



**Testimony
Before the
Committee on Energy and Commerce
United States House of Representatives**

**Advances in Synthetic Biology:
Significance and Implications**

Statement of

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Mr. Chairman and members of the Committee, thank you for the opportunity today to discuss the recent advance in synthetic biology made by Dr. J. Craig Venter and his colleagues at the J. Craig Venter Institute (JCVI), the potential practical applications of this advance, and the broader implications of synthetic biology. I am Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), the lead component of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), for research relating to infectious diseases, including research on the genomics of infectious microbes.

NIAID Research

NIAID supports research related to the basic understanding, treatment and prevention of infectious, immune-mediated and allergic diseases that threaten millions of human lives. NIAID-supported studies include basic research, such as microbial biology and physiology; applied research, including the development of medical diagnostics, therapeutics and vaccines; and clinical trials to evaluate experimental drugs and vaccines. We also conduct and sponsor research to understand the genomes of disease-causing microbes. A genome is the complete set of DNA (or in some cases, RNA) that contains the genes and instructions—a blueprint—for the maintenance, growth, and reproduction of an organism. Research fields such as genomics are creating a wealth of information about infectious diseases. Using advanced technologies,

researchers are developing a clearer understanding of infectious microbes, the mechanisms by which they cause disease, and the host immune responses necessary to prevent and control an infection.

NIAID has made significant investments in genomic-related activities that provide comprehensive genomic, functional genomic, bioinformatics, and proteomic resources to the scientific community for basic and applied research to rapidly address the Institute's mission and meet the public health preparedness needs of the United States and the world. NIAID-supported researchers have sequenced the complete genomes of hundreds of disease-causing organisms, defining the genetic blueprint for pathogens responsible for malaria, tuberculosis, and seasonal and pandemic influenza, among others. Data generated through NIAID-supported initiatives are rapidly made available to the research community. NIAID genomic programs not only provide the scientific community with valuable research resources, but also have enhanced NIAID research efforts in a number of areas including studies of the mechanisms by which microbes cause disease, and the development of drugs, vaccines, and diagnostics.

Although NIAID did not fund the work by the JCVI that we are discussing here today, we are supporting a number of investigators who are conducting research applying recombinant DNA technologies, genomics, and other related disciplines to study infectious diseases. Research on genomics and other advanced technologies supported by the NIH and other federal departments and

agencies—as well as private entities such as JCVI —will provide the knowledge that will allow further advances in the field of synthetic biology.

Synthetic Biology and Its Practical Applications

“Synthetic biology” can be defined a number of ways. Generally, it is considered to be the use of molecular biological techniques and chemical synthesis to mimic and even redesign natural biological systems. Advances in recombinant DNA technology and genomics, in a sense, represent the early stages along the continuum of synthetic biology and have laid the groundwork for the next frontiers of synthetic biology, which I will discuss later in my testimony.

In the early 1970s, the advent of genetic engineering using recombinant DNA technology revolutionized molecular biology. These technologies refer to techniques by which DNA molecules that code for a protein of interest are either cut out of another genome or, as technical advances occurred, are synthesized using the blueprint of a known genetic sequence. Then, by a variety of enzymatic techniques, these genetic sequences or genes are transferred into another organism. This modified organism then uses its own genetic capabilities together with the inserted gene to produce the protein of interest. These techniques of genetic engineering have been invaluable in biological and medical research, and have led to important, practical medical applications. In 1982, the Food and Drug Administration (FDA) approved the first medicine made by recombinant DNA technology—human insulin produced from a recombinant

strain of the bacteria *Escherichia coli*. In 1986, the first recombinant vaccine was approved by the FDA—a vaccine against hepatitis B virus.

As you know, last week Dr. Venter and colleagues announced that they were able to chemically synthesize the entire genome of *Mycoplasma mycoides* based on the known sequence of the microbe, replace the DNA from the bacterium *Mycoplasma capricolum* with this synthetic genome, and produce functioning bacterial cells that mimicked *M. mycoides*. This research is an important technical breakthrough in synthetic biology and our efforts to engineer and potentially synthesize novel microbes that are able to benefit humans and the environment. The potential practical applications of this advance are broad. Certainly, we hope that synthetic organisms might one day be used to create new biofuels. Organisms might be engineered to degrade waste and byproducts that are detrimental to the environment. Scientists might one day be able to create organisms that have a positive impact on agriculture and food production. And, there also are possible medical applications, including the production of biological products and vaccines.

While this is no doubt an important technical breakthrough and a leap forward for the field of synthetic biology, there is still much work to be done in this field. The researchers at JCVI took the known sequence of *M. mycoides*—its genetic blueprint—and were able to mimic it synthetically, but this effort was more complex and challenging than anticipated, occupying many talented scientists for

more than a decade at the cost tens of millions of dollars. One task ahead is the creation of a new blueprint—something that does not yet exist—that will perform the task that scientists ask it to do: sequester carbon dioxide, produce fuel, clean up waste, etc. The creation of a completely novel blueprint from scratch will be extraordinarily challenging because scientists are only beginning to understand all of the intricate circuits involved to put together such a blueprint.

Synthetic Biology and Its Broader Implications

As is the case with many of the genomic technologies that have been developed over the last several decades, synthetic biology technology potentially could be used to engineer microbes that are beneficial, but also to create microbes that may be harmful to humans and the environment. Such technologies that have both beneficial and potentially harmful applications are commonly referred to as “dual use”.

While the advance made by JCVI scientists potentially could be used by those who intend to do harm, we also must recognize that this was not a simple experiment; it was an extraordinarily complex project that took many years, people, and millions of dollars to complete. While there certainly is a chance that the technology developed by JCVI researchers might be used for nefarious purposes by those with extensive resources, it is important to point out that similar, albeit simpler techniques, are in widespread usage and are an integral and vital tool in life science research and science education, including high

school through post-graduate curricula. We also must keep in mind that nature itself is already an expert at creating microbes that can cause great harm to humans. This recent advance in synthetic biology does not necessarily bring us closer to harm's way than existing technologies or nature itself.

Dual-use technologies, including synthetic biology, have been the subject of active and ongoing discussions in the scientific community for many years, and Dr. Venter and his colleagues have been active and invaluable contributors to this dialogue. This dialogue involving a substantial number of scientists has taken place in national and international scientific bodies such as the U.S. National Academy of Sciences and the Royal Society, the United Kingdom's national academy of science. Advisory bodies to the federal government, such as the NIH Recombinant DNA Advisory Committee (RAC) and the National Science Advisory Board for Biosecurity (NSABB) also have played a major role in this discourse.

The RAC was established in 1974 in response to public concerns about the safety of manipulating genetic material through the use of recombinant DNA techniques. While the membership and responsibilities of the RAC have evolved with technology over the years, it continues to serve the NIH, as well as the scientific community and lay public, as a critically important forum for open, public deliberation on the scientific, ethical, and legal issues raised by recombinant DNA technology and its basic and clinical research applications.

The RAC first issued the NIH Guidelines for Research Involving Recombinant DNA Molecules (found at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html) in 1976. While compliance with the NIH Guidelines is mandatory for investigators at institutions that receive NIH funding for recombinant DNA research, the NIH Guidelines have become a universal standard for safe scientific practice in this area of research. Other federal agencies, such as U.S. Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs, have made compliance with the NIH Guidelines a term and condition of their awards. The NIH Guidelines also are followed voluntarily by many companies and other institutions not otherwise subject to their requirements. At its quarterly meetings, the RAC discusses research proposals that raise novel or particularly important scientific, safety, or ethical considerations. By helping to foster awareness and understanding of these matters among scientists, the RAC has fostered a culture of responsibility among the genomic sciences community.

In addition to the RAC, NIH also manages the NSABB, which was established in 2004 to advise the Federal government on strategies to minimize the risks and harm that could result from the malevolent use of information from legitimate research, i.e., dual-use research. The NSABB advises HHS on the efficient and effective oversight of federally conducted or supported dual-use biological research, taking into consideration national security concerns and the needs of the research community. The NSABB also provides advice on the interpretation

and application of federal guidelines on dual-use research in instances where a research institution seeks additional advice.

In addition to the dual-use implications, the recent advance in synthetic biology has broadened the range of organisms that may be developed, including those with entirely novel functions. As such, this advance raises broader societal and ethical concerns about this and future advances in this field. As such, the President has directed the Presidential Commission for the Study of Bioethical Issues to undertake, as its first order of business, a study of the implications of this scientific milestone, as well as other advances that may lie ahead in this field of research. The President has asked that the Commission consult with a broad range of constituencies and provide a report of its finding and recommendations within six months.

As I have described here, the Federal government has a number of existing committees and advisory bodies that have been discussing and will continue to discuss the risks and benefits related to this advance. The President has acted swiftly to ensure that more comprehensive discussions of its implications occur outside of the scientific community. In addition, the federal government will review its existing authorities to ensure that the current legal, regulatory, and oversight framework is sufficient to mitigate the risks associated with synthetic biology.

Conclusion

As discussed above, the advance announced by Dr. Venter and his colleagues is an important step forward for the field of synthetic biology. While it is important to ensure that we proceed cautiously with this technology and protect the public against its potential misuse, we also must take care to avoid any hasty response that would harm our scientific enterprise and hamper scientific progress. It is important that we do not act rashly and place undue restrictions on our best and brightest scientists that would prevent the United States from developing and utilizing this technology effectively and responsibly for the good of mankind in addition to competing effectively with other countries who will surely adopt these techniques.