

Frequently Asked Questions

Q: What is synthetic biology?

A: Synthetic biology is the name given to an emerging field of research that combines elements of biology, engineering, genetics, chemistry, and computer science. Synthetic biology – called “synbio” for short – joins the knowledge and techniques of biology with the practical principles and techniques of engineering. Achievements in synthetic biology rely on artificially created DNA to create new biochemical systems or organisms with novel or enhanced characteristics.

A major breakthrough in the field was announced in May 2010 by researchers at the J. Craig Venter Institute. The Venter Institute copied and modified an entire genome of a small bacterial cell, inserted it into a living cell of another species, and by doing so created a new, synthetic organism.

Q: What are some uses and applications of synthetic biology?

A: Synthetic biology offers opportunities to apply biological and engineering principles to benefit humankind in unprecedented ways. Clean energy sources, customized vaccines and targeted medicines, environmental cleansers, and hardy crops are some of the potential applications of this burgeoning field of science. While most of the fruits of synthetic biology remain in early stages of development, some applications are expected to come to market within a few years. And each new use will create jobs in the fields it touches.

Q: Why did the Commission take up synthetic biology?

A: President Obama requested that the Commission study synthetic biology. The Commission takes on projects either as a result of a direct request from the President or as a result of a Commission vote to initiate a new area of inquiry. The Commission was offered the perfect opportunity to highlight five principles to guide a socially responsible approach to *all* emerging biotechnologies: public beneficence, responsible stewardship, intellectual freedom and responsibility, democratic deliberation, and justice and fairness. The report’s recommendations are all guided by these ethical principles.

Q: Did the Venter Institute scientists “create life?”

A: No. In our deliberations, we heard that while Venter’s achievement marked a significant technical advance in demonstrating that a relatively large genome could be accurately synthesized and substituted for another, it did not amount to the “creation of life.” The researcher’s man-made genome was inserted into an already living cell. The synthesized genome itself was a variant of a genome of an existing species. The technical feat of synthesizing a genome for its chemical parts so that it becomes self-replicating when inserted into a bacterial

cell of another species, while significant, does not represent the creation of life from inorganic chemicals alone.

Q: What are the major findings of the synthetic biology report?

A: In all, the report contains 18 recommendations to the President. Our major recommendation is that the federal government, through the Executive Office of the President, start to coordinate and oversee what all Federal agencies are doing in the field of synthetic biology. We do not recommend that additional agencies or oversight bodies need to be created to oversee synthetic biology. But we do recommend that the government stay current on the advances with the science and remain forward looking about the potential benefits and risks to the public. We want all researchers – from clinical researchers to engineers – to go through ethics education. And we want to find ways to better educate the public about synthetic biology. One idea is to create a biology version of FactCheck.org, which would let the public sort through claims made about the science in order to figure out what is true and what isn't.

In addition, the Commission takes very seriously the principle of responsible stewardship. That means that we take responsibility for those who can't protect themselves. Our report on synthetic biology makes clear the obligation of the government to make sure that we're minimizing risks for our children and grandchildren regarding scientific advances that may occur in the future. We promote the idea of "prudent vigilance," advocating reasonable risk assessment strategies and charting a middle ground between extreme demands for complete proof of safety before permitting research, an idea often referred as "the precautionary principle," and calls for unfettered and laissez-faire scientific freedom in the absence of proven risks.

Q: What are the potential benefits?

A: We have an unprecedented opportunity in the emerging field of synthetic biology to do great good for the public. We see several possibilities on the horizon, in the areas that include speeding up vaccine development, creating medicines, and developing new biofuels as clean energy substitutes for fossil fuels.

Q: What benefits are likely to be seen soon?

A: One particularly promising example is developing a synthetic version of the antimalarial drug Artemisinin, which is an herbal treatment for parasitic infections and malaria. This is particularly important because the natural supplies of Artemisinin are limited, and this drug is the most effective one to fight malaria, especially severe malaria, around the world. If realized, this creation of a synthetic drug could save hundreds of thousands of lives each year.

Q: Are there major risks to synthetic biology?

A: At this time, no. All the experts who testified before the Commission agreed that any danger is far off in the future. But that is not to say that dangers won't ever happen. That's why the

Commission has opted for a moderate course. It is operating on the principle of “prudent vigilance.” It is advocating for ongoing federal oversight to make sure that if risks develop, the federal government will be prepared to respond to them.

Q: What kind of fears do people have about synthetic biology?

A. The biggest concerns we heard were about environmental and biodiversity risks from a release into the environment of an organism without adequate protections against proliferation, cross-breeding or crowding out of existing species. At this early stage of development, we found that the potential for harm through inadvertent environmental release of organisms of other bioactive materials produced by synthetic biology requires safeguards and monitoring.

Q: What do you recommend to address fears about threats to biodiversity and the environment?

We recommend that the government conduct an ongoing review of the ability of synthetic organisms to multiply in the natural environment and identify reliable containment and control mechanisms, such as “suicide genes” or other types of self-destruction triggers. A reasonable risk assessment should be carried out prior to any field release and include plans for staging release as necessary. The government, as part of a coordinated approach under the leadership of the Executive Office of the President, should ensure that regulators have adequate information to conduct risk analysis, undertake a thorough review to identify any gaps in current risk assessment practices, including pre-review of field release, and promote harmonization of these standards.

Q: What does the Commission recommend in regard to oversight of the DIYBiology movement – the do-it-yourselfers who often operate in small labs in garages or basements?

A: The Commission wanted to strike a balance here. We recognize that the DIY community is contributing to the field and we welcomed their input during our deliberations. It is very important for an open dialogue to exist between these groups and the government as we go forward. Presently there appear to be no serious risk of completely novel organisms being constructed in non-institutional settings like the DIY community. The technical challenges and costs are too high. The Commission recommends that the government continue to monitor this field through a coordinated effort under the Executive Office of the President, and in coordination with the Department of Homeland Security and others, periodically update its analysis and make public the results to the extent permitted by law. DIY scientists need to understand the constraints necessary to protect public safety and security. The Commission recommends that the government should continue to actively engage with these groups to communicate and discuss applicable limits.

Q: How do you propose to regulate people working in their home labs? Or, labs generally?

Today the Federal government has in place an array of protections to regulate safety and security in research laboratories and to protect against unauthorized access to dangerous pathogens. The Commission recommends that these provisions continue and that the government undertake an ongoing process to assess their effectiveness as the science of synthetic biology continues. At this point in time, these provisions appear adequate.

Q: What about moral objections to synthetic biology?

Flowing from the principle of responsible stewardship, the Commission observed that careful and deliberate attention should be paid to discussions of potential moral objections as the field advances. Such moral objections include concerns that synthetic biology may conflict with essential conceptions of human agency and life; that its overall impact may be harmful to biodiversity, ecosystems or food and energy supplies; and that it may fail to respect the proper relationship between humans and nature. The Commission devoted particular time and attention to discussing these possible moral objections during its deliberations. It heard relatively few objections from religious or secular ethicists concerning the present status of the field. Although the field currently is capable of significant but limited technical achievements, potential developments might raise further moral objections—for example, applications relying on the synthesis of genomes for higher order or complex species. Current objections to synthetic biology on moral grounds are often based upon concerns regarding activities that the field is currently incapable of carrying out. However, continued evaluation and efforts to reach and maintain consensus will be needed as this field develops.

Q: What are the next steps for synbio?

A: This report is just the start to a process. What happens now is continued public engagement on synthetic biology and engagement by the federal government on many levels. It is very important that we continue to hear the views of a range of people working on or interested in synthetic biology. In addition, the Commission has recommended that the government continually review the advances in synthetic biology as the science unfolds.

Q: What will the Commission do after the synthetic biology report?

A: The Commission will begin work on two new projects, one involving the ethics of genetic and neurological testing, and the other reviewing human subject trials to ensure that all people, internationally and domestically, who participate in these trials are protected from harm and unethical treatment. Following recent disclosure of U.S. government sponsored research in Guatemala from 1946 to 1948 that intentionally infected people with sexually transmitted diseases, President Obama charged Dr. Gutmann with convening an international working group to conduct a review of current standards for international human subjects trials. The working group will report to the Commission, which will determine if Federal regulations and

international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal government.