The Presidential Commission for the Study of Bioethical Issues

James W. Wagner, Ph.D., Vice-Chair

Presentation to the President's Council of Advisors on Science and Technology

January 7, 2010

The Presidential Commission
for the Study of Bioethical Issues

NEW DIRECTIONS

The Ethics of Synthetic Biology and Emerging Technologies

The Commission

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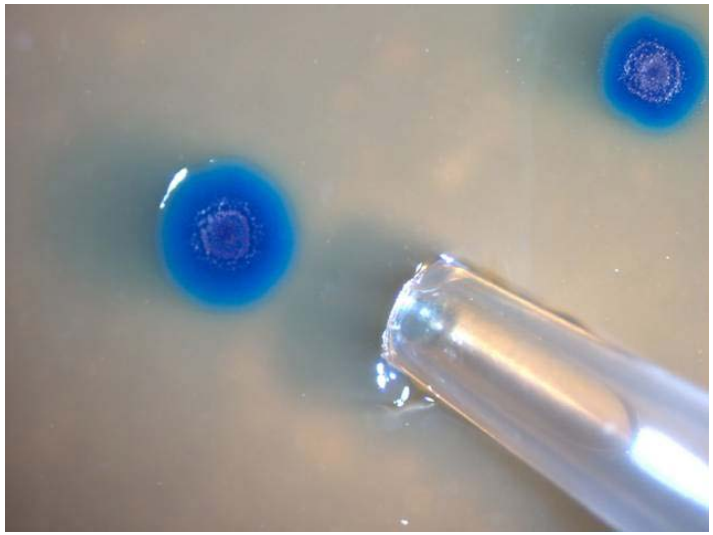
"Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome"



Gibson, D.G., et al. (2010). Creation of a bacterial cell controlled by a chemically synthesized genome. *Science* 329(5987):52-56.

Immediate Public Reaction

Synthetic life? Synthetic hysteria more like

Mail Online

Scientist accused of playing God after creating artificial life by making designer microbe from scratch - but could it wipe out humanity?

Was life really created in a test tube? And does it disprove biblical creation?

Request from President Obama
May 20, 2010

- Review the developing field of synthetic biology;
- Consider the potential medical, environmental, security, and other benefits as well as potential health, security, or other risks; and
- Identify appropriate ethical boundaries to maximize public benefits and minimize risks.

Overriding Goal

- To maximize public benefits while minimizing risks to the public.

Rare and Exceptional Opportunity

- To be forward looking instead of reactive.

Public Meetings

- July 8-9, 2010, in Washington, DC
- September 13-14, 2010, in Philadelphia, PA
- November 16-17, 2010, in Atlanta, GA

Developed Principles for Assessing *All* Emerging Technologies

- Public Beneficence
- Responsible Stewardship
- Intellectual Freedom and Responsibility
- Democratic Deliberation
- Justice and Fairness

Commission Findings

- Synthetic biology is a field in its infancy.
- At least three potential near term benefits:
  - More effective and efficient production of vaccines;
  - Environmentally friendly biofuel production; and
  - Ability to improve synthesized pharmaceuticals.
- Major foreseeable risks are still far off.
- JCVI work was not the “creation of life” as a scientific or moral matter.

Recommendations

- The Commission does not recommend creation of additional agencies or oversight bodies focused specifically on synthetic biology.
- Instead, the Commission urges the Executive Office of the President, in consultation with relevant federal agencies, to develop a clear, defined, and coordinated approach to synthetic biology research, development, and oversight.

Managing Potential Risks: Prudent Vigilance and Deliberative Democracy

- Establish a coordinated approach for risk assessment across the government that is ongoing as the science develops;
- Require a reasonable risk assessment or scientifically sound exception prior to field release; and
- Provide ongoing review of the ability of synthetic organisms to multiply or for genetic material otherwise to promulgate in the environment and promote reliable containment and control mechanisms.

Implementing Prudent Vigilance

- Ensure through coordinated process that synthetic biology advances to improve human health and public welfare;
- Put in place appropriate processes to identify, assess, monitor, and mitigate risks;
- Require reasonable risk assessment before field release; and
- Apply regulatory parsimony – restraint only as needed to mitigate identified risks.

Implementing Deliberative Democracy

- Expand public education and engagement on emerging issues in:
  - Synthetic biology, and
  - Science generally.

- Continue to engage with the wide range of people working on or interested in synthetic biology, including the DIY community.

The Presidential Commission for the Study of Bioethical Issues

The Commission respectfully submitted its first report to President Obama with 18 recommendations on December 15, 2010.

Thank you.