Testimony
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Statement of
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Chairman Bucshon (R-IN) and distinguished members of the Committee, thank you for the opportunity to testify at this important hearing, and for your strong and sustained support for science and technology development. My name is Jay Keasling, and I am a Professor of Chemical and Biomolecular Engineering and of Bioengineering at the University of California, Berkeley and Senior Faculty Scientist at the Lawrence Berkeley National Laboratory. I serve as the Director of the National Science Foundation-funded Synthetic Biology Engineering Research Center and CEO of the Department of Energy-funded Joint BioEnergy Institute.

Today, I would like to tell the story of how we engineered a microbial production process for a much-needed drug to combat a deadly disease that affects millions around the world, and how repurposing this same process allows us to meet needs not only for health, but also for energy and the environment. In doing so, I will argue that sustained federal investments that encourage the growth of synthetic biology, an emerging, multi-disciplinary field, is a critical component of both continued U.S. economic prosperity and security with enormous societal benefits.

There are approximately 300 million cases of malaria at any one time, approximately one million people die from the disease every year, and 90 percent of those are children under the age of five. Conventional quinine-based drugs are no longer effective, and while plant-derived artemisinin combination therapies are highly successful, for many malaria victims, they are also cost prohibitive.

To bring down the cost of the therapy and stabilize the supply, we engineered a microorganism to produce a precursor chemical to the drug. To do this, we transferred the genes responsible for making the drug from the plant to a microorganism. This process of producing artemisinin is akin to brewing beer. The microorganism consumes a sugar and secretes a precursor to artemisinin rather than alcohol, which the yeast would produce naturally from sugar.

We have licensed this microbial production process to Sanofi-Aventis, who has scaled the process to industrial levels. This year, Sanofi-Aventis produced 70 million doses of artemisinin and is on track to produce 100-150 million next year, roughly half of the world’s need. We predict that the drug produced by this engineered organism could save a large fraction of annual one million child victims of malaria.

Begun in 2004, the artemisinin project was supported by $25 million from the Bill and Melinda Gates Foundation and roughly 150 person-years of work. We were able to complete the project in that brief time largely due to ready access to well-characterized biological components, a significant point that I will return to shortly.

The artemisinin story demonstrates the significant medical benefits of engineering biology, but also reveals how these benefits extend to chemical manufacturing as well. For example, 1,3-propanediol is an important industrial chemical used to make carpets, textiles, cosmetics, personal care and home cleaning products. In 1993, Dupont embarked on a major research effort to engineer the microbe *E. coli* to produce 1,3-PDO, in order to replace the petroleum-based process used to make the chemical. It took 15 years and $130 million in research and development for Dupont to make a bio-based, sustainable process that consumes 40% less energy and produces 20% less greenhouse gases.

Artemisinin and propanediol are just two examples of how engineering biology can create a more cost effective and sustainable manufacturing process, and even save lives. Unfortunately, engineering biology is still time-consuming, unpredictable and expensive and many urgent challenges in health, energy and the environment remain needlessly unsolved. Today, most of our bulk chemicals and materials are derived in whole or in part from petroleum. What if we could take plants, CO_2 and sunlight and output useful, sustainable substitutes for petroleum-derived products? What if we could engineer biological systems to generate medical cures like artemisinin and green chemicals like bio-PDO in months rather than years?

Efforts aimed at making biology easier to engineer have come to be known as “synthetic biology.” As was the case with the development of synthetic artemisinin, synthetic biology represents a convergence of advances in chemistry, biology, computer science, and engineering. Experts in these fields work together to create reusable methods for increasing the speed, scale, and precision with which we engineer biological systems. In a sense, this work can be thought of as the development of a biology-based “toolkit” that enables improved products across many industries, including medicine and health.

About ten years ago, around the start of the artemisinin efforts, several colleagues and I set out to develop these more generalizable approaches to making biology easier to engineer. We believed we could engineer microorganisms to produce virtually any important chemical from sugar. Yet there was a severe lack of publicly accessible tools for building biological processes and products. So we went to the National Science Foundation and proposed a center dedicated to building such tools for the research community. In response, the NSF established the Synthetic Biology Engineering Research Center. Synberc is a ten-year multi-institutional research project designed to help lay the foundations for the emerging field of synthetic biology. Synberc’s investigators come from across the US, and from a range of disciplines, including chemistry, biology, computer science, engineering and the social sciences. Now eight years since its founding, Synberc has produced a broad range of “toolkits” that are being deployed in the fields of energy, agriculture, health and security, and offer an array of economic and societal benefits.

When Synberc was established in 2006, it was the nation's single largest research investment in synthetic biology. Eight years later, this and other federal funding have catalyzed the growth of academic research centers across the country, the production of many synthetic biology-enabled chemicals in the private sector, five start-up companies from Synberc itself, and a robust private-public consortium that helps guide research from the lab bench to the bedside. This U.S. model has been so successful that other countries – particularly China and the U.K. – are developing aggressive, nationally coordinated research programs in an effort to surpass the U.S. to become the global leaders in biological engineering.

The U.S. has been a leader in this field because of early and focused federal investment, but we now face stiff competition from overseas and uncertainty in the future of our pre-competitive investments here at home. I believe that now is the time for the federal government to work with academic and industrial researchers to launch a national initiative in engineering biology to establish new research directions and technology goals, improve interagency coordination and planning processes, drive technology transfer, and help ensure optimal returns on the Federal investment. Here are specific areas where the Federal government can play a crucial role in advancing engineering biology for the greatest public benefit:

- Sustained **Federal investment in foundational tools and research** would expand the biological toolkit to accelerate processes in health and medicine, as well as in other fields, and make entirely new applications possible;
- Interagency coordination would enable a **shared research agenda and vision** for achieving outcomes consistent with public values and priorities;
- Promotion of **industry-academic-government collaboration** is needed to align strategic research aims, spur economic development, promote commercialization of academic research, leverage private investment and encourage new start-up ventures;
- **Policy coordination and regulatory research and development capacity** is needed to address potential economic, security, safety, and environmental effects of engineering biology, establish regulatory jurisdiction, reduce regulatory uncertainty, and address ethical, legal and social concerns;
- **Education and leadership development** is needed to create tomorrow's practitioners, educators, legislators, and regulators, and a workforce that is diverse in socioeconomic background, discipline, and thought;
- Development of **public infrastructure**, such as libraries of genetic information and materials, core facilities for biological manufacturing, and practices for managing intellectual property, and establishing engineering standards, will provide the pre-competitive platform for innovators to thrive; and
- **Public engagement at the national level** is needed to educate, inform, learn, and engage in a robust debate about how to create science that is toward in the greatest public interest, and carried out in a transparent and just manner

In short, we need a national infrastructure that continues to support collaboration, constructive competition, and the production of tools and knowledge needed to responsibly and productively harness the capabilities of engineering biology. *The federal government's support for foundational tools and technologies are the real key to U.S. competitiveness.*

I have focused on health-related applications and synthetic chemical production today, but the potential benefits of synthetic biology are by no means limited to those sectors. Agriculture, materials, energy, and bioremediation all stand to benefit greatly from this advanced engineering and manufacturing platform. Indeed, the microorganism that we engineered to produce artemisinin is also being used to produce cosmetics and biofuels.

Just as the information age transformed life in the 20th century, so too the engineering of biology is poised to bring tremendous changes to society in the 21^{st} century. And we will be able to do it more quickly, more cost-effectively, and more precisely than ever before. But we must act quickly to put a national initiative in play; the role of the U.S. in the bioeconomy that results from the tools of synthetic biology will be determined by the actions of the federal government in the next five years.

Thank you for giving me the opportunity to talk to you about the remarkable potential of biological engineering, and the important role that it has to play in our nation's research and innovation enterprise. We cannot realize this potential, however, unless together we pursue a national initiative in engineering biology. Your actions and the support of Congress will determine whether the efforts described here today are ultimately successful. We stand ready to assist in any way we can as you explore and learn more about this exciting, game-changing research area.