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

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[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-

[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

[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 memorandum[15] 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.

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[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