



PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Synthetic Biology

AGENCY: Department of Health and Human Services, Office of Public Health and Science,
The Presidential Commission for the Study of Bioethical Issues.

ACTION: Notice.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the emerging science of synthetic biology, including its potential applications and risks, as well as appropriate ethical boundaries to assure that America reaps the benefits of this new technology.

DATES: To assure consideration, comments must be received by October 1, 2010.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by email to info@bioethics.gov or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW, Suite C-100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Ms. Diane M. Gianelli, Director of Communications, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue, NW, Suite C-100, Washington, DC 20005. Telephone: 202/233-3960. E-mail: info@bioethics.gov. Additional information may be obtained by viewing the web site: <http://www.bioethics.gov>.

SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that assure ethically responsible conduct of scientific research, healthcare delivery, and technological innovation. In undertaking these duties, the Commission will identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for dynamic international collaboration on these issues, and recommend legal, regulatory, or policy actions as appropriate.

As its first order of business, the Commission has begun an inquiry into the emerging science of synthetic biology. The President asked the Commission to address this topic on May 20, 2010, following the announcement that the J. Craig Venter Institute had successfully engineered a synthetic cell – the insertion into a bacterium of a complete, functional genome synthesized entirely from a digitized sequence that replaced the native genome of the host over a series of replications. Daniel G. Gibson et al., *Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome*, SCIENCE EXPRESS (May 20, 2010). The President charged the Commission to consider any potential medical, environmental, security, and other benefits, as well as any related risks. Additionally, the President

asked the Commission to develop “recommendations about any actions the Federal government should take to ensure that America reaps the benefits of this developing field of science while identifying appropriate ethical boundaries and minimizing identified risks.” The Commission will report back its finding and recommendations later this year.

To begin its work, the Commission convened a public meeting in Washington, D.C. on July 8-9, 2010. At that meeting, representatives with expertise in science, ethics, and public policy, as well as advocates with diverse perspectives on this new field provided information and insight to help guide the Commission in its thinking. Leading scientists in the field created context for the discussion by explaining the state of the science and discussing possible applications. Among the anticipated benefits discussed were employing bacterial cells as microscopic factories in the production of pharmaceuticals and biofuels.

Additionally, with regard to potential risks, the Commission heard discussion about possible biosafety, biosecurity and environmental concerns, including risks that may arise as synthetic biology relies on organisms that can evolve and self-replicate, and existing practices to protect against these risks. The Commission also heard discussion about ethical boundaries and the views of faith communities.

As the approaches to, and applications of, synthetic biology proliferate, the Commission wishes to develop a multifaceted understanding of its scientific and technological implications, and learn more about the views of the public on the existing or potential ethical and social ramifications. To this end, the Commission is inviting interested parties to provide input and advice through written comments. Among other issues, the Commission is interested in receiving comments on the

potential benefits that the emerging field of synthetic biology is likely to yield, now or in the future, the risks that may arise, the ethical boundaries that should be considered, and policies and strategies to assure that the public will benefit from these new tools and products.

Please address comments by email to info@bioethics.gov, or by mail to the following address:

Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW, Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

DATED: August 17, 2010

Valerie H. Bonham

Executive Director, The Presidential Commission for the Study of Bioethical Issues