



PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

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Presidential Commission on Bioethics Calls for Enhanced Federal Oversight in Emerging Field of Synthetic Biology

In first report, panel identifies risks and benefits of pioneering research that could lead to new vaccines, drugs and biofuels; develops framework to evaluate emerging technologies

Citing uncertainty about risks, Commission urges enhanced coordination and transparency, ongoing risk analysis, public engagement, and stepped up ethics education for researchers

Washington, DC – The Presidential Commission for the Study of Bioethical Issues today released its first report—a wide-ranging review of the emerging field of synthetic biology—issuing 18 recommendations including a call for coordinated federal oversight of scientists working in both large institutions and smaller settings.

The panel, comprised of 13 scientists, ethicists, and public policy experts, said that the very newness of the science, which involves the design and construction of laboratory-made biological parts, gives regulators, ethicists and others time to identify any problems early on and craft solutions that can harness the technology for the public good.

“We comprehensively reviewed the developing field of synthetic biology to understand both its potential rewards and risks,” said Dr. Amy Gutmann, the Commission Chair and President of the University of Pennsylvania. “We considered an array of approaches to regulation—from allowing unfettered freedom with minimal oversight and another to prohibiting experiments until they can be ruled completely safe beyond a reasonable doubt. We chose a middle course to maximize public benefits while also safeguarding against risks.”

Dr. Gutmann said the Commission’s approach recognizes the great potential of synthetic biology, including life saving medicines, and the still distant risks posed by the field. “Prudent vigilance suggests that federal oversight is needed and can be exercised in a way that is consistent with scientific progress,” she said.

President Obama asked the Commission to study the implications of synthetic biology following the May 20 announcement by the J. Craig Venter Institute that it had inserted a laboratory-made genome into a bacterial cell, creating an organism not found in nature. In three public hearings held over the past five months in Washington, D.C., Philadelphia, and Atlanta, the Commission heard from over three-dozen ethicists, scientists and others close to the issue and considered a range of possible actions the government could take to prevent problems that might occur in the future.

Several experts explored potential benefits of synthetic biology, including the development of vaccines and new drugs and the production of biofuels that could someday reduce the need for fossil fuels. Discussions addressed the risks posed by the technology, including the inadvertent release of a laboratory-created organism into nature and the potential adverse effects of such a release on ecosystems. To reduce any possible threat, some scientists and ethicists advised careful monitoring and review of the research.

The Commission concluded that while the technical challenges of synthetic biology remain daunting, the field is likely to become more decentralized as the relevant tools become increasingly available and affordable—a change that may pose novel challenges with regard to oversight

“While the ‘Do-It-Yourself’ community has an important role to play in advancing synthetic biology, we recognize that technical challenges and costs are too high right now for a completely novel organism to be developed in a non-institutional setting,” said Dr. James W. Wagner, Commission Vice Chair and President of Emory University. “We strongly support an open dialogue between DIY groups and the government as we go forward so that scientists and government can discuss the research constraints necessary to protect public safety as the field continues to evolve.”

The Commission recommended the following steps in order to minimize risks and to foster innovation:

- The Executive Office of the President, possibly through the Office of Science and Technology Policy, should coordinate federal agencies that oversee areas related to synthetic biology, including oversight, product licensing and funding.
- Risk assessment activities across the government need to be coordinated and field release permitted only after reasonable risk assessment.
- The Executive Office of the President should remain actively engaged with “do it yourself” groups to communicate and discuss applicable safety and security issues.
- Recognizing that international coordination is essential for safety and security, the Department of State, in concert with the Department of Health and Human Services and the Department of Homeland Security, should collaborate with governments around the world, as well as leading international organizations, such as the World Health Organization to promote ongoing dialogue about emerging technologies like synthetic biology.
- The National Institutes of Health, the Department of Energy and other federal agencies should evaluate research proposals through peer-review in order to make sure that the most promising scientific research is conducted on the public’s behalf.
- Educational classes on the ethical dilemmas raised by synthetic biology should be a mandatory part of training for young researchers, engineers, and others who work in this emerging field.
- Forums should be established to improve the general public’s understanding of this field, including the creation of a biology equivalent to FactCheck.org, in which a private group would track statements about the science and offer an independent view of the truth of such claims.

Dr. Gutmann noted that the issues considered are relevant well beyond government officials and emphasized the value of informed public conversation regarding scientific research.

“The public, journalists, and policymakers need facts and reliable analyses to help them understand the benefits as well as the risks of new technologies,” said Gutmann. “To aid public understanding of emerging scientific issues, the Commission is recommending that an independent organization do for synthetic biology and biotechnology what factcheck.org does for politics—be an online resource to check the truthfulness of prominent claims and criticisms about new scientific discoveries and help spur informed discussion.”

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Embargoed copies of the report are available on request. Please email Jemma Weymouth: jweymouth@burnesscommunications.com.

The Presidential Commission for the Study of Bioethical Issues (PCSB) is an advisory panel of the nation’s leaders in medicine, science, ethics, religion, law, and engineering. PCSBI advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner. For more information about PCSBI, please see www.bioethics.gov