assurances and certifications that could greatly reduce company external technology validation timelines.

Third, because traditional manufacturing of some products involves the use of toxic solvents and high temperatures, which are energy intensive and result in significant greenhouse gas emissions and hazardous waste, many large companies are considering moving from traditional manufacturing toward biomanufacturing to reach corporate sustainability goals. However, a transition from traditional to biomanufacturing faces many hurdles, including significant capital expenditures and lack of technical expertise in-house. Without human capital having technical expertise capable of successfully driving such a transition, investors are wary if not unresponsive. National laboratories are already beginning to respond to this challenge by providing opportunities for companies to "embed" industry researchers for purposes of

transferring engineering biology technologies and expertise directly to companies through hands-on training to forge industry capacity in biological engineering.

Fourth, companies agree that fermentation process scale-up is a major challenge and potential hurdle to production of chemicals and fuels. Successfully predicting production organism performance across scales – from microtiter to shake flasks to small fermenters to production scale fermentation – remains an aspiration, achieved likely only via intensive interdisciplinary efforts involving chemical engineering, cell physiology, automation, statistics, and modeling. Understanding the basic biological principles of “the science of scale” is an undertaking likely characterized as “off-mission” by corporate investors but perhaps well suited for national laboratories, especially those with existing flexible pilot scale fermentation facilities and supercomputing and modeling capabilities such as Berkeley Lab.

To fully realize the potential of biomanufacturing through the creation of robust engineering biology platforms, the development of measurement infrastructure is imperative. Standards, reference data, predictive models and other forms of biometrology will enable the types of predictability, specialization, interoperability, and reliability central to other manufacturing settings to fuel commerce from engineering biology. Berkeley Lab has engaged the National Institute of Standards and Technology (NIST) as a partner in its prototype biofoundry efforts, and appreciates that NIST’s leadership in the development of standards and metrology for biomanufacturing and risk-assessment in evaluating new biotechnologies will help forge a responsible path forward.

I applaud the committee for its interest in the topic of engineering biology and believe that a vision for a strong long-term research and development program, including research in the ethical, environmental, and social aspects of engineering biology, is needed for the U.S. now that biology is at this critical inflection point. In the way that the 21st Century Nanotechnology Research and Development Act of 2003 provided for strong interdisciplinary nanotechnology research that included societal, ethical, and environmental concerns, the nation could similarly benefit from a research initiative that paves a path toward real-time technology assessment engaging in fundamental, problem-oriented research on the broad-ranging implications of these new engineering biology technologies. It is critical that research in this area explore responsible innovation and ways in which engineering biology research responds to, creates, and interacts with social and ethical issues. In addition, the provision for technical expertise to inform the development of guidelines and safeguards for new products, processes, and systems of engineering biology will lay a solid foundation on which to build a robust and responsible biomanufacturing future.

In conclusion, I would like to briefly raise the issue of America's competitive standing internationally in advancing engineering biology for national needs. Many countries such as the UK and other European nations have developed roadmaps that will guide their investment decisions in a coordinated and efficient manner. Also, in October of this year, over 60 science and technology ministers from around the world met in Korea to discuss the development of global science and technology innovations, and the resultant declaration invited the Organisation for Economic Co-operation and Development to explore innovation policy frameworks needed for the "next production revolution", a large part of which is expected to involve biomanufacturing solutions around the world. The federal government must help to ensure the nation's leadership in advanced biosciences by developing a more cohesive, coordinated and aggressive initiative. A focused and coordinated national engineering biology initiative would help drive U.S. leadership in biomanufacturing, enable new fundamental discoveries, deliver solutions to national challenges, and fuel the U.S. bioeconomy.

Thank you.

Dr. Mary Maxon is the Biosciences Principal Deputy at Lawrence Berkeley National Laboratory. Previously, she was Assistant Director for Biological Research at the White House Office of Science and Technology Policy (OSTP) in the Executive Office of the President where she was the principal author of The National Bioeconomy Blueprint. Before moving to OSTP, Dr. Maxon ran the Marine Microbiology Initiative at the Gordon and Betty Moore Foundation, which supports the application of state-of-the-art molecular approaches to the field of marine microbiology with the goal of developing comprehensive models to detect and validate environmentally-induced changes in marine microbial ecosystems. Prior to that, Dr. Maxon served as Deputy Vice Chair at the California Institute for Regenerative Medicine, where she researched and drafted intellectual property policies for California stem cell grantees in the non-profit and for-profit research sectors. Previously, she was Associate Director and Anti-infective Program Leader for Cytokinetics, a biotechnology company in South San Francisco. Her biotechnology experience also includes a position at Microbia, Inc., based in Cambridge, Massachusetts, where she contributed to the discovery and development of the Precision Engineering technology for production of commercial products from microorganisms using metabolic engineering. Dr. Maxon received her Ph.D. from the University of California, Berkeley in Molecular Cell Biology, and did postdoctoral research in biochemistry and genetics at the University of California, San Francisco.

Chairwoman COMSTOCK. Thank you, Doctor.

And Mr. Lipinski has now joined us so I'm just going to take a little break here on the witness testimony and allow Congressman Lipinski to give his opening statement.

Mr. LIPINSKI. Thank you, Chairwoman Comstock. And I thank the witnesses for being willing to deal with this little interruption here. I want to thank the Chairwoman for holding this hearing and look forward to—I thank Dr. Maxon for her testimony and look forward to all the testimony here this morning.

One of the reasons I chose to be on the Science Committee, and on this subcommittee in particular, is that we have the opportunity to learn firsthand about new and emerging research fields and technologies that will transform society and to hear what the federal government can do to help society benefit from these technologies.

This morning is no different. Today, we will hear about new technologies that have the potential to transform the energy, agricultural, and manufacturing sectors. A number of these new biotechnologies are based in engineering biology research, which is research at the intersection of biology, physical sciences, engineering, and information technology. This emerging field has been fueled by the development and increased affordability of technology such as DNA sequencing and DNA synthesis.

In the case of DNA sequencing, the Human Genome Project, an international research project to sequence the human genome, was coordinated by the Department of Energy and the National Institutes of Health, and it took over a decade and cost \$2.7 billion. Remarkably, sequencing the human genome now costs less than \$1,500.

Federal agencies under this committee's jurisdiction have significant programs in engineering biology. The Department of Energy has invested in programs focused on bioenergy. The National Science Foundation has invested in this area both in individual research awards and through their support of an engineering research center, Synberc at UC Berkeley.

NASA and NIST also have programs in this area. NIST has a particularly important role in the development of technical standards for a future biomanufacturing economy. And of course, agencies outside the Committee's jurisdiction, including DARPA, NIH, and the Department of Agriculture, are also significant players in this research.

Due to the importance of this growing research field, the Nation would benefit not just from increased investment at individual agencies but also from coordination of federal efforts under some kind of national plan or strategy.

Additionally, we should ensure that we are facilitating public-private partnerships. Given the potential commercial applications across nearly all sectors of our economy, there is a need to engage and encourage private sector collaboration at a pre-competitive level. I look forward to hearing from all of our private sector witnesses what they are looking for in partnerships with federal agencies, national labs, and universities.

And finally, we must pay careful attention to the issues of human and environmental safety and ethics when it comes to engi-

neering biology research, including support of research on these topics.

The future of biotechnology could include automotive and even jet fuels produced cheaply, cleanly, and safely by specifically engineered bacteria, also, more drought- and pest-tolerant crops and feedstocks, and also, transformation of materials manufacturing with applications across our economy. These technologies would have significant economic benefit for the United States. So it is important that we make the necessary federal investments in the foundational research and partner with the private sector across the potential application areas.

I look forward to the rest of the witness testimony and the Q&A, and I thank you for being here today. I yield back the balance of my time.

[The prepared statement of Mr. Lipinski follows:]

OPENING STATEMENT

Ranking Member Daniel Lipinski

House Committee on Science, Space, and Technology
Subcommittee on Research and Technology

"The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing"
December 8, 2015

Thank you Chairwoman Comstock for holding this hearing on the future of biotechnology. I also want to thank all the witnesses for being here this morning. I look forward to your testimony.

One of the reasons I chose to be on the Science Committee and this Subcommittee in particular is that we have the opportunity to learn firsthand about new and emerging research fields and technologies that will transform society, and to hear what the federal government can do to help society benefit from these technologies. This morning is no different. Today we will hear about new technologies that have the potential to transform the energy, agricultural, and manufacturing sectors.

A number of these new biotechnologies are based in engineering biology research, which is research at the intersection of biology, the physical sciences, engineering, and information technology. This emerging field has been fueled by the development and increased affordability of technologies such as DNA sequencing and DNA synthesis. In the case of DNA sequencing, the Human Genome Project, an international research project to sequence the human genome that was coordinated by the Department of Energy and National Institutes of Health, took over a decade and cost 2.7 billion dollars. Remarkably, sequencing the human genome now cost less than 1500 dollars.

Several agencies under this Committee's jurisdiction have significant programs in engineering biology. The Department of Energy has invested in programs focused on bioenergy. The National Science Foundation has invested in this area both in individual research awards and through their support of an engineering research center, SynBERC, at U.C. Berkeley. NASA and NIST also have programs in this area. NIST has a particularly important role in the development of technical standards for a future bio-manufacturing economy. And of course agencies outside the Committee's jurisdiction, including DARPA, NIH, and the Department of Agriculture are also significant players in this research. Due to the importance of this growing

research field, the nation would benefit not just from increased investment at individual agencies, but also from coordination of federal efforts under some kind of national plan or strategy.

Additionally, we should ensure that we are facilitating public-private partnerships. Given the potential commercial applications across nearly all sectors of our economy, there is a need to engage and encourage private sector collaboration at a pre-competitive level. I look forward to hearing from our private sector witnesses what they are looking for in partnerships with federal agencies, national labs, and universities.

And finally we must pay careful attention to issues of human and environmental safety and ethics when it comes to engineering biology research, including through support of research on these topics.

The future of biotechnology could include automotive and even jet fuels produced cheaply, cleanly, and safely by specially engineered bacteria, more drought and pest-tolerant crops and feedstocks, and a transformation of materials and manufacturing with applications across our economy. These technologies would have significant economic benefit for the United States, so it is important that we make the necessary federal investments in the foundational research and partner with the private sector across the potential application areas.

I look forward to all of the witness testimony and the Q&A, and I thank you all for being here today. I yield back the balance of my time.

Chairwoman COMSTOCK. Thank you.
And I'll now recognize Dr. Evans for his five minute testimony.

**TESTIMONY OF DR. STEVE EVANS,
FELLOW, ADVANCED TECHNOLOGY DEVELOPMENT,
DOW AGROSCIENCES**

Dr. EVANS. Good morning, Chairwoman Comstock, Ranking Member Lipinski, and Members of the House Subcommittee on Research and Technology. Thank you and—for inviting me here to represent my company Dow AgroSciences in this hearing on emerging biotechnology applications.

We trace our roots in agriculture back 60 years, and we emerge from the Dow Chemical Company, a company that has been transforming technology into viable solutions since 1897.

The drivers for application of biotechnology into agriculture are clear. The global demands for food, fuel, fiber, and feed are strong and rising. The solutions to meet this global need must be met within increasing constraints and unpredictability, reinforcing the need to make newer product offerings even more sustainable.

We have all heard of the challenge set forth for global needs by 2050, and between now and that point in time, agriculture will need to produce more food than the sum total of what has been produced in the last 10,000 years. Since their introduction in the mid-1990s, agriculture biotechnology offerings have made significant contributions to global food security, and biotechnology-based crops are the fastest-adopted crop technology in the history of modern agriculture.

If you were to visit an early-stage laboratory in—R&D laboratory in Dow AgroSciences, you would see the tools and techniques that are used in common bioscience endeavors. Early-stage ag biotechnology benefits from the same molecular biology, bioinformatics, DNA sequencing, high-throughput analytical systems, and other advances from basic life sciences that have been funded by federal research.

One of the ways that Dow AgroSciences has benefitted from advances in related fields is by being able to provide input and shape ideas for technology in something like the NSF engineering research centers. Synberc, as has already been mentioned, brings together 37 professors, 18 universities, and 47 companies with the stated mission of making biology easier to engineer. As past Chair of that Industrial Advisory Board, I note that a portion of the companies they are represent established ag companies but also smaller startups with concepts in the agricultural space.

The RC provides a unique precompetitive venue for industry participation and influence in the technology development. And some of the tools that have been developed there are now being brought into our company directly and used by Dow AgroSciences. I recently examined some patent activity by other ag players, and you can see that those technologies are being broadly adopted at the early stages of most of the agricultural companies.

But to really understand and develop a realistic expectation for when these things would appear in agricultural products, you'd have to understand a little bit about biotechnology development timelines. A typical range of development spans seven to ten years

and an average investment price tag of over \$130 million per product. While laboratory tools and technologies just described play an important role in performing and accelerating that front end, we are still faced with multiple challenges at national and international regulatory frameworks.

Companies can understand and manage the risks related to product performance and customer choice. However, because of the time horizon of nearly a decade and a cost of \$100 million, to make informed investment decisions, we need to have a regulatory approval process that is predictable to enable scientific planning. That regulatory process needs to be science-based and proportionate to risk.

In addition to using biotechnology for modern crops, we have an offering in Dow AgroSciences that is based on agrochemicals derived from natural products. We—taken together, products and chemistries that are inspired by natural products account for 1/4 of the global ag chemistry sales. One challenge in developing those natural products, whether for farm or ag, is that we need to attain sufficient productivity to make that product economically viable.

Dow AgroSciences platform to integrate those biotechnology tools, either from external sources or from internal capabilities aimed at rational engineering of our strains is how we use engineering biology in our platform. Nationally funded research has enabled key milestones in that field, but the United States is not alone in recognizing the economic and environmental benefit to be derived from commercial manufacturing of novel natural products or chemistries inspired by them.

So finally, I will propose that a framework for involvement of the federal government can be understood in terms of three C's. Number one, continue to support exceptional science; number two, convene forums for discussion on development and risk-proportionate oversight; and number three, create a strategic vision for the United States biotechnology investments to produce exceptional solutions for the world's most pressing needs.

These actions are important to maintain the United States' position of leadership and development in this technology, and it's an increasingly competitive and global race. Within these fields, these investments provide technology, a workforce of new skill talent and predictable science-based regulatory framework from which companies like ours can make informed investment decisions for products taking over a decade to bring to market.

Thank you.

[The prepared statement of Dr. Evans follows:]

Testamony

Dr. Steven L Evans
Fellow, Dow AgroSciences

The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing
Subcommittee on Research and Technology
Committee on Science, Space and Technology
U.S. House of Representatives
December 8, 2015

Good morning Chairwoman Comstock, Ranking-Member Lipinski, and Members of the House Subcommittee on Research and Technology.

Thank you for inviting me to represent my company, Dow AgroSciences, in this hearing on emerging biotechnology applications. We trace our roots in agriculture back 60 years and emerged from within The Dow Chemical Company – a company that has been transforming technology into viable product solutions since 1897.

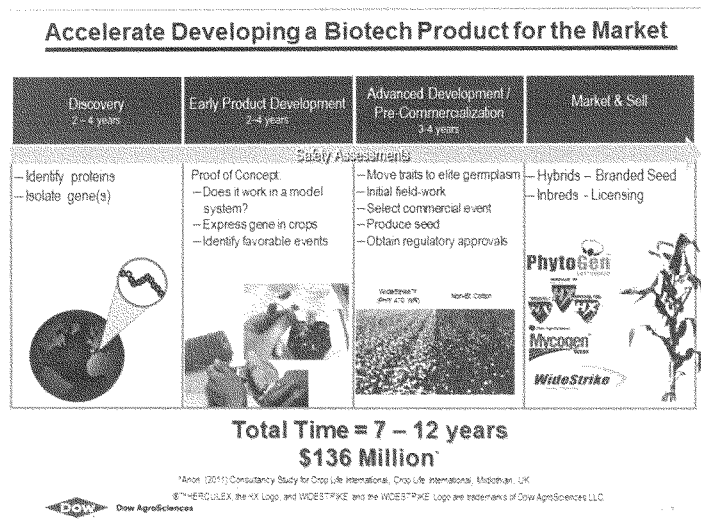
The drivers for application of biotechnology to agriculture are clear. The global demands for food, feed, fiber and fuel are strong and rising. The solutions to meet this global need must be met within increasing constraints and unpredictability, reinforcing the need to make newer product offerings even more sustainable. We have all heard the challenge set forth for global needs in 2050. To meet the global need in 2050, agriculture will need to produce more food in this timeframe than the sum total of what it has produced in the last 10,000 years. Since their introduction in the mid-1990's agricultural biotechnology offerings have made significant contributions to global food security, and a long term reviewer of the field argues that biotechnology-based crops are the fastest adopted crop technology in the history of modern agriculture.

If you were to visit the early stage R&D laboratories at Dow AgroSciences, you would see tools and techniques in use that are common to other bioscience endeavors. Early stage Ag biotechnology research benefits from the same molecular biology, bioinformatics, DNA sequencing, high throughput analytical systems and other tools that benefit labs involved in basic life sciences to biopharma. For this reason, we are able to directly incorporate many of the advances in basic life science development funded by federal research.

One of the ways that Dow AgroSciences has benefited from advances in related fields, and helped provide industry input to shape outcomes, is by participation in NSF Engineering Research Centers, or ERCs. The SynBERC ERC brings together 37

professors in 18 universities with 47 companies with the stated mission "to make biology easier to engineer". As past Chair of the Industrial Advisory Board I can affirm that a portion of the participating companies represent both established agricultural entities and startups with concepts in the agricultural space. The ERC has provided a unique pre-competitive venue to allow both industry participation and influence in technology development. Some of the inventions and technologies created by the universities within SynBERC are already present in offerings by several tool and technology suppliers and are used by Dow AgroSciences today in our research. From an examination of recent patent activity by large agricultural biotechnology companies, it is clear that such tools and technologies are being broadly adopted in the early R&D efforts disclosed by patent applications. But to form a realistic expectation for the timeline for appearance of such technology in products, it is important to understand the general Ag biotech development timeline.

The typical range of development spans 7-12 years and comes at an average investment price tag of over \$130 million per product. While the laboratory tools and



technologies just described play an important role in performing and even accelerating the front end of developing products we still face multiple challenges within the national and international regulatory framework. Companies understand and can manage risks related to product performance and customer choice. However, because our time

horizon is approximately a decade and the cost of development well over \$100 million, to make informed investment decisions we need to have a regulatory approval process that is predictable to enable realistic planning. The regulatory process needs to be science based and proportionate to risk.

We can illustrate potential impact of this uncertainty by considering an area of very active research, development and federal investment today which has roots dating to the 1980s. Recent advances in tools and technologies allow researchers to understand the microbes associated with other living organisms to a degree simply not possible even five years ago. These are the so-called microbiomes. Most famous are human microbiomes, but plants, insects and other systems relevant to agriculture have associated microbial communities. The recent "Report of the Fast-Track Action Committee on Mapping the Microbiome"¹ identified \$300 million in annual funding for this area, with some research already aimed at agriculturally or environmentally relevant areas. The ability to understand and ultimately positively manipulate these naturally-occurring microbial communities could have profound effects on plant or insect health. Early stage academic researchers are obviously interested in using biotechnology tools to manipulate these microbial communities to improve their agricultural utility.

However, my personal history in this area dates back to small biotech companies in the late 1980's and early 1990's which sought to do just this – use what was then the newest tools of biotechnology to manipulate plant associated bacteria for new agronomic properties – only on a much smaller scale than currently being investigated. Half dozen or more companies were engaged in developing products for the agricultural or environmental space utilizing genetically engineered plant associated microbes. The pathway through the regulatory environment for deliberate release of live, engineered microbes was uncharted. My company, Mycogen Corporation, solved the problem by developing an industrial scale technology to kill the engineered microbes after fermentation, thus releasing a formulation containing dead microbes as the ultimate product. While successful for a particular purpose, the real benefit from such products would have been maximized if they were able to be released as live microbes.

Nearly 25 years later, there are still few if any examples of commercial products destined for environmental release based on live, genetically engineered microorganisms. And so, cutting edge research being funded today in the area of agriculturally or environmentally relevant microbial communities will undoubtedly produce intriguing and impactful product concepts that could be critical components of a sustainable agricultural offering in the ramp up to 2050 (for instance, by increasing nutrient availability, impacting soil fertility, improving plant vigor). However, these

¹ https://www.whitehouse.gov/sites/default/files/microsites/ostp/NSTC/ftac-mm_report_final_112015_0.pdf

product concepts likely will not be adopted and commercialized because of regulatory approval uncertainties or excessive regulation that is not proportionate to risk if there is not a parallel investment in developing and publishing new, fundamental research assessing scientific questions related to deliberate release of engineered microbes which is informed by the experiences of the past 25-30 years.

In addition to using biotechnology to develop modern crops that are offered to the farmer, Dow AgroSciences is a leader in commercializing agrochemicals derived from natural products. These are substances produced by organisms and are important products because they have benefit to the farmer or other producers in the Ag value chain. Taken together, products and chemistries inspired or derived from natural products account for one quarter of global Ag chemical sales. Historically one challenge in developing natural products, whether for pharma or for Ag, is attaining sufficient productivity in fermentation to make the process economically viable. Another is genetically engineering the organisms to increase their production of the intended organic substance, again at an economically viable level. Today the advanced techniques being developed and deployed to tackle these challenges stem from the field of engineering biology. Dow AgroSciences' platform to integrate biotech tools from both external sources and internal capabilities is aimed at rationally engineering our strains to solve these productivity challenges. Nationally funded research has enabled key technological milestones in this field, but the United States is not alone in recognizing the economic and environmental benefits to be derived from commercial manufacturing of novel natural products or of chemistry inspired by them. Unlike the biotech concepts destined for direct release into the environment, here the engineered organisms are designed for use in contained fermentation facilities. The timelines for commercialization are still surprisingly similar in length than previously described for biotech crops (around a decade) but the investment cost is over \$250 million.

Finally, I will propose that a framework for involvement of the Federal government can be understood in terms of Three C's. 1) Continue to support exceptional science, 2) Convene forums for discussion on development and risk-proportionate oversight, and 3) Create a strategic vision to ensure U.S. biotechnology investments produce exceptional solutions for the world's most pressing needs. These actions are important to maintain a U. S. position of leadership in development and application of this technology in an increasingly competitive, global race. Within our field, these investments help provide technology, a workforce of new skilled talent and a predictable, science based regulatory framework from which companies like ours can make informed investment decisions for products taking over a decade to bring to market.

Thank you.

National Needs – Three C's

- National scientific funding agencies:
 - > Continue to support exceptional science that is foundational for biotechnology
 - Deployable tools in many areas of application
 - Serves the public good
 - > Convene forums for discussion on development and oversight to include public engagement, dialogue, outreach and education
 - Bringing science to policy venues and to the public
 - Input can drive new research programs providing science-based, proportionate risk analysis tools benefiting all interested parties
 - > Create a strategic vision to ensure this US biotechnology investments move in a direction that is responsible and produces exceptional solutions to pressing needs
 - Technical, societal, regulatory, policy integration
 - National and International presence

Steven L. Evans, Ph.D.
Fellow, Dow AgroSciences Seeds Discovery



Steve received B.A. and B.S. degrees in Chemistry and Microbiology, respectively, from the University of Mississippi in 1981 where he was an NSF Undergraduate Research awardee in natural products analytical chemistry. He completed a Ph.D. in Microbial Physiology from the University of Mississippi Medical Center in 1985 with an emphasis on trace metal metabolism and siderophore production. Subsequently he was an NIH Post-doctoral Fellow in the Department of Chemistry at the University of California, Berkeley exploring bidentate siderophores as analogs for transferrin. All of the work up to the postdoctoral project was focused on biomedical applications and was cross-disciplinary in scope, usually blending high resolution chemical analysis with enzymology.

Steve opted for a second Post-doc at the USDA National Lab in Peoria to enter into agricultural applications of biotechnology with a focus on ruminal anaerobes. From there he joined Mycogen Corporation in 1988 and joined Dow AgroSciences in the acquisition in 1997. At Mycogen he lead development of a novel bacterial herbicide for grass weeds, co-discovered fatty acid based synergists for glyphosate now used in consumer lawn and garden glyphosate formulations. A primary technology focus was developing the bioanalytical infrastructure for the Cellcap™ recombinant biopesticide product line.

Since joining Dow AgroSciences Steve has been involved in development of several traits stemming from the Mycogen pipeline (cry1F, cry34/35) and in capability development in bioanalytical sciences. In his current role as a Fellow at Dow AgroSciences, Steve continues to help identify and acquire differentiating bioanalytical capabilities and to enable EXZACT™ Zinc Finger technology. He is also past chair of Dow AgroSciences Fellows Organization. Externally he is active in the precompetitive area of synthetic biology technology development and has functioned as past chair of the Industrial Advisory Board of the SynBERC synthetic biology consortium funded by the NSF and co-chair of the BIO Organization IES synthetic biology subteam.

Chairwoman COMSTOCK. Thank you, Dr. Evans.
Now, I will recognize Dr. Shetty for a five minute statement.

**TESTIMONY OF DR. RESHMA SHETTY,
CO-FOUNDER, GINKGO BIOWORKS**

Dr. SHETTY. Chairwoman Comstock, Ranking Member Lipinski, and distinguished Members of the Subcommittee, I would like to thank you for the opportunity to testify here today on the future of biotechnology and its applications in energy and agriculture and manufacturing. My name is Reshma Shetty, and I'm a co-Founder and President of Ginkgo Bioworks, a biotechnology startup in Boston, Massachusetts. I hold a Ph.D. in biological engineering from MIT and have been active in the field of biological engineering for over 10 years.

Today, I was asked to testify a little bit about Ginkgo's story as a case study for how federal investment in emerging technologies can stimulate the growth of new companies and new industries and make recommendations for how the U.S. Government can continue to stimulate the growth of the domestic biotechnology industry.

Ginkgo is an organism company. We design and build microbes such as yeast to spec for customers. Our customers use Ginkgo microbes in fermentation. Fermentation is a process by which cooking is done with microbes rather than heat. Humans have been fermenting foods and beverages like yogurt, beer, and wine for more than 9,000 years, so it's a very old technology.

At Ginkgo we design yeast to make new products from fermentation or what we call cultured products. Our first commercial organisms are microbes for the production of cultured ingredients, so ingredients end up in household consumer goods, things like sweeteners, flavors, fragrances, vitamins. So, for example, Ginkgo is developing a yeast to produce a rose fragrance, what we call a cultured rose. Other companies are making cultured products such as animal-free cultured leather, animal-free cultured meat, cultured milk, cultured silk for making jackets, and so on.

I started Ginkgo in 2008 with four fellow MIT Ph.D.'s, including Tom Knight, who is widely considered to be a father of the field of synthetic biology. Quite frankly, at the time I knew almost nothing about what it took to start and run a company. What I did know was that biological technologies were going to be incredibly important in this century, and I had ideas about what were the important technologies to be working on and developing.

Federal grants and contracts from the NSF SBIR program, DOE ARPA-E, NIST, and DARPA all provided absolutely critical funding for Ginkgo in our early days as we transitioned from MIT and university life to the real world. Today, we've raised more than \$50 million of private investment, have built an 18,000 square foot facility in Boston for manufacturing of microbes, and we have commercial contracts for more than 20 different cultured ingredients. In the last 6 months we've doubled our workforce and more than 1/4 of which actually live in the 5th District of Massachusetts and are represented by Congresswoman Clark. In short, your investments help make Ginkgo what it is today.

In the early days of the computer industry, the U.S. Government played a critical role in nurturing the nascent industry through

both R&D funding and through serving as an early customer for integrated circuits via the Apollo program. This federal investment was critical in creating demand for integrated circuits and stimulated a significant later private investment in this space. The computer industry would not be the major economic and job engine for the U.S. economy that it is today if it weren't for the U.S. Government's role.

I believe that the U.S. Government has an opportunity to play a similar role in the emerging biological engineering industry. Ginkgo itself is evidence of the payoff that the federal R&D investments can generate, and I urge you to build on these early R&D investments in this space by recognizing the importance of the U.S. Government as an early adopter of biotechnology products.

With countries like the United Kingdom and China having well-coordinated national programs in this area, the United States is at risk for losing its competitive edge. By serving as an early customer and stimulating demand for the products of biotechnology, the U.S. Government could play a central role to biotechnology today, as it did in the 1960s to the computer industry.

In short, I suggest that the Committee 1) enhance U.S. competitiveness in biotechnology via direct R&D funding for public domain foundational technologies that are available for all to use without intellectual property restrictions; 2) continue to garner bipartisan support for H.R. 591 to establish a national engineering biology research and development program; and 3) recognize the importance of the U.S. Government as an early customer for biologically engineered products.

Thank you.

[The prepared statement of Dr. Shetty follows:]

**Written Testimony of:
Reshma Shetty
Co-Founder & President, Ginkgo Bioworks, Inc.**

**Before the:
Subcommittee on Research and Technology Committee on Science, Space, and Technology
U.S. House of Representatives**

The Future of Biotechnology: Energy, Agriculture, and Manufacturing

08 December 2015

Chairman Comstock, Ranking Member Lipinski, and distinguished Members of the Subcommittee on Research and Technology, I thank you for the opportunity to testify before you today on the future of biotechnology and its applications for energy, agriculture, and manufacturing.

I am Reshma Shetty, co-founder and President of Ginkgo Bioworks. I hold a Ph.D. in Biological Engineering from MIT and have been active in the field of biotechnology for over 10 years. I would like to provide an overview of Ginkgo Bioworks along with synopsis of the science behind biological engineering. I will focus my testimony on two key areas relating to U.S. biotechnology:

1. The importance of Federal funding for realizing the commercial and economic potential of biotechnology in the United States.
2. Current and future biotechnology applications.

Before I discuss these key issues, I would like to thank the Subcommittee for its continued leadership and advocacy for the National Science Foundation. Without the NSF's support, it is likely that I would not be here before you today.

- An NSF STEM fellowship supported my own graduate education.
- NSF grants provided early critical support to both the iGEM competition – an international intercollegiate competition in synthetic biology which has grown from 5 U.S. teams to more than 250 teams representing over 32 countries and to SynBERC - a major U.S. research consortium in synthetic biology. Together, iGEM and SynBERC have directly or indirectly educated a significant share of the U.S. workforce in synthetic biology including myself.
- Finally, in 2015, Ginkgo raised more than \$50M in private capital. This fundraising was only possible because of the early investments made by Federally-funded research awards from NSF, DOE ARPA-E, NIST and DOE ARPA-E in Ginkgo Bioworks.

Ginkgo Bioworks was founded in 2008 by a team of 5 MIT PhDs, including Tom Knight who is widely considered to be the father of synthetic biology. We now employ 50 people; 13 of whom reside in Congresswoman Clark's 5th District of Massachusetts. Ginkgo Bioworks is the organism company: we design and license microbes such as yeast to customers. These microbes can create a wide variety of products that are either costly or inaccessible through conventional manufacturing techniques. Analogous to the microelectronics industry, we use a centralized

factory or foundry for microbe design and fabrication. Our first foundry is Bioworks1: a highly automated, 18,000 square foot facility in Boston, Massachusetts. Ginkgo currently has more than 20 microorganisms under contract with a variety of customers including Fortune 50 companies.

Synopsis of the science

Fermentation is a process by which cooking is done with microbes rather than heat. Fermentation is a deep part of most cultures: beer, wine, cheese, yogurt, bread, coffee and chocolate all involve microbes. We can use the tools of biotechnology – our ability to read and write DNA - to study fermentation and to design microbes to make new products from fermentation. We call these new products “cultured products” and they include new ingredients like sweeteners, flavors, fragrances, new foods such as animal-free meat and milk and new materials like silk and leather.

New and emerging technologies Ginkgo is developing or supporting

To date, much of biological research has been done in what is effectively an artisanal process. Apprentices study for years under a master to learn the techniques and approaches needed to perform biological research. Indeed, technically skilled biologists are often said to have “good hands.” At Ginkgo, we take an engineer’s approach to biological design. We apply software, automation and standardization to the process of microbe design and fabrication. This spring, we launched our first foundry for organism design called Bioworks1. Bioworks1

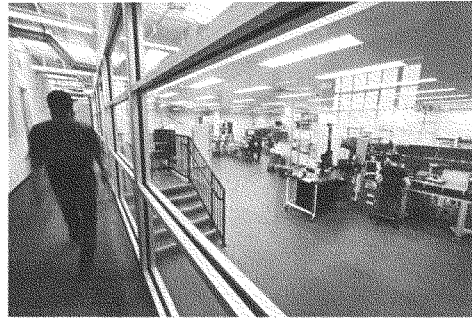


Figure 1: Ginkgo Bioworks' organism foundry: Bioworks1

automates what are traditionally by hand processes required for biological engineering through the use of integrated software and hardware. Thus, we seek to usher in a new kind of manufacturing: manufacturing for the design and construction of microbes to spec for customers.

Bioworks1 is the first generation of Ginkgo’s organism engineering foundry. We are currently in the process of building a second foundry—Bioworks2 — which is scheduled for completion in 2016. We have adopted Intel’s chip fabrication facility philosophy; when a new wafer is invented, a new fabrication facility is built as opposed to shutting down and reconfiguring the existing fabs. By allowing the existing fabrication facilities continue to operate Intel increases their total production capacity with each new chip. Bioworks2 will be twice as large as Bioworks1 and will scale and improve upon our existing capabilities. Ginkgo already has plans for Bioworks3 in place. Each new foundry both expands our domestic organism manufacturing capabilities and spurs job creation in a wide variety of professional fields from construction to science.

Current or potential practical applications

Ginkgo is actively working with various governmental and commercial entities on several applications for biotechnology including:

Cultured ingredients: The 2014 global flavors and fragrance market was worth an estimated \$27.5 billion¹ and will continue to grow as more people enter the middle class. The U.S. can capture that market with cultured ingredients. By engineering yeast strains to produce the desired ingredients we can move growth and manufacture processes to the United States. For example, Ginkgo is currently designing yeast to produce a culture rose scent. The introduction of a cultured rose will mark the first new rose oil on the market in 150 years. Cultured ingredients have several advantages over the corresponding plant extract including:

- Lower cost of goods
- Improved product consistency
- Supply stability
- Supply chain transparency
- 'Unlimited' scale
- Remove allergens
- No pesticide residues
- Lower environmental impact
- Creates skilled and non-skilled labor requirements

Probiotics: According to the CDC, "*Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections. Many more people die from other conditions that were complicated by an antibiotic-resistant infection.*"² With DARPA's support, we are developing probiotics to prevent drug resistant bacterial infections in the gut by specifically preventing the acquisition of antibiotic resistance genes in the gut microbiome. This technology allows existing antibiotics to continue to be an effective treatment for infection and does not negatively effect the existing gut microbiome.

Strain improvement: By leveraging the power of Bioworks1, Ginkgo can optimize existing fermentation processes. For example, we have a partnership with Ajinomoto, a global manufacturer of foods, beverages, amino acids, pharmaceuticals and industrial chemicals, to improve their existing fermentation process.

¹ Leffingwell & Associates. 2010 - 2014 Flavor & Fragrance Industry Leaders. http://www.leffingwell.com/top_10.htm. Accessed December 4, 2015

² Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013. <http://www.cdc.gov/drugresistance/threat-report-2013/index.html>. Accessed December 3, 2015

Role of the Federal Government in supporting, coordinating and commercializing the science

The U.S. Government has long had a critical role in nurturing nascent industries long before they are attractive to private investment. Historically, this has often happened via a two pronged strategy in which the U.S. Government initially provides R&D funding for critical, high impact technology development and then, as the technology matures, the U.S. Government serves as an early customer for the resulting products. As a result of this activity and customer demand, private investment begins to flow stimulating the creation of a new industry. This pattern played out in the early days of the microelectronics industry in which the U.S. Government was an early customer for integrated circuits via the Apollo and Minuteman programs.

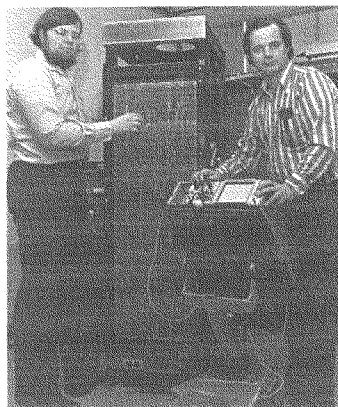


Figure 2: Ginkgo founder Tom Knight (left) standing next to an early computer – a Lisp machine.

The U.S. Government has a similar essential role to play in the future of biotechnology. My co-founders and I were able to bootstrap Ginkgo from scratch on the basis of various federal awards from NSF, DOE ARPA-E, NIST and DARPA. This early U.S. Government R&D funding was critical to allowing us time and resources to refine our foundry approach to designing and fabricating microbes and build our business. Over the past 18 months, we've been able to raise more than \$50 million in private investment as a result. Technology developed with NSF and DOE ARPA-E funding directly led to two of our commercial contracts today.

The National Engineering Biology Research and Development Program proposed under H.R. 591 would coordinate and streamline the Federal Government's ongoing and future R&D support in bioengineering. I thank for Representative Johnson for recognizing this need and introducing H.R.591 as well as Representatives Sensenbrenner and Peters for their co-sponsorship. Bipartisan support of this bill is a clear sign that biological engineering R&D supports the national interest.

Economic, technological or regulatory challenges or barriers to bringing the products to market

Unlike with the microelectronics industry, however, the U.S. Government has thus far not been an early customer for the nascent synthetic biology industry. With countries like the United Kingdom and China having well coordinated national programs in synthetic biology, the United States is at risk for losing its competitive edge in this area. By serving as an early customer and

stimulating demand for the products of biotechnology, the U.S. Government could play as central a role to the biotechnology industry as it has in the past for integrated circuits.

A common concern raised regarding biotechnology is whether there will be public acceptance of these cultured products. We are likely to see a significant shift in the public understanding of these technologies in the near future. The first consumer products of biotechnology are entering the marketplace. North Face has partnered with the Japanese biotechnology firm Spiber to product a winter jacket from cultured spider silk. A new generation of food tech companies are advancing cultured meat and cultured milk as animal-free alternatives. The U.S. Government can help to ensure these cultured products make it to the marketplace and are able to fairly compete with traditional products by encouraging the growth of domestic bio-manufacturing capacity. Expanding U.S.-based fermentation capacity will promote job growth and ensure that the U.S. reclaims its manufacturing competitiveness.

Members of the Subcommittee, on behalf of Ginkgo Bioworks, Inc., I would like to thank you for the opportunity to testify on the future of biotechnology. We believe this technology provides new opportunities to enrich consumer experiences and broadens their purchasing options. This is a very exciting time for biological engineering: it has the potential to reinvigorate American manufacturing and drive economic growth and job creation. I would be happy to answer any questions from the Subcommittee.

Thank you.

Reshma Shetty co-founded synthetic biology Ginkgo Bioworks, Inc. in 2008. Spun out of MIT, Ginkgo's mission is to make biology easier to engineer. Started in a Cambridge, MA apartment, Reshma has helped to grow the company to 50 people and raised \$50M in financing. In Spring 2015, Ginkgo launched Bioworks1, its 18,000 square foot facility for design, fabrication and testing of custom designed microbes. Ginkgo is concurrently engineering more than 20 organisms to spec for customers.

Reshma has been active in the field of synthetic biology for 10+ years and co-organized SBI.0, the first international conference in synthetic biology in 2004. In 2005, Reshma and colleagues founded OpenWetWare.org, a wiki for the free sharing of information among biological and biological engineering researchers. In 2006, she was an advisor to the international Genetically Engineered Machines (iGEM) competition where she was best known for engineering bacteria to smell like bananas and mint. In 2008, Forbes magazine named Reshma one of Eight People Inventing the Future and in 2011, Fast Company named her one of 100 Most Creative People in Business. In 2014, Ginkgo became the first biotech company to participate in YCombinator.

Reshma Shetty has a B.S. degree in Computer Science from the University of Utah and a Ph.D. in Biological Engineering from MIT. As a graduate student, Reshma's research was supported by the National Science Foundation Graduate Research Fellowship, the Whitaker Graduate Fellowship in Biological Engineering and the Andrew and Edna Viterbi Fellowship in Computational Biology. As an undergraduate, Reshma was supported by the Barry M. Goldwater Scholarship, the Beckman Undergraduate Research Fellowship, the Pfizer Undergraduate Research Fellowship and the University of Utah Presidential Scholarship.



Chairwoman COMSTOCK. Thank you.
I now recognize Dr. Dickman for five minutes.

**TESTIMONY OF DR. MARTIN DICKMAN,
DISTINGUISHED PROFESSOR AND DIRECTOR,
INSTITUTE FOR PLANT GENOMICS
AND BIOTECHNOLOGY,
TEXAS A&M UNIVERSITY**

Dr. DICKMAN. Thank you, and good morning, Chairwoman Comstock, Ranking Member Lipinski, and members of the subcommittee. Thank you.

Among other things, I am also the Director of the Norman Borlaug Center at Texas A&M University. I'm a plant pathologist specializing in fungal diseases. But I wanted to use that title as a prelude to just mention Dr. Borlaug, who is largely responsible for the development and implementation of the Green Revolution. And he has been widely acclaimed for this work, including such awards as a Nobel Prize, which is the only agriculturist to be awarded this honor; the U.S. Presidential Medal of Freedom—he's in company with Mother Teresa—U.S. Congressional Gold Medal; and on and on and on.

But what Dr. Borlaug represented besides breeding plants that had desirable attributes was a dogged determination to try to ensure his best possible of feeding people throughout the world. And he's had a modicum of success with that. In fact, one of his other achievements is that he saved a lot of lives, but he has considered to have saved more lives than any other living human being ever.

So the mission of our institute, the Institute of Plant Genomics and Biotechnology in the Borlaug Center, is to foster these ideals and progress using what's available and these developing technologies that we've heard a little bit about already this morning to increase our understanding of how things work in the ag biotechnology space. We want to improve agronomic traits for crop plants, and importantly, we want to prepare young scientists with the necessary technical and conceptual tools to face the inevitable challenges that lie ahead.

As food safety and security concerns continue and are likely to increase, it is clear that a new green revolution is needed. There is increased urbanization limiting land availability, increased water use and energy demands, unpredictable climate changes, coupled with pollution and soil erosion. When taken together collectively, they all contribute to a reduction in yield, and from a grower's point of view, yield is certainly the bottom line. We now face the task of growing more food on the same or even diminishing amounts of land.

So on the remainder of my time this morning I just want to highlight three biotechnological approaches that have varying degrees of risk but all have the potential for really, really high rewards. And again, because of time, I will pick and choose some of the success stories that we in the institute, as well as around the world, have employed to address some of these biotechnological approaches. So the three approaches I'm going to talk about is synthetic biology, which has already been mentioned; the phytobiome;

and genome editing, which you've heard about in the past, and their impact on agriculture and food production.

So in terms of synthetic biology, I'm going to talk about a cotton project that we have been undertaking at—in Texas A&M. Cotton has a very, very high degree of protein in its seed. It's about 25 percent. That's a lot. Therefore, the potential for cottonseed to help feed people is evident. However, the cottonseed also contains immune problems and cause male sterility, thus sort of precluding their application in the real world. So breeders at A&M bred out—very simply bred out that particular compound called gossypol so it was no longer present in the plant and everything looked pretty good. The problem was gossypol is also a defense compound in plants limiting insect and fungal diseases, and when you got rid of gossypol, the plants were basically open game to these pathogens and parasites, and so the operation was a success but the patient died.

So how to explore this was done with some of these new techniques, which I won't get into too much detail unless you're interested, and that is using virus-induced gene silencing and plant—and genomics and synthetic biology work at A&M was able to not only knock the gene out that made gossypol but also direct that construct into the seed tissue itself. These are very nice, powerful, significant techniques. So now, gossypol would be expressed in the plant. However, it would not be expressed only in the seed. Therefore, they were gossypol-free and the seed could be produced, okay?

To give you an idea of the scope of this, and we have sent—several patents filed and many, many field tests that have gone on around the world with these cotton plants is that it is estimated that with the addition of this cottonseed as a protein source, 500 million more people can now be fed. So this is the kind of conclusions we would like to see more of and highlight, but it also illustrates the approaches. There was no way these experiments and these conclusions could have been obtained without biotechnological approaches that were implemented and have been relatively new on the scene.

Now, the other sort of crop example I want to give is bananas. I better hurry up. Bananas, very quickly, are seedless. And I'm not going to go into the details. But if you go to the store and buy a banana, there's no seed. Therefore, genetics and breeding are impossible. Now, bananas are a staple in a number of developing countries, and when they have diseases now, there's no program to study these diseases and solve this problem.

So we have transgenic approaches going on with bananas right now both in Africa and Australia and in the United States that are successfully impacting banana diseases. If the banana diseases are uncontrolled in banana-consuming countries, people starve, people die.

All right. The next topic I'm going to whiz through is the phytobiome. And all I want to point out here is it turns out the microflora, the endophytes, if you will, is a fancy word, and it found in virtually all plants impact a great deal of attributes that enhance the crop in question. So these—the phytobiome will—for example, will enhance drought tolerance, disease control, but only in the areas where they need this to happen.

So in work, for example, done by Dr. Rodriguez, he found in Yellowstone that a certain type of microflora associated with thermal-tolerant plants looked different from microbiome in the ocean, which conferred salt tolerance. So what I'm getting to is the fact that we can utilize phytobiome research to establish these probiotic microorganisms, and plants will make the necessary changes to control the stress that they are faced with. This is a new, high-risk, but very user-friendly control mechanism.

The last part is involving CRISPR, which I know you've already heard about. So all I'm going to say about CRISPR, which doesn't have the same implications as the human application, CRISPR in plants has two major advances that are very exciting to the plant community. One is multi-plexing and the ability to put numerous genes—numerous gene mutations in one genetic background, and the other is breeding. CRISPR is likely to revolutionize breeding. Breeding is a game of creating variation in plants and then going through all the characterization that needs to be done to understand the nature of that variation. Well, with CRISPR, you can make—you can make unlimited genetic variation by using this tool, thus obviating the need for chemicals and all the considerable work and time and effort that need to be done.

So I will just come to my conclusions and just say that I want to remind everyone that all food that's consumed is genetically modified. We need a new green revolution to face the coming needs and continuing needs of people throughout the world, and we need to support basic research to make the conclusions verified. In other words, many of the great discoveries are only done by unintended consequences, penicillin being a good example, which you could call him sloppy microbiologist. He found contamination that was inhibiting bacteria, and really that's the key. And the other one is CRISPR, which is really a study of immune issues in a bacterium led to the CRISPR technology that we discussed in quite a bit of detail here and in previous meetings of this group.

Thank you.

[The prepared statement of Dr. Dickman follows:]

**U.S. House of Representatives Committee on Science, Space and Technology
Subcommittee on Research and Technology**

The Future of Biotechnology: Solutions for Energy, Agriculture, and Manufacturing

Testimony of Dr. Martin Dickman

Texas A&M University

Tuesday, December 8, 2015

Thank you. Good morning Chairwoman Comstock, Ranking Member Lipinski, and members of the subcommittee; I appreciate the opportunity to testify here today and discuss emerging biotechnologies and applications in Agriculture.

My name is Marty Dickman. I am a University Distinguished Professor of Plant Pathology at Texas A&M University and the Christine Richardson Professor in Agriculture. I also serve as the Director of the Institute for Plant Genomics and Biotechnology (IPGB) in the Norman Borlaug Center at Texas A&M University. Dr. Borlaug and several colleagues were largely responsible in developing the “Green Revolution” of improving crops and importantly crop yields in the poorest of developing countries. Dr. Borlaug has been widely acclaimed for these efforts most notably through awards such as the Nobel Peace Prize, (the only agriculturist to be awarded this honor) U.S. Presidential Medal of Freedom and the U.S. Congressional Gold Medal. Dr. Borlaug’s approach was straightforward but intense: the use of scientifically rigorous breeding approaches to address and solve some of the most pressing food security issues of our time. He saved millions of lives; in fact he is known to have saved more lives than anyone in history.

We continue these efforts through the mission of the Borlaug Center which centers on a balance between fundamental and applied research. The mission of the IPGB is to develop plant biotechnology, genomics, and related life science technologies and to foster technology utilization and crop improvement through multidisciplinary research activities with model plant

systems, field crops and horticultural plants. These are achieved by implementing modern and available technologies to increase our understanding of basic and applied (translational) issues in the Agricultural Biotechnology space, improve agronomic traits for crop plants and prepare young scientists with the necessary technical and conceptual tools to face the inevitable challenges that lie ahead.

As food safety and food security concerns continue and are likely to increase; it is clear a new Green Revolution is needed. The issues we face in developing such a new revolution now differ. There is increased urbanization which limits land availability, increased water use and energy demands, unpredictable climate changes coupled with pollution and soil erosion, and when taken together, collectively, all contribute to reduction in yield. We now face the task of growing more food on the same or even diminishing amounts of land.

In the remainder of my time, I will focus on three biotechnology approaches – (i) Synthetic Biology, (ii) the Phytobiome and (iii) Genome Editing -- and their impact with respect to agriculture and food production. I will highlight for illustration, some of the exciting work at our Institute [and other units] that are in progress to address these crucial food safety and food security concerns.

I. SYNTHETIC BIOLOGY

The early 1970s ushered in a new paradigm for biological research--molecular biology. This change totally transformed the landscape of life science research, bringing with it a revolution in biotechnology. There is now a new paradigm, synthetic biology, which may be just as transformative for biological research as molecular biology. This is an exciting time for life science research.

Synthetic biology refers to the integration of molecular tools, engineering principles, and mathematical modeling to engineer organisms toward previously unattainable functions. This

multidisciplinary discipline often requires integration of life sciences with engineering and modeling. Synthetic biology is still in its infancy of development, yet already has provided breakthroughs in crop production and in a wide array of other fields, including therapeutics, energy production and environmental remediation. Plants are being used to develop and commercialize novel and important products. For example, vaccines made against the anthrax toxin are being synthesized in plant “factories” grown hydroponically (which offers several advantages) using synthetic biology approaches to maximize production and purity. Similarly, plants are being used to synthesize artemisinin, an antibiotic/antimalarial toxin that is difficult to synthesize in sufficient quantity; again by application of synthetic biology. These approaches were built on several core research areas including genetic circuits design, metabolic engineering, high-throughput screening, and synthetic genome construction.

A synthetic biology design often depends on or integrates with the systems biology studies, and in some respects, synthetic biology is an extension of systems biology, which is the study of biological systems with the goal of moving beyond strictly observational studies to a new predictive view of biological systems. Systems biology is enabled by modern genomic tools, as well as computational resources, that allow high throughput analysis of the various components of the whole organism. During the past decade, synthetic and systems biology has delivered tremendous progress in crop improvement and other agricultural applications (see banana and cotton examples below) that are entirely dependent on biotechnological applications for success.

Cotton/Gossypol

Cottonseed has the potential to provide a protein to the world, especially for poor nations, but it contains gossypol, with major health issues such as male sterility and immune disorders. At Texas A&M, we were successful in developing a cotton plant where the seed did not contain gossypol but other issues of plant health arose. However, with the tools of synthetic biology and molecular biotechnology, we can address the plant health challenge and the outlook is a major inexpensive source of protein for the future population.

Cotton is a major crop grown in the state of Texas. It is well established that cotton seed is an excellent and abundant source of protein; nearly 25% of the seed dry weight. It is also known that gossypol, a common component of cotton seed and a plant defense compound has several characteristics making the seed unfit as food for human consumption or even as feed for non-ruminant animals for human consumption. Thus the application of cotton seed protein for food and feed is not viable. However there were potential alternatives to capture this rich protein source, including conventional breeding. Why not perform crosses and screen for cotton that is gossypol free? This is very doable from a breeding perspective, and in fact was successfully done and the resulting plants were shown to be gossypol free; but these plants were also extremely susceptible to fungi and insects and while gossypol free, entire fields were lost! This was a costly lesson to show that gossypol confers protection from insect parasites and fungal pathogens. But is there an alternative strategy? This is where the power of biotechnology provides recourse.

(This following work was done by Dr. Keerti Rathore and colleagues in the Borlaug Center). Briefly, the biochemical pathway for gossypol biosynthesis in plants is known. Employing a synthetic biology approach, Rathore used a regulatory element that directed genes specifically to the seed ("tissue specific"). When this element was coupled to the enzyme making gossypol and turned off by Virus Induced Gene Silencing (VIGS), the enzyme was inactivated but only in the seed, thus yielding gossypol free cottonseed. The rest of the cotton plant still made gossypol and thus was protected from pathogens. Importantly, yields were maintained. These transgenic plants are thus gossypol free in the seed and the rest of the cotton plant synthesizes normal levels of gossypol and is protected from biotic stress. Gossypol levels in these plants are well below FDA recommendations and several patents have been issued. Thus, the potential of cottonseed in contributing to the nutrition requirements of the burgeoning world population may be realized. Thus, in this particular example, this research is impossible without the availability of the new biotechnology tools, which were the only alternative.

Banana

The work to be summarized was part of a joint collaboration between Dr. Marty Dickman (IPGB-Borlaug Center-Texas A&M) and Professor James Dale (Queensland Institute of Technology in Australia).

Banana is grown throughout the tropical and subtropical regions of the world and is a key staple food in many developing countries, as well as a source of income for subsistence farmers. Diseases are major constraints wherever banana is produced. The vast majority of edible bananas grown today are selections that have not undergone improvement through conventional breeding due to the important and key fact: they are essentially **sterile** and thus an effective breeding/genetic program is not a viable option. Thus, a “molecular breeding” approach is widely considered the most promising strategy to generate disease resistance and stress tolerance in this crop, almost by default.

Diseases reduce yields by debilitating plants and reduce the quality of fruit before and after harvest. Diseases range from esthetic problems that lower the marketability of the harvested product to lethal constraints that devastate local or regional production. Disease is the key reasons that banana-breeding programs have been created worldwide. The major diseases of banana are due to fungi; in particular fungi that secrete toxic metabolites. The Dickman lab studies cell death and has identified genes that are cytoprotective (anti-death). This was done using bioinformatics and was based on structural predictions that would not have been noticed by conventional screens. As a result we can modulate cell death transgenically and have shown that if we can prevent cell death (as in this case), the pathogen is unable to kill host plants and acquire nutrients; these fungal pathogens eventually die of starvation and the plant is protected. We have performed molecular breeding directed field studies in Australia where bananas are grown commercially and have selected several promising lines.

Bananas also illustrate a common scenario in modern agriculture with respect to plant diseases; the so-called “Arms race.” When large acreages of genetically uniform disease resistant plants

are grown, selective pressure often results in the pathogen adapting and overcoming the formerly resistant plant. Breeders then come in and breed against these new strains, and an arms race is on as has occurred throughout history. This has occurred in banana as well as wheat. This new fungal (killer) strain is very aggressive, is spreading and there is no genetic resistance. Growers are concerned and rightfully so. In the past, these diseases have led to starvation and even death in developing countries. We are currently testing our lines against this strain (race), and we are cautiously optimistic these transgenic plants will provide resistance.

The Dale lab is also involved with bio-fortification in banana by transgenically increasing carotenoid (Vitamin A) levels in banana in an analogous situation to the Golden Rice situation. Deficiency of Vitamin A causes blindness in young children. According to the World Health Organization, dietary vitamin A deficiency (VAD) compromises the immune systems of approximately 40 percent of children under the age of five in the developing world, greatly increasing the risk of severe illnesses from common childhood infections, and causing hundreds of thousands of unnecessary deaths among them. The Dale lab has been remarkably successful in generating banana with biologically relevant levels of Vitamin A; tests for human consumption and allergens of banana are in progress.

II. PHYTOBIOME

The plant microbiome (“Phytobiome”) is a relatively new field of study with intriguing potential applications that are in the early stages of development. The phytobiome is analogous to probiotic studies in humans (e.g. gut microbiome). The plant microbiome is an assemblage of microbes living in, on and around plants. These biomes function as a community of microorganisms with predictable compositions and are partners for life. Importantly microbial endophytes (resident internal microflora) involved with agricultural plant hosts have recently been shown to confer or are correlated with enhanced and in some cases remarkable positive agronomic traits (e.g., drought tolerance, disease resistance and others). Phytobiomes can influence or be influenced by plants or the plant environment. Key questions include:

- 1) Can these relationships be tapped to improve crop health, safety, quality and productivity?
- 2) Can we develop microbes that reduce effects of drought, flood, and salinity, or develop microbes to enhance root growth hormonally – more and deeper roots! This is an opportune time for these studies as robust tools are now available (especially sequencing, “omics” and various computational approaches). We can address a number of questions previously unable to be asked about microbes in the environment—including who, how, what and why with tremendous precision, impact and accuracy often with unexpected results. Remember >99% of the soil meta-genome is completely uncharacterized and in most cases cannot be grown without a plant host. Lots of untapped resources and commercial opportunities exist in this realm of research.
- 3) Can we breed plants that select for a beneficial microbiome? (e.g., disease is associated with shifts in microbiome composition.) Such shifts can be diagnostic for disease. (e.g., take all of wheat and suppressive soils). Microbes have been shown to reduce effects of drought, flood, and salinity. Microbes form biofilms, reducing ion movement into the plant. More work is needed to establish the relevant underlying mechanisms.
- 4) Do plants control their microbiome composition? It appears they do, based on research conducted by Dr. R. Rodriguez. Dr. Rodriguez initiated his work in Yellowstone Park, surveying and characterizing thermotolerant plants. He discovered that all heat tolerant plants that were studied had a specific, consistent associated fungus in the roots. Sensitive, non thermotolerant plants did not. Thus, thermotolerance correlated with the presence of the fungus. Similarly, his research in Seattle looked at plants growing in salt water, on the beach and on a hill overlooking the beach, and again he identified fungi that conferred the “proper” stress tolerance. Finally, in Oklahoma, during a melon study, he identified fungi that conferred disease resistance in melons.

III. GENOME EDITING (CRISPR/Cas9)

Briefly, genome engineering involves generating targeted alterations to the genome of an organism or cell. This can result in deletion insertions or modification. Targeted genome editing has recently exploded with significant experimental potential and power in both model and crop plants. As several limitations have been overcome, ease of use and affordability has occurred. The recent advances in several genome editing technologies, including the ability to specifically customize these engineered nucleases, particularly, the emergence of the CRISPR/Cas system (Clustered Regularly Interspersed Short Palindromic Repeats) has fueled considerable interest in the genetics plant improvement as well as in the biomedical arena. With particular emphasis on plants; two important advances include multi-plexing (addition of several genes in one experiment), and breeding. Breeders now have a powerful, high throughput tool to generate variation; the cornerstone of breeding. These features are likely to change the face of contemporary breeding approaches.

This remarkable (“Game changing”) technology now provides the ability to customize and generate informed genetic modifications for **any** number of plant phenotypes. Plants are in the early stages of this technology with the bulk of the work thus far involving proof of concept and establishing experimental parameters. The clear potential awaits rigorous testing, the promise and potential are formidable all of which is likely the tip of the iceberg.

Conclusions

In closing, I want to reiterate that a new Green Revolution is necessary to meet the challenges that lie ahead. As the population increases, resource constraints increase, and climate becomes less predictable, the need for more food continues to rise. We must take advantage of all the tools available to address this need. Significant discoveries/paradigm shifts are often unexpected or unintended (e.g., penicillin, CRISPR) and support for fundamental research support is critically important to create opportunities for these discoveries and to provide new tools to address these problems. Research allows us to understand the mechanisms, how the technology works, and to optimize, improve, and commercialize new technologies. To commercialize an

agricultural product require lots of time and lots of resources. These traits are often outside the comfort zone of a professor, and private companies are often far better equipped for high throughput scaling up. User friendly commercialization procedures could encourage increased development of commercial potential.

This is an exciting time for life sciences research.

Biographical Paragraph

Dr. Martin B. Dickman
Ph.D 1986, University of Hawaii
Joined Texas A&M, December 2005
Specialty: Plant-Microbe Interactions, Programmed Cell Death, Comparative Pathobiology, Biotechnology

Dr. Dickman is an internationally recognized and distinguished scientist specializing in the genetics and molecular biology of fungi and fungal-plant interactions. Dr. Dickman's primary emphasis is on programmed cell death regulation and the extent to which parallels exist between plant and animal systems. Dr. Dickman established that parallels exist between plant and animal systems diseases and infection strategies, and he developed the concept that cell death can be beneficial or helpful for a pathogen depending on context and pathogen lifestyle. Another widely held perception at this time was plants were incapable of PCD. Dr. Dickman's work conclusively demonstrated that plants do in fact broadly exploit PCD as a key component of their development, immunity and stress responses.

Dr. Dickman founded the field of comparative pathobiology and demonstrated that PCD is broadly conserved across phylogenetic kingdoms. Going against the current dogma he not only showed that genes that negatively regulate PCD in animals can be expressed in plants but remarkably such mammalian genes were fully functional in plants. These observations were game changing as previous studies between plants and animals indicated that plants lack DNA sequences encoding hallmark PCD genes. Dr. Dickman showed that these genes were similar at the structural level level Thus, predicted protein structure, independent of nucleotide or amino acid sequence, was needed to accurately predict biological function. Using this approach, his group identified the plant BAG gene family some members of which are being deployed in crop plants in Texas and around the world.

Dr. Dickman received the Distinguished Alumni Award from the University of Hawaii and the University of Nebraska Institute of Agriculture and Natural Resources Junior Faculty Recognition for Excellence in Research Award. At the University of Nebraska he was named the Charles Bessey Professor. At TAMU, he is currently the Christine Richardson Professor of Agriculture.

In 1993, Dr. Dickman was elected as a Fellow in the American Phytopathological Society. His work was described as "among the most thorough and significant contributions in plant pathology." In 2011 he was elected Fellow in the American Association for the Advancement of Science (AAAS). The AAAS is the world's largest general scientific

society. The award, cited Dr. Dickman's "excellence in research in the genetics and molecular biology of fungal-plant interactions." This past year, he was awarded Fellow of the American Academy of Microbiology (ASM) in recognition for "excellence, originality, and creativity in the microbiological sciences."

In 2011 he received the prestigious EC Stakman Award. Nobel prize winner Norman Borlaug was Dr. Stakman's first student and the first recipient of this award. I received this award for "Distinguished and exceptional contributions to plant-fungal interactions...for pioneering research in programmed cell death and for elucidating common mechanisms in pathogen infection and host responses...for creating a contagious excitement for science. Professor Dickman's dedication to scientific excellence and exceptional use of innovative approaches for advancing plant health embody the qualities and spirit of the Stakman award." In 2015, he was named University Distinguished Professor at Texas A&M.

Chairwoman COMSTOCK. Great. Thank you, Dr. Dickman. And I know we did go over our time, but you're educating us, and so I figured it's better for you to take up that time probably than some of us. So thank you, and we appreciate your enthusiasm, all of you. I now recognize Dr. Serber.

**TESTIMONY OF DR. ZACH SERBER,
CO-FOUNDER, CSO, AND VICE PRESIDENT
OF DEVELOPMENT, ZYMERGEN**

Dr. SERBER. Good morning. Thank you, Chairwoman Comstock, Ranking Member Lipinski, and the rest of the Committee, for the opportunity to testify today on a topic that I've devoted my career to expanding the impact of advanced biotechnology.

A decade ago I was one of hundreds if not thousands of early career scientists and engineers who left academia to devote our human capital to extending the reach of biotechnology. Whereas biotechnology is synonymous for many people with the field dedicated to medical therapeutics, biotechnology also has the potential to transform other fields, including energy, agriculture, and manufacturing. The prospect of vastly expanding the societal and economic impact of our technical expertise attracted me and many other scientists, including Dr. Shetty, to new endeavors focused on realizing these potential far-reaching applications.

Single-celled organisms—microbes—are the most versatile chemical factories on the planet. Dr. Shetty has already explained how engineering microbes can be used as microscopic biofactories. This is the basis for what has been dubbed the new bioeconomy in which companies increasingly rely on biology to source the materials used in their products.

This is, however, not a new manufacturing paradigm. Today, chemicals made via large-scale fermentation are employed in a wide variety of agricultural and industrial applications, and, excluding ethanol, comprise over \$66 billion in revenue globally, or roughly ten percent as much as petrochemicals. While a relatively small percentage, the rate of growth of chemicals made biologically is greater than ten percent annually, whereas the petrochemical market is growing at less than seven percent. In time, chemicals made via fermentation may come to dominate the overall chemicals market.

My company, Zymergen, was founded recently in 2013 to contribute to this expanding market. Our core business is to use biotechnology to rapidly and reliably engineer microbes used in the manufacturing of chemicals for a variety of applications. Zymergen is under contract with Fortune 500 companies to improve the manufacturing economics of chemicals they currently make in large-scale fermentation by engineering the single-celled biofactories they already use.

Our ability to realize this incredible potential relies not only on scientists and engineers but also on government policy that supports this type of research and innovation. Having interacted with dozens of large domestic producers of goods made through fermentation, I should mention that Zymergen fully supports the July 2 White House memorandum on modernizing the regulatory system for biotechnology products, which directs the relevant federal

agencies to develop a long-term strategy to ensure that the biotechnological regulatory system is prepared for the rapidly changing future of our industry.

I can confidently say that the current regulatory system is full of inconsistencies and scientifically unsound characterizations. This regulatory system has not kept up with changes in the technology, creating confusion, delays, and inefficiencies. It is our hope that the EPA, FDA, and USDA can efficiently and rapidly update the coordinated framework.

Two-and-a-half years ago, Zymergen had three founders. Today, we have 93 employees. Growth has not slowed and we are on pace to more than double in staff size in 2016. This rapid growth is not based on speculation. Quite the contrary, our challenge to date has been excessive market demand. We are working day and night to keep up. Our customers are large, established manufacturers of chemicals made through fermentation. As they seek to reduce costs and increase manufacturing productivity and competitiveness, they see Zymergen and our technology as essential to maintaining competitiveness.

Zymergen depends on cross-disciplinary research. Our engineers and scientists are trained in fields including microbiology, genetic engineering, robotics, chemical engineering, and machine learning. Our most valuable employees are rare individuals with expertise in multiple relevant domains, able to bridge the gaps between, for example, genome editing and software engineering. Federally supported educational and training programs are critical to providing us with the staff we need to grow and fulfill our potential.

Recent activities in our space supported both through public and private sector investment have dramatically altered what is now possible through biotechnology. So while Zymergen has initially devoted our insights to improving the economics of existing products, the approaches developed enable us also to expand the palliative chemicals that can be made through biology. This amounts to a technological revolution likely as important to advancing societal well-being, national security, and economic productivity and competitiveness as the invention of the transistor or the invention of heavier-than-air flight.

In keeping with this promise, we recently contracted with the DARPA's new Biological Technologies Office under their Living Foundries: 1000 Molecules program. This program is developing new capabilities that will enable biomanufacturing of known or novel chemicals on demand and at scale. As few as three years ago, entire companies in this arena were founded to develop a single chemical product. With the support of DARPA, we at Zymergen are pushing the technology to develop new biosynthetic pathways for over 300 specific chemicals of interest. We are targeting an overall 20-fold cost reduction in new product development.

Further, our team of biologists, engineers, and material scientists are choosing these chemicals to form the basis for new materials. These materials are expected to have novel properties in categories as wide-ranging as thermal stable plastics, marine adhesives, and antiseptic battlefield dressings.

While the potential application of each new material generates considerable interest, what excites me and my colleagues at

Zymergen most is the creation of a cutting-edge technological platform designed to accelerate innovation in new materials, an area where innovation has slowed, and importantly, an area historically completely unrelated to biotechnology. This is but an example of the myriad ways biotechnology can impact the U.S. economy and improve society. I am pleased this hearing presents an opportunity to engage in dialogue about ways we can work together to realize the potential of this industry.

Thank you.

[The prepared statement of Dr. Serber follows:]

Subcommittee on Research and Technology Hearing - The Future of Biotechnology: Solutions for Energy,
Agriculture and Manufacturing

Tuesday, December 8, 2015 - 10:00am

2318 Rayburn House Office Building

Dr. Zach Serber, Zymergen

Testimony

Good morning. Thank you Chairwoman Comstock, Ranking Member Lipinski, and the rest of the Committee for the opportunity to testify on a topic that I have devoted my career to: expanding the impact of advanced biotechnology.

A decade ago I was one of hundreds if not thousands of early-career scientists and engineers who left academia to devote our human capital to extending the reach of biotechnology. Whereas the term 'biotechnology' is synonymous for many people with the field dedicated to medical therapeutics, biotechnology also has the potential to transform other fields including energy, agriculture, and manufacturing. The prospect of vastly expanding the societal and economic impact of our technical expertise attracted me and many other scientists to new endeavors focused on realizing these potential – and far-reaching – applications.

Single-celled organisms—microbes—are the most versatile chemical factories on the planet. When they consume carbon (often some form of sugar), their normal metabolic processes convert that carbon into a wholly different product. Which is to say that if we are able to reliably program these microbes, we can essentially use them as microscopic "biofactories" that churn out valuable raw materials. This is the basis for what's been dubbed the "New Bioeconomy," in which companies increasingly rely on biology to source the materials used in their products.

This bioconversion process is traditionally called fermentation. You know it as the process that gives us beer and wine, but ethanol is just one of many products generated through fermentation. Today, chemicals made via large-scale fermentation are employed in a wide variety of agricultural and industrial applications and, excluding ethanol, comprise over \$66B in revenue globally [1], or roughly ten percent as much as petrochemicals [2]. While a relatively small percentage, the rate of growth of chemicals made biologically is greater than ten percent annually [1] whereas the petrochemical market is growing at less than seven percent [2]. The difference in the rates is also growing. In time, chemicals made via fermentation may come to dominate the overall chemicals market.

My company, Zymergen, was founded in 2013 to contribute to this expanding market. Our core business is to use biotechnology to rapidly and reliably engineer microbes used in the manufacture of chemicals for a variety of applications. Zymergen is under contract with Fortune 500 companies to improve the manufacturing economics of chemicals they currently make in large-scale fermentation by engineering the single-celled "biofactories" they already use.

Our ability to realize this incredible potential relies not only on our scientists and engineers, but also on government policy that supports this type of research and innovation. Having interacted with dozens of large domestic producers of goods through fermentation, I should mention that Zymergen fully supports the July 2nd White House Memorandum on Modernizing the Regulatory System for Biotechnology Products, which directs the relevant federal agencies to develop a long-term strategy to ensure that the biotechnology regulatory system is prepared for the rapidly-changing future of our industry [3]. I can confidently say that the current regulatory system is full of inconsistency and scientifically unsound categorizations. The regulatory systems have not kept up with changes in the technology, creating business-sapping confusion, delays, and inefficiencies. It is our hope that the EPA, FDA, and USDA can effectively and rapidly update the Coordinate Framework.

Additionally, I'm pleased to see that Congress is considering the ways the Federal government can proactively support biotech research through H.R. 591, introduced by Congresswoman Johnson and Congressman Sensenbrenner. Bills like H.R. 591, the Engineering Biology Research and Development Act of 2015, help facilitate a comprehensive strategy to ensure the United States remains globally competitive in biotechnology as it shapes nearly every industry of our economy.

Two and a half years ago Zymergen had just three founders. Today we have 93 employees. Growth has not slowed and we are on pace to more than double in staff size in 2016. This rapid growth is not based on speculation. Quite the contrary, our challenge to date has been excessive market demand; we are working day and night to keep up. Our customers are large, established manufacturers of chemicals made through fermentation. As they seek to reduce costs and increase manufacturing productivity, they see Zymergen and our technology as essential to maintaining competitiveness.

Zymergen depends on cross-disciplinary research; our engineers and scientists are trained in fields including microbiology, genetic engineering, robotics, chemical engineering, and machine learning. Our most valuable employees are rare individuals with expertise in multiple relevant domains, able to bridge the gaps between, for example, genome editing and software engineering. Federally supported educational and training programs are critical to providing us with the staff we need to grow and fulfill our potential.

Recent activity in our space, supported through both public and private sector investment, has dramatically altered what is now possible through biotechnology. So while Zymergen has initially devoted our insights to improving the economics of existing products, the approaches developed enable us also to expand the palette of chemicals that can be made through biology. This amounts to a technological revolution likely as important to advancing societal well-being, national security, and economic productivity and competitiveness as the invention of the transistor or the invention of heavier-than-air flight.

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novel properties in categories as wide ranging as thermostable plastics, underwater adhesives, and antiseptic battlefield dressings.

While the potential application of each new material generates considerable interest, what excites me and my colleagues at Zymergen most is the creation of a cutting-edge technological platform designed to accelerate innovation in new materials development, an area where innovation has slowed and, importantly, an area historically unrelated to biotechnology. This is but an example of the myriad ways biotechnology can impact the US economy and improve society. I'm pleased that this hearing presents an opportunity to engage in dialogue about the ways we can work together to realize the potential of this industry.

Thank you.

References:

[1] Carlson, R. Bioeconomy Capital LLC; Biodesic LLC. [Estimating the Contribution of Biotechnology to the Economy of the United States](#). [DRAFT]. October, 2015.

[2] Transparency Market Research. [Petrochemicals Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2014 – 2020](#). July, 2015.

[3] Executive Office of the President. Office of Science and Technology Policy, Office of Management and Budget, United States Trade Representative, and Council on Environmental Quality. [Modernizing the Regulatory System for Biotechnology Products](#). July 2, 2015. Retrieved December, 6 2015, from https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_bio_tech_products_memo_final.pdf

Zach Serber is a scientist and entrepreneur devoted to finding alternatives to petroleum. He recently co-founded Zymergen to expand the impact and reach of industrial microbial fermentation. Zymergen applies radical new methods to design and improve microbes by rewriting their DNA. This capability allows the company to generate novel chemicals and advanced materials far faster, at lower costs, and with less risk than ever before. Dr. Serber was previously the Director of Biology at Amyris where he worked on manufacturing bio-derived transportation fuels, on lowering the cost of the anti-malarial drug Artemisinin, and on developing advanced tools for engineering biology. Dr. Serber has 17 peer-reviewed publications, six filed patents, and has worked as a research fellow at Stanford University Medical School. He has a PhD in Biophysics from UCSF, an MSc in Neuroscience from the University of Edinburgh, and a BA from Columbia University.

Chairwoman COMSTOCK. I thank the witnesses for their testimony. Now, I recognize myself for questions for five minutes.

Dr. Shetty, you've testified that one of the potential barriers to biomanufacturing is public acceptance of these products and sometimes concerns that come up. Can you discuss that a little, both the concerns and how to address them? And I really would invite all of you—I think you've all addressed that a little bit—but how we can best proceed in this and address some of the more alarming reactions in an informed and scientific way.

Dr. SHETTY. Absolutely. Thank you for the question, Chairwoman Comstock.

It's interesting. To date, biotechnology has largely been behind the scenes, right? The—people are not always aware that the foods they eat, the medicines they take are made with the products of biotechnology. However, I think we're seeing a shift. As the technologies are improving, more and more consumer-facing products are coming out onto the marketplace. So Ginkgo's cultured rose is an example. I also alluded to others in my testimony, so animal-free versions of milk, of meat, and, you know, there are companies making spider silk using yeast and spinning that into jackets. So a Japanese company named Spiber is partnering with North Face to bring out a spider silk jacket that's currently touring Japan.

So I think what you're going to see over the next few years is that biotechnology is going to be interacting more and more directly with the consumer, and this is going to change a—drive a shift in attitudes naturally. And with that shift in attitudes, you're going to see a greater public acceptance of this—of these kind of technologies.

That being said, we continue to have a responsibility to ensure transparency in our sector. So, you know, there are obviously a lot of concerns around, you know, what does a supply chain look like for the products I buy? Should I be seeing certain labels on my foods or in my—the products I buy?

I think really a lot of those conversations really stem from a desire for information, a desire for knowledge. And what I'm excited about actually is that through biotechnology we can actually increase the transparency of our supply chains. If my yeast are growing these products in a fermenter in the middle of Iowa, it's a lot easier for me to understand where exactly my—the products I'm buying at the grocery store come from.

And so, in short, I would suggest that were seeing a transformation happen. As the tools get better and better, more and more consumer-facing products are going to be coming out onto the market and drive a change in attitudes.

Dr. DICKMAN. If I could just chime in quickly—

Chairwoman COMSTOCK. Yes.

Dr. DICKMAN. —to be the devil's advocate, I think in the past—and I agree with much of what you said, Dr. Shetty—I would argue that academic scientists who are unfamiliar with have—we have not done a great job in communicating to the public what it is we do and why it is so vitally important. I think that's changing now, but the—a lot of what you see in the newspapers are sort of peer-based sort of newsworthy items. You never hear about the success stories that are also going on and actually in much more abun-

dance. So I think we just need to be sensitive to the public to a large part being uninformed properly to what it is we do. And we're all—myself, as well as companies, until recently have not really dealt with that. In my view, we can do a better job of showing the great things that this powerful set of technologies can in fact do.

Chairwoman COMSTOCK. Okay. Okay. Well, thank you very much. And I will now yield to Mr. Lipinski for five minutes.

Mr. LIPINSKI. Thank you. It's been really very interesting, and I've learned a lot here, although I still can't say I exactly know what you're doing.

But I want to throw this more general question out there and have everyone tell me what you think can be done because I know that Dr. Shetty had talked about U.K. and China have work—well-coordinated national programs in synthetic biology. So I want to start with Dr. Shetty. And you talked a little bit about this, but what do you think along those same lines that we should be doing? The big thing here is you're here to tell us what we can do to be helpful in moving things forward and we have the best benefits for our society here. So, Dr. Shetty, what would you—anything else you would recommend? I know you talked about quite a few things.

Dr. SHETTY. Yes, so I think one of the things we need to appreciate is that biotechnology today is not just about health and medicine, right? And I think this hearing is testimony to that. Biotechnology in the future is going to have major impacts in many other areas besides health and medicine, including, you know, manufacturing, agriculture, and energy. So I think what needs to happen is that there needs to be a national recognition of that importance, and we need to push forward a more organized national funding program in this area. And so H.R. 591 is a step in this direction, and I would encourage you to garner bipartisan support for this bill and push it forward.

Mr. LIPINSKI. Thank you. Dr. Serber, do you have anything? So what are other countries doing? You know, what can we do that we're not doing?

Mr. SERBER. A couple of things come to mind. So amongst them is a coordinated roadmap. The efforts in the United States are fragmented. The support for this growing industry doesn't have a clear home base for lobbying, for support, for garnering the kind of widespread development of the tools that we're going to require to push forward the sector.

I mentioned a couple of times that we're receiving DARPA support, and I believe that today in the field of synthetic biology DARPA has far and away provided more support than any other federal agency for this enterprise. I think it amounts to roughly 60 percent of the dollars spent by the federal government in 2015 to this new field.

DARPA's a very small agency, and they can't go it alone, and their focus is on creating a preventing strategic surprise. So their application space is understandably focused. I'm looking forward to other agencies using that as inspiration to build support base, funding for additional research both in academia and translational research. I'm looking for educational programs to help give the cross-disciplinary familiarity because to succeed in this field requires expertise not in the silos of biology or chemistry or physics

or computer science, but rather cross-trained individuals who are equally versed in aspects of all of the above to really push the field forward.

Mr. LIPINSKI. Thank you. Anyone else wants to go? Dr. Evans?

Dr. EVANS. So I think one of the things that you can see looking over the history of this technology space, the United States, through some very aggressive, risky, early technology investments, pioneered the field. I think when people are rewriting—or writing the history looking back from 100 years or so, they will see that these early federal efforts pioneered the field nationally and led globally with the idea that engineering biology could become that next revolution on the scale of technology development along the first Industrial Revolution.

However, as Dr. Serber was showing, there isn't now in the United States a coordinated framework of either the research or of how it can be effectively moved into market acceptance. And so when you look at some of the things that the other countries are doing, they are attempting to make sure that industry and academics are being pushed together to an extent. So the centers that are being funded particularly in the U.K. require some joint industry, government, and academic input. And I continue to point to Synberc as a very good example of that domestically.

But all of this will have the same challenge that the U.S. biotechnology industry had in the mid-1980s when we were trying to apply genetic engineering techniques to recombinant bacteria for release into the environment for bioremediation and other things that are going to be logical outcomes of all of the biome research. So we're going to have paper after paper that says wouldn't this be cool or important if we could do this in engineering a phytobiome? But there's not going to be a regulatory path to get an engineered prokaryotic organism out into the environment because we just haven't dealt with those questions. They were brought up, stopped, and dropped.

And so coordinating that kind of federal research that helps build extramural research centers that might be needed to deal with questions around release will be very important to realize the broad application of some of the engineering technologies that require deliberate release outside of contained fermentation.

Mr. LIPINSKI. Thank you. And I'm over time here so I'm going to—I think I'm going to have to yield back. Thank you.

Chairwoman COMSTOCK. Great. Thank you. And I now recognize Mr. Moolenaar for five minutes.

Mr. MOOLENAAR. Thank you, Madam Chair, and I want to thank all of you for being with us here today and for your testimony.

And I wanted to follow up on some of the things that have been discussed. One is in the area of coordinated research you mentioned, both long-term research, you know, market acceptance, coordinated roadmaps, strategic plan. It seems like those themes keep coming up. And then there's also the coordinated framework for the regulation of biotechnology that hasn't been updated since 1992. And I'm assuming the memo—the White House memo was instructing that that would be updated. Is that correct?

Who—I've heard different agencies mentioned, the EPA, USDA, FDA. Who is the point on that? Is there one agency that the convener in that? Dr. Maxon?

Ms. MAXON. The Office of Science and Technology Policy is working with all three agencies because all three agencies regulate products that are biotechnology products. One of the challenges I think my colleagues have referred to is there are bio-innovations that straddle agencies, that seem to belong partly in the domain of the USDA and partly in the domain of the FDA, and the EPA for that matter. There are examples where all three agencies might be involved.

So I think what's really promising about this is there will be an opportunity to not only update but also to clarify the roles of the agency. Who is the lead agency when a company wants to have discussions? So all three and the Office of Science and Technology Policy are working together.

Mr. MOOLENAAR. And are you all giving input to that process? Do you feel like you're at the table discussing that with them?

Dr. MAXON. I know there was a recent request for information. Several companies did submit information. There will be another chance. A couple of more—I think there are two more public meetings scheduled. The first one was held on September 30, I believe, at the FDA. There'll be two other meetings scheduled around the country starting in January, I believe. There'll be plenty of opportunity.

Mr. MOOLENAAR. Okay. And then what's the timing on—would it be a new rule, a new regulation, a framework that comes out and then there'd be a public comment period after that framework comes out?

Dr. MAXON. I can't speak to the definite product of the expected products. I do know that in addition to the work at the agencies, their will—around the coordinated framework itself, there will be—there's an expectation, as outlined in the memo, for a long-term strategic plan to be delivered in a fairly short time frame by the agency. So they have a couple of jobs to do. But I do believe that there will be open comment on any product that comes out.

Mr. MOOLENAAR. Okay. Any others have any comment on that?

Dr. SERBER. Many of the partner companies we work with who are already engaged in large-scale manufacturing are stimulated to become involved in this process by—the writing is on the wall for them that if they don't embrace the new technology, their competitiveness with the products that they make will be eclipsed by others who have. So this framework is really required to maintain the United States' lead in the manufacturing of many of these goods, without which we will be stuck manufacturing products using 1980s, 1990s technologies, and others will be employing the more advanced technologies and have better economics around manufacturing.

Mr. MOOLENAAR. And is the framework the same as the strategic plan or is that totally different?

Dr. MAXON. These are two different—

Mr. MOOLENAAR. Okay.

Dr. MAXON. Yes.

Mr. MOOLENAAR. And then who is driving the strategic plan?

Dr. MAXON. I believe from the memo the effort is the Administration with the Office of Science and Technology Policy in concert with the three regulatory agencies. But I believe OSTP is working with the agencies. I didn't want to say they're running it but they're coordinating it.

Mr. MOOLENAAR. Okay. Dr. Evans, did you have a comment on that?

Dr. EVANS. Not on the last question, I was—on your question before. You know the thing that is important is the predictability. That is what is important for us in, say, the ag industry where our development timelines are a decade. And so when you have policy shifts or in—particularly when you have policy frameworks that don't have a strong science base so that you can bring data to the decision to try to move and have an informed and data-driven process. That's where things get increasingly challenging for us to make investment decisions that are reliable and robust.

Mr. MOOLENAAR. Okay. Thank you, Madam Chair. And thank you for your insights.

Chairwoman COMSTOCK. I now recognize Congressman Abraham.

Mr. ABRAHAM. Thank you, Madam Chairman.

Dr. Dickman, let's go back to you for just a second. You referenced the MAGE and the CAGE, the multiplex automatic genomic engineering and the computer-aided on your research. It's certainly my belief and I think the belief of many of us that world security is the food scarcity or having food security for underdeveloped nation. And I think one of the criteria for being an underdeveloped nation is that you simply can't provide enough food for your people. So in my opinion this is another piece of the pie that we fight world terrorism with, that we're able to feed the people that can actually do some good and do some good things.

So I guess the question is how far in your crystal ball are we away from really getting there to some of these underdeveloped nations of these technologies where you can potentially grow wheat in the middle of a desert or you can increase yields by five to ten percent? Where are we in the timeline there?

Dr. DICKMAN. Well, it depends if the glass is half-full or half-empty.

Mr. ABRAHAM. Right.

Dr. DICKMAN. Certainly, there are a lot of positive progresses that are being made in developing countries, but it's a complex—it's not a compound, but it's a complex issue. There's a lot of politics involved, and while the growers generally support these kinds of plans and roots to food production, they're often hampered by politicians and people of other interests. So the hurdles to overcome, depending on the country you're talking to, are considerable.

But I might add, for it—but it can be done. Let me—bananas, to use something I know a little bit about, are now in human field trials actually in Iowa with the hope that the hoops have gone through sufficiently to put them out on a humanitarian effort in Africa in another year as bananas—you know, the rice—Golden Rice, which is even making vitamin A and preventing blindness in children, has run into lots of—which has been heavily advertised and it's sort of the poster child for transgenic crop plants has slowed down considerably due to regulatory hurdles.

So to answer your question, to where it would be a viable economy with an assortment of crop plants, we're probably talking ten years as well I would say realistically.

Mr. ABRAHAM. Okay. That's a good enough ballpark. At least we've got some thing we can—maybe put our toe in the water in so to speak.

Dr. Serber—and I'll go to Dr. Evans or anybody on the panel who wants to answer this—you mentioned the Swiss cheese, I guess, effect of our regulatory process here in the States, but you also mentioned that we need to accelerate innovation, and those two are pretty much diametrically opposed. But anytime we regulate, we slow down the process tremendously.

So the balance of—I'll flip to the health side for just a minute with the CRISPR technology and the Cas9. We have the potential and the ability, I think even now, to cure single mutations, single gene mutations, but again, we have countries that are abusing this to the point of trying to manufacture a—the perfect child or the perfect person. Where is the middle ground here? Where do we start, I guess, is a question of how we can accelerate innovation but at the same time make sure that this wonderful technology doesn't fall into the hands of some nefarious people?

Dr. SERBER. The quick answer from my—and really, it's just from our point of view—is the place to start is in simpler systems. The mammalian application of these technologies is more complicated when it comes to the ethical and legal considerations. The application—the technology actually began as a natural phenomenon in bacterium, and it has been applied across the animal kingdom in very short order, given its power.

We at Zymergen apply those sorts of technologies in the application of microbes like bacteria that—from which they were originally found for the purposes of improving them in the biocatalysis that they are used in large-scale fermentation. This is a—makes for us from our perspective a nice testbed for assessing the suitability of the technology in a regime that certainly has oversight—I'm not implying for a moment it doesn't—but doesn't raise as many issues as other applications have. And as I think we learn more about the technology and its applications and grow more comfortable with it in this sector, it will be much easier and more natural to move it and expand it into other sectors, which will include human health.

Mr. ABRAHAM. All right. Thank you. I'm out of time, Madam Chair.

Chairwoman COMSTOCK. I now recognize Mr. Westerman for five minutes.

Mr. WESTERMAN. Thank you, Madam Chair, and thank you to the witnesses for being here today.

I grew up in a time where I read stories about Dr. George Washington Carver and the amazing things that he did, sort of the man who can make something out of nothing with his research on peanuts and sweet potatoes.

When I was in high school I thought I was just getting out of school for a day but I was very involved in the Future Farmers of America, and I got invited to a conference. It was called the Governor's Conference on Agricultural Innovation. It was hosted by then-Governor Bill Clinton and the special guest was Norman

Borlaug, so I got to be a member of that panel. I'm not sure how that happened. If I'd known the significance of it at the time, I might have listened a little bit closer.

But, you know, there was a time when people who did this research and came up with all these great ideas were given Nobel Prizes. There were departments at colleges named after them. They won all kinds of awards and were viewed as heroes, yet today, if you fast-forward, as a Member of Congress, I get a lot of constituent feedback in opposition to the GMOs or any kind of biological research. I did also—I attended forestry school, and the time I was there it was during the—a lot of the genome—human genome research. My undergraduate degree was in biological and agricultural engineering, so I've kind of followed this for a while.

But at the time the human genome was being mapped, the genome of the pine tree was not—or was being worked on but it was about seven times more complicated than the human genome. And I believe in 2014 they finally mapped—or sequenced the pine tree genome with about 23 billion pairs to it. And I know that when you talk about biofuels, if you look at pine trees and you look at the amount of lignin in the tree versus cellulose, you could engineer a tree to make a lot more lignin, which would create more biofuels or you could engineer it to make more cellulose, which would be better than paper. So there are a lot of benefits to this. But also, there seems to be a lot of pushback.

Dr. Dickman, do you believe that gene editing technology is related to crossbreeding or hybridization techniques that have been used for thousands of years, or is it something totally new that we should be afraid of?

Dr. DICKMAN. You're properly managed. I'll learn one of these days.

I think—again, as was stated previously, the gene editing technology is a much more serious issue in the biomedical field because you're talking about generating transgenic people and there's lots of ethical issues. But in terms of plants, they've been mixing—naturally mixing populations, as you said, thousands of years and naturally for the most part selecting traits of interest.

But CRISPR and genome editing in general can convert the plants field is a much more significant leap of time to get to the desired product, much more power—experimental power. So they're basically under the same—under a similar umbrella but have different rates of progress. That is one reason why CRISPR and genome editing is so exciting because the potential to create variation in terms of breeding practices is virtually unlimited and much, much more rapid and much more informed as—toward the breeding population. So it confers a number of advantages. Again, it comes back to public understanding what exactly this is and how it works and why it's beneficial as opposed to just being something, you know, with—DNA-related and more concern that really should be alleviated.

Mr. WESTERMAN. And I know from the forestry side there was concerns about Franken-trees—

Dr. DICKMAN. Right.

Mr. WESTERMAN. —you were going to plant these trees and they would take over the landscape.

Dr. DICKMAN. The monster that ate Cleveland.

Mr. WESTERMAN. Right.

Dr. DICKMAN. It hasn't happened yet.

Mr. WESTERMAN. But most of these genetically modified organisms, they require more of a specific environment to survive, and in the natural world they can't propagate themselves as well is my understanding of that.

Dr. DICKMAN. That's true. There's a lot of microbes out there. I mean, as I was rushing to say, in the phytobiome work, it's now become clear that these microorganisms confer a number of different traits to the host plant that they're residing in, and if you remove those microorganisms, you lose the trait, you lose tolerance, you lose disease resistance. So if we can understand the microbiome in plants or in any other—or even in the human gut where it's being done quite extensively, that gives us another avenue of approach to try to generate the kinds of things we need to better the world.

Mr. WESTERMAN. And, Dr. Evans, what are the environmental, safety, and health impacts of genetically engineered plants and animals?

Dr. EVANS. I think that's a great question. Those are things that have been well covered by the history of the coordinating framework in bringing products through from the—from initial registrations in 1995, 1996 on with the original BD crops.

So both nationally and internationally these products have had a large degree of oversight. There have been hundreds of studies conducted by third parties, so independent researchers. Of course, companies have to provide data. Even the universities that are attempting to move some of these products as they try to get into field trials have to provide safety and environmental data.

So I think the concept of what is there from the large company perspective, we don't see major gaps where we could just try to drive something unregulated through the system. We have a lot of desire to be able to want the public to have confidence in these products because they're going to consume them.

And so the thing we still need though is, you know, after 20 years the regulatory burden, the familiarity with the products, and the technologies don't appear to be decreasing the submission packages or time. And so things just keep getting added and added, and they do not appear always to have a strong scientific base.

And so I think the federal government can help provide some research in some of the questions and independent research by federal land-grant universities and such that could help move that question down the road because we aren't going to be able to feed the population of the planet, as has already been discussed, by simply applying and hoping for the next incremental increase in a breeding approach. There are things that need to be brought to bear in this time frame to 2050 that require novel solutions.

Mr. WESTERMAN. Thank you. Thank you, Madam Chair, for your indulgence.

Chairwoman COMSTOCK. Thank you.

And I now recognize Mr. Tonko for five minutes.

Mr. TONKO. Thank you, Madam Chair. And welcome to the panelists.

As a nation, we are woefully under-producing scientists and engineers. In order to remain a competitive global economic power in the 21st century, I believe that we as a nation need to place a strong focus on STEM education. I fear that without an increased commitment to STEM education, American students will not be represented in the STEM fields and American workers will be unable to compete for jobs or grow careers in the enhancing STEM industries that exist.

It seems that this is the case in this area as well. In fact, Dr. Saber's testimony mentions the need for employees with expertise in multiple relevant domains. So to any of our panelists, my question would be would you please discuss the skills that are necessary, essential for emerging interdisciplinary fields like the field that we're discussing here today? Anyone?

Dr. SERBER. I'll start but I think other members of the panel have something to say about it. It's worth highlighting that a panel like this is composed of people who've spent at least a quarter-century in school apiece getting the skills required to reach a level of just pure competence in the field. And it's especially difficult given the long time horizons of the educational program to stay current in a rapidly evolving system. And having federal support to be nimble and flexible around that to change the educational programs and support as the technology improves is absolutely critical.

I found myself recently in conversations with faculty at UC Berkeley discussing new master's programs that they want to install with an eye towards training staff for jobs in businesses and companies like that of Zymogen, the company that I founded with two others, which certainly involves a lot of biology but also more automation, robotics, computation, computer science than you would think. And I'm finding that there are certain educational programs across the United States when I go higher that are particularly adept at cross training graduate students and undergraduates for a future in this career, which will be intrinsically cross-disciplinary. It is no longer sufficient to get ahead in a technical field to be an utter specialist in one area, at least by my estimation.

Mr. TONKO. Thank you. I believe, Dr. Evans, you were going to say something?

Dr. EVANS. I think that if you look at what we need and the students that are interesting to us, one of the places that I get a lot of encouragement is looking at something like iGEM, the program that's focused at not only the college level but there are high school teams competing in iGEM now. And a number of them developed products, concepts, projects that are related to agriculture, the environment. They're very sensitive to detection and remediation.

And so what do you have—what you have in common there is a need to understand questions and to be able to inform ways of thinking about questions that are often not just, say, one gene at a time anymore or even one question at a time. If you start thinking about the interaction of these microbials, these would be multiple microbes interacting with a plant that might be interacting with an insect. So everything about it is interaction-based, and so scientific skills that can help students begin to comprehend interactions.

But those interactions also have an important metaphor, which is interaction with the community at large. Just because we can do something, people need to ask the question should we or how should we. And those interactions of science with their technology at the bench, being able to go have a conversation with someone who is in another department in the school with no science background at all, those skills are very unique and quite lacking. And so we need to be able to integrate a good sense of science, of—across a number of disciplines, but the ability to think and ask questions, at least understand or comprehend questions, that there could be policy or health or ILSI implications is important.

Mr. TONKO. Right. Dr. Maxon, I think you had a comment you wanted to share?

Dr. MAXON. Yes. Yes, thank you. Sorry. I have a bit of a cold and I'm making sure I can get through this.

A couple of thoughts come to mind. In the United States approximately 50,000 people per year receive doctorates. More than half of those people—it depends on the field, of course—but more than half of those people don't end up in 10-year-track academic positions. You're looking at a table here with a bunch of people who got academic training through the apprenticeship model that gives us our Ph.D.'s.

But what we are not trained to do is understand the skill sets, I think—to underscore the points made by my colleagues—to work in industry, to manage a budget, to understand how to write a business plan. These are not things we learned in the system.

And so on the level of graduate education I would say that the United States should work a little harder to broaden the exposure of graduate students to the kinds of skills they're going to need, depending on what field they're going to end up in, whether it's going to be science journalism or academic research or a medical research or plant research, at a company. It doesn't matter. I think we can do a better job at that.

At the undergraduate level, a couple of thoughts occurred to me there, too. 1) Most importantly, I think we see the best outcomes in developing scientists and engineers when we give them immersion opportunities, not just canned lab experiments to do that thousands of students before us have done, but actual research experiences where we are the first people to ever actually do an experiment in an undergrad environment. I know that's hard to do and I know it's expensive, but there are people who are doing it and I think it's very good trend in the right direction.

And lastly, community colleges, I know some of the national labs, ours included, are working very hard to establish relationships with community colleges to put into the curricula critical inspirational pieces for understanding how to engineer biology. So I think there's a lot of work we could do.

Mr. TONKO. Thank you very much. I think you've all cited a need for investment, and I endorse that.

Madam Chair, I don't know if Dr. Shetty had any comment. It looked like you wanted to share some thoughts.

Chairwoman COMSTOCK. Sure. You're welcome to—

Ms. SHETTY. Yes, the one comment I want to add to my fellow panelists is that STEM education starts—needs to start early. It's

not—doesn't begin at the undergraduate level. I myself had the benefit of doing a research experience at my local university as a high school student. And those early exposures to STEM education is critically important to fostering the scientists today, particularly when you're talking about young women, right? There are a lot of—the balance of genders between men and women in science and math fields is very skewed in a certain direction, and so we're not tapping into the full potential workforce with those statistics.

And so as I look forward encouraging young girls to participate in STEM fields is absolutely important. And as a mom with a young daughter, you know, I want that for her.

Mr. TONKO. Super. Madam Chair, thank you, and I yield back.

Chairwoman COMSTOCK. Thank you. And I'm glad we got to have you mention that opportunity. I started a Young Women's Leadership Program so we could do that very thing, and my daughter is a biology major, did not get any of that from me so—but she had a lot of great women teachers at George Mason here in her master's program.

I'll now recognize Mr. LaHood for five minutes.

Mr. LAHOOD. Thank you, Madam Chair. And I want to thank the witnesses for being here and for your testimony and all the work that you do.

Dr. Shetty, question for you. There's been discussion about how the United States is losing our competitive edge with China and the United Kingdom when it comes to synthetic biology, and I guess trying to understand the reasons for that and why we're falling behind and what steps we need to take to maintain our competitive advantage in biotechnology.

Ms. SHETTY. Yes, thank you for the question. So I think probably the best example of interest in—the worldwide interest in this area is the International Genetically Engineered Machines competition. This is an undergraduate competition in synthetic biology where teams from universities design and build genetically engineered machines, organisms. And for the past few years most years the winner is not from the United States, right? It's coming from Europe, coming from China, coming from overseas. So I think this is a reflection of what is to come if we don't make domestic investments in this area.

And so I think part of the problem or part of what needs to happen in this country is that we need an organized program of investments, right? No one piece is enough because there's a lot of synergy to be had between having the agencies understand and coordinate their research efforts both on the basic R&D side but also on the translation into industry through SBIR programs, and then finally, as I alluded to in my opening remarks, the U.S. Government serving as a customer for biotechnology products as these nascent industries are getting going.

And so we need a coordinated, multipronged strategy, and that has—that coordinated strategy has been pushed forward by the United Kingdom, by China, by other countries in the EU, but so far, we have not done the same here in the United States.

Mr. LAHOOD. In the competition that you referenced, when did that change occur where the United States hasn't been the winner? Was that recently or 5—how long ago?

Ms. SHETTY. The competition started in about 2004. I would say by 2005, 2006 there started to be—the winners of the competition started to become schools from outside the United States rather than within the United States even though this field largely has its original roots in the United States. I was there. I was part of it.

Mr. LAHOOD. Got you. Dr. Maxon, as a follow-up, my home State of Illinois has a large and diverse bioscience industry with over 78,000 jobs and 3,400 businesses that contribute to the State's economy as it relates to bioscience. I know you were the author of the National Bioeconomy Blueprint in 2012 that outlined steps that federal agencies should take to drive the bioeconomy in the United States. I know we referenced that a little bit earlier, but what's the status of those recommendations in that report?

Ms. MAXON. Thank you for that opportunity to talk about what's happened since the release of that policy document.

I think the recent memo on July 2 from the White House talking about taking a look at the regulatory framework—the coordinated framework is a direct reflection of one of the five strategic objectives of the National Bioeconomy Blueprint. So I would say in that regard right at the top of the list is taking a look at the coordinated framework.

Workforce development was another. You've heard some ideas of how we might be able to jumpstart the system, get a few more chemical processing engineers, that kind of thing, still need some work to be done there.

Public-private partnerships for biosciences, I think what could be done there—and there are some efforts underway right now I believe, funded by the NSF, to identify precompetitive research challenges that industry shares that might actually benefit from government—public-private partnership with both government and company investment.

So those are three right away. A couple more, strategic research investments, that was the number one objective in the National Bioeconomy Blueprint. I think you've heard most of the people, if not all the people on the panel, say the same thing. We could do a better job here. And one of the reasons, to answer your last question, to address your last question about why are we falling behind in synthetic biology specifically, I look at this as another example of technology. Nanotechnology is an example, emerging technologies. Technology in general sort of falls between the cracks in the federal agencies, and so I think the idea of a coordinated—federally coordinated strategic approach to lift the technology is where I think some opportunity still remains.

Mr. LAHOOD. Thank you. Madam Chair, if I could ask one last question of Dr. Shetty?

Chairwoman COMSTOCK. Okay.

Mr. LAHOOD. Thank you. Dr. Shetty, one of your company's projects funded by DOE ARPA program supports R&D to capture natural gas flared by shale. Can you describe how your company is using that biotechnology to conduct this work, and what have those outcomes been thus far?

Dr. SHETTY. Thank you for the question. So there's an interesting transition that's happened in recent years in this country, which is

that on a per-carbon basis, carbon derived from methane, natural gas, methanol is cheaper than carbon derived from other sources, say, sugar. And so there's a growing interest in—both within our company and others in using these as feedstocks for bio-production of various chemicals and fuels.

And so we had initially had DOE ARPA-E funding in this area to develop some nascent technologies, and we've since partnered that work with a commercial partner and are taking it forward. Now, unfortunately, because it's partnered, I'm under some confidentiality restrictions and so I'm not able to speak to the details of that program, but suffice it to say, this is an area of interest both for ourselves and others, and it's a potential new frontier when it comes to bio-production of these types of fuels.

Chairwoman COMSTOCK. Thank you. And I now recognize Mr. Hultgren.

Mr. HULTGREN. Thank you, Madam Chair. Thank you all so much for being here for this important discussion. I do believe this is an important hearing.

And as technology continues to evolve and new opportunities materialize, it's increasingly necessary that we keep our regulatory structure up-to-date while developing biotechnology in the most ethical way possible. This means coordination and communication between our researchers, their institutions, our government, and also among government agencies.

Dr. Maxon, I wonder if I could address my first couple questions to you. You mentioned the Human Genome Project in your testimony, which for me has been an excellent example of the unique capabilities of the Department of Energy to bring to the table in computing, among other things. DOE basically had to start the project to prove the concept before NIH was able to take this up as a serious cost-effective endeavor. How has the Human Genome Project benefited the nonhuman health biotech sectors? And also, is there a similar systematic sequencing project needed for agriculture or naturally occurring chemicals as well?

Dr. MAXON. Thank you for your question. I apologize. I have a bit of a cold today. To your first question, Human Genome Project, how has it benefited the non-biotechnology. I assume you mean the non-biomedical world?

Mr. HULTGREN. Yes, I'm sorry.

Dr. MAXON. No, thank you for clarification. I think one thing that that human genome sequencing project did was democratized DNA sequencing. So laboratories everywhere, whether you're studying viruses or the plant microbiome, whatever it is, people can now sequence DNA very quickly as a consequence of the human genome sequencing project.

So I think that—and in fact, I don't think it's overestimating it to say all of biology has benefited in that way. Anything that has DNA, if you can sequence DNA quickly and cheaply and in a democratic fashion, everything has benefited. So I think the magnitude of that can't be underscored. If you could remind me of your second question?

Mr. HULTGREN. Yes, the second question was, you know, as far as agriculture or other naturally occurring chemicals is there a

similar systematic sequencing project that we need or where we should focus?

Ms. MAXON. A similar systematic sequencing project, wow. I am not in a great position to answer that question. I think I would defer that to my agricultural colleagues.

Mr. HULTGREN. Does anybody else have a—yes.

Mr. DICKMAN. There is actually quite a bit being done in agricultural sequencing if you will. In fact, NSF has a plant genome program that is actually very well-funded, nice to hear, and has been ongoing for a number of years. There's also microbial genome sequencing program that just finished.

So—and also independently, now that it has gotten so relatively inexpensive and available and doable in a rapid fashion, there's a lot—there's a great many agricultural-related genome sequencing projects going on now.

Another area to be marketable in is bioinformatics and computation because back when I was a student, you know, we cloned the gene was your thesis. Now, you go home, it's 25,000 genes and you have to figure out what to deal with it. So there's a massive amount of data handling, but that is being done to the United States' credit in support of those kinds of projects.

Mr. HULTGREN. That's great. Thank you. I'm going to go back to Dr. Maxon if that's all right. From your time at OSTP and now with the lab, surely you've seen the difficulties of getting agencies to work together, especially in getting them to leverage one another's resources, tools, and human expertise. It sounds to me like there is great potential if agencies would work more closely together in this space, for instance, if ag aggressively leveraged the synthetic biology and genomic capabilities of the national labs. I wonder, will this work and what do you suggest? How do we—from your experience, how do we best work together?

Dr. MAXON. Thank you for that question. I'm tremendously optimistic about this. I do think there's an incredible opportunity here. The potential is amazing. I was heartened to see the President's Council of Advisors on Science and Technology in December of 2012, or at least a report called "Agricultural Preparedness." And in that report they recommended that the USDA work with the DOE and the NSF to set up new innovation ecosystem hubs for agriculture. I think an idea like that where the DOE, that knows how to set up innovation hubs, working with the USDA, could go a long way with NSF in making something like this happen.

I was also heartened to see not long after that report that the USDA, in its budget, requested funds for a biomanufacturing institute. So I think we're very close and I'm very optimistic. So I think it will work. It just might take a little bit more time.

Mr. HULTGREN. Great. My time is almost expired. I will yield back my last 7 seconds. Thank you.

Chairwoman COMSTOCK. And I now recognize Mr. Weber for five minutes.

Mr. WEBER. Thank you, Madam Chair. And let the record show I have five minutes and second seconds.

Thank you for the opportunity to be here and participate.

And, Dr. Dickman, this question is for you. The past—this past year public researchers involved in communicating the science of

biotechnology and its impacts have been—actually been targeted both professionally and personally. I'm sure you're aware that. Doctor, as a public scientist, can you give me more background kind of into the current academic feeling on this public outreach? You all are getting targeted a lot of—some stuff has been aimed at you. What's the feeling amongst your peers?

Dr. DICKMAN. Well, a number of things, disappointment and things of that nature when you see a greenhouse that's been destroyed by stones, for example, with all kinds of messages written on them. It's a bit disconcerting. But in terms of people's research, I don't think that has impacted it. I mean people are still doing what they plan to do and continue to do and get funded to do. So it's an unfortunate circumstance. I really don't think it's really had a strong impact on people's ability to do work with the exception that there is some material things that have been destroyed that needed to be replaced. It's been—is actually not too bad now.

Mr. WEBER. Not too bad? You actually said I believe in your discussion with the Chairwoman that you felt like you all needed to do a better job of showing capabilities, I guess educating the public?

Dr. DICKMAN. Very much so.

Mr. WEBER. Has that been progressing?

Dr. DICKMAN. Well, I do it by—on sort of a grassroots level. We don't have any organized framework with which to do this. I think we do. We do need that, whether it be from academic or—and/or companies—

Mr. WEBER. Have you done the genomic sequencing on that grass? You said grassroots level.

Dr. DICKMAN. That's actually in the queue for other reasons.

Mr. WEBER. All right. So you're doing it at the basic level is what you're saying.

Dr. DICKMAN. Well, there's a number of turf breeders who work strictly on golf course turf you might want to talk to.

Mr. WEBER. There is a shock, huh? Well, we'll thank you for that.

And, Dr. Evans, as you know, Dow Chemical has a lot of industry in my district there in Texas. In fact, I was going to tell the gentleman from Illinois—he left before I could—that there was 78,000 jobs associated with this. In Texas, there's 81,000 jobs. Things are bigger in Texas.

So—but, Dr. Evans, you also mentioned in the three C's of national needs both continuing to support national scientific funding agencies and convening forms of discussion for the public engagement or outreach that Dr. Dickman and I were just discussing. With limited resources in public research, what role do companies, for example, like Dow Chemical play in promoting that scientific interest?

Dr. EVANS. Well, I think one of the ways that we have been involved last year with the help of the NSF, the Woodrow Wilson Institute, there was a convening of companies, regulatory bodies, and nongovernmental entities that had interest in the environmental release of microorganisms, whether they be algal strains that might do chemical production or concepts that synthetic biology might want to bring into the environment. That group at least pub-

lished recommendations where things could go, with some of those recommendations being specific federal funding.

Now, companies I do think need to be able to know where to direct their research, and their research needs to be aimed at their product technology space and legitimate questions around that product area. But there are some things that just are big enough in scope or they are fundamental questions of biology or biotechnology that are more properly addressed in integrative lab studies from multi-university settings or they might be appropriate to be something that would be the outcome of a national lab and a focused program. And—but industry could then, even in that scenario, be an appropriate partner. The—I think the thing from the public perspective is we need to make sure that the public can see transparently where those contributions are being made and—

Mr. WEBER. That's a good point, you know, in your discussion with the gentleman from New York, Representative Tonko, I think you said, just because we can do something, you should ask the question should we do something. And if the public perceives that a company is getting involved, is that a conflict of interest? I think you were the one who said—let me quote you. Earlier, you said that we needed more feed, fuel, fiber, and food, more—and by 2050 than in the last 10,000 years. That's an astounding fact. And with limited resources available I think if the public knew, you know, what was at stake here, that they might not be so suspicious. But I appreciate your testimony and, Madam Chair, your indulgence. And I yield back.

Chairwoman COMSTOCK. Thank you. And I think by agreement Mr. Westerman has a few more questions, and I'm going to let him have the chair because I'm going to have to depart. But I want to thank the witnesses very much for a very interesting and insightful hearing and appreciate all the great research you're doing. And I'm glad we have two women here, too. So thank you. And we certainly appreciate the men, but thank you for your comments, Dr. Shetty, and we will keep those in mind going forward, too. Thank you.

Mr. WESTERMAN. [Presiding] I guess that's one way to get to ask another question.

So, Dr. Maxon, you mentioned this briefly in some remarks, but talking about nanoscience, and I was able to tour the Institute for Nanoscience and Engineering Technology at my alma mater, the University of Arkansas. It was very exciting to me, the possibilities there. So I was wondering if the panel could address the opportunities in nanoscience as it relates to biotechnology. And is this an area that needs more research funding?

Dr. MAXON. I'm not an expert in nanotechnology but I'll kick this off and then allow my colleagues to respond.

I know that nanotechnology intersects with biotechnology in some of the high-level treatments that are being done now to target certain therapeutics at certain parts of the—very specific parts of the body. I know that nanotechnology is used in the process of doing some diagnostic kinds of analyses, again, in the biomedical space. I don't—like I said, I'm not an expert. I don't know much about how nanotechnology intersects with the non-biomedical fields. It'd be interesting to hear from my colleagues whether there are any.

Dr. EVANS. There was in fact a small NSF industry and university consortium that was established at the University of Illinois to try to bring together—it was established at a former nanotechnology center. Well, it still is a nanotechnology center, but they brought in industry that was involved in agriculture, some other industry that was involved in food and diagnostics and medicine to try to come in and bring products to market rapidly that could be based on nanotechnology.

I think if you just step way back—I'm not a physicist, but the thing that nanotechnology did to material sciences has helped re-envision what was possible. We thought we knew what was possible with our understanding of the physics and of the performance of materials at a certain scale, but nanotechnology changed that, and remarkable products and concepts came out of that.

I think engineering biology is doing the same thing to biology. We had a framework of what was possible that was rocked with the development of recombinant DNA technology in the early '80s. Insulin came very quickly after that, a Nobel Prize. Now, we have high school students that could do the same level of engineering that formed early products. And so this is reengineering what is—or reimagining what is even possible using biology for what it's very good at, making things, making nano-structured things. Biology makes wonderfully complicated nano-structured materials in things besides carbon. And so how does it do that? And how could technology be brought to bear to do that?

And so I think it's questions like that that a good, well-thought-out national plan for bringing students and bringing the technology to bear could follow on that metaphor of nanotechnology. And I had to bring in associated concepts of regulatory and safety all at the same time.

Mr. WESTERMAN. Dr. Maxon?

Dr. MAXON. To follow on the point that Dr. Evans just made, the National Nanotechnology Initiative is a great example of a coordinated effort that gave rise to coordinated federal research, coordinated interest in public science, the public understanding of the science. I think that that model exists that could be applied here.

Mr. WESTERMAN. Anybody else like to address the nanoscience question?

Dr. SERBER. Only very briefly that biology is already the supreme source of nano-exquisite molecular structures. Biology and the enzymes that it employs to do chemistries are there for us to make use of as we attempt to expand the chemical palette of building blocks that we can use to make new materials. So there is a definite overlap in some of the applications.

Mr. WESTERMAN. And, Dr. Serber, just as a quick last question, your work in biofuels, can you describe some of the barriers that exist for bringing biofuels to market? I know there's been a lot of attempts, not really any successful attempts.

Dr. SERBER. Yes, quickly, so I'm currently no longer working on biofuels, but I did spend about seven years pursuing biofuels. And the challenges that that sector faces are driven by the macro-economic forces having to do with the price of oil in the price of feedstocks for the fermentation products.

It's worth highlighting that in the course of pursuing biofuels, both with private and federal funding, all the tools that we are—this panel is making use of to drive other applications and other technology, a lot of that began with biofuels. The biofuels have not yet reached the economic tipping point to be competitive, but things only need to change a little bit for that to turn around. And we'll be ready when they do.

Mr. WESTERMAN. Okay. I'd like to thank the witnesses for their valuable testimony and the Members for their questions. The record will remain open for two weeks for additional comments and written questions from Members. The witnesses are excused and this meeting is adjourned.

[Whereupon, at 11:52 a.m., the Subcommittee was adjourned.]

Appendix I

ADDITIONAL MATERIAL FOR THE RECORD

PREPARED STATEMENT OF COMMITTEE RANKING MEMBER

EDDIE BERNICE JOHNSON

Thank you, Madam Chairwoman for holding this hearing. I want to thank you and the Ranking Member for putting together such a distinguished panel of witnesses who represent the national laboratories, large companies, start-up companies, and academia.

This morning, we are talking about emerging biotechnologies and their applications for the energy, agricultural, and manufacturing sectors.

A number of these new technologies are based on engineering biology research that allows researchers to safely re-engineer existing biological systems and to learn from and mimic existing biological systems to perform novel tasks and develop novel materials and products.

These new technologies are exciting and have the potential to solve some of society's greatest challenges, including providing food for a growing population, reducing our dependency on fossil fuels, and dramatically transforming manufacturing. Additionally, they have numerous applications for the biomedical sector, some of which we heard about at a hearing this past summer.

Given the promise of this research and its applications, I introduced the Engineering Biology Research and Development Act of 2015, with my Science Committee colleague, Mr. Sensenbrenner.

The bill would establish a framework for greater coordination of federal investments in engineering biology and lead to a national strategy for these investments. The bill would also focus on expanding public-private partnerships and on education and training for the next generation of engineering biology researchers.

Additionally, the bill will ensure that we address any potential ethical, legal, environmental, and societal issues associated with engineering biology. It will also ensure that public engagement and outreach are an integral part of this research initiative.

The goal of this legislation is to ensure that the United States remains pre-eminent in this critical area of science and technology. As I anticipate hearing this morning from our witnesses, if we do not make the necessary investments, we will lose our leadership position in engineering biology.

We are already seeing other countries make significant progress. The EU and others are investing, working on coordinated strategies across their research enterprises, and developing action plans to execute those strategies. Right now, we are still a leader in engineering biology, but we must continue our work to ensure that we do not cede this leadership position.

This field has the potential to grow our economy, create jobs, and improve our quality of life. Even though we are in an increasingly interconnected world, it is important to do all we can to promote innovation and job creation here at home.

I am hopeful that we can work together across the aisle to ensure that the United States remains a leader in engineering biology.

In closing, I want to thank the witnesses for being here today and I yield back the balance of my time.

