

Presidential Commission for the Study of Bioethical Issues

Nov 24, 2009 - Established within DHHS

The Commission shall **advise the President on bioethical issues that may emerge** as a consequence of advances in biomedicine and related areas of science and technology. The Commission shall pursue its work with the goal of **identifying and promoting policies and practices** that ensure scientific research, healthcare delivery, and technological innovation are conducted in an **ethically responsible manner**

Chair - Dr. Amy Gutmann (President, University of Pennsylvania)

Vice Chair - James Wagner (President, Emory University)

May 20, 2010- President requests commission to examine Syn Bio following Venter Institute publication re: synthetic genome in new host

Report & Immediate Reactions

(Dec 16 2010)

PCSBI Report & Press Release

NY Times Article

Response from FoE & others

PCSBI Report Summary

18 Recommendations

7 req ongoing govt review - action within 18 months

- EOP (OSTP) should coordinate fed agencies that oversee syn bio
- Risk assessment should be coordinate across govt and precede release
 - EOP should remain engaged with DIY re: safety, security
- DOS, DHHS, DHS, World Govts and Intl Org should promote dialogue on syn bio
- NIH, DOE and other agencies should evaluate research proposal through peer review
 - Ethics training should be required of all practitioners
- Public forums and fact-check mechanisms should be established by a private group

syn bio can proceed responsibly by embracing a middle ground between declaring a moratorium until all risks are determined and mitigated, and just 'letting science rip'

Five Basic Ethical Principles for Assessing Emerging Technologies

Public Beneficence

Responsible Stewardship - *Prudent Vigilance*

Intellectual Freedom & Responsibility - *Regulatory Parsimony*

Democratic Deliberation

Justice and Fairness

Prudent Vigilance: “Establishing **processes for assessing likely benefits along with assessing safety and security risks** both before and after projects are undertaken. A responsible process will **continue to assess** safety and security as technologies develop and diffuse into public and private sectors. It will also include **mechanisms for limiting their use** when necessary.” - PCSBI report

Regulatory Parsimony: “Recommending **only as much oversight as is truly necessary** to ensure justice, fairness, security and safety while pursuing the public good.” PCSBI report

Precautionary Principle: “When an activity raises threats of harm to human health or the environment, **precautionary measures should be taken even if some cause and effect relationships are not fully established** scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also **involve an examination of the full range of alternatives, including no action.**” - Wingspread Consensus

Recommendations - Promoting Public Beneficence

1. Public Funding Review and Disclosure**

...federal govt should undertake a coordinated evaluation of current public funding for syn bio, incl. ... risk assessment... &...ethical and social issues

2. Support for Promising Research

Advancing public good should be the primary determinant of ... public investment. [Funding agencies] ... should continue ...peer-review...

3. Innovation Through Sharing**

...EOP...should lead an effort to determine whether current research liscensing and sharing practices are sufficient...to promote innovation...

Recommendations - Promoting Responsible Stewardship

4. Coordinated Approach to Synthetic Biology

...no need to create additional agencies or oversight bodies..rather...the EOP
..[should] develop ... a coordinated approach to syn bio R&D... . A mechanism
or body should be identified to:

- 1) leverage existing resources by providing ongoing and coordinated reviews...
- 2) ensure regulatory requirements are consistent and non-contradictory...
- 3) periodically and on a timely basis inform the public of its findings.

5. Risk Assessment and Field Release Gap Analysis**

...EOP should convene an interagency process to discuss risk assessment
activities..[and] identify any gaps..in practices related to field release...

Recommendations - Promoting Responsible Stewardship

6. Monitoring, Containment and Control

...EOP should direct an ongoing review of the ability of synthetic organisms to multiply in the natural environment and identify, as needed, reliable containment & control mechanisms. For example, “suicide genes”...

7. Risk Assessment Prior To Field Release

Reasonable risk assessment should be carried out... prior to field release of research organisms or commercial grade products involving synthetic biology technology. This...should include...staging introduction or release...

Recommendations - Promoting Responsible Stewardship

8. Internal Coordination and Dialogue

...govt should act to ensure ongoing [intl] dialogue about emerging technologies such as syn bio...

9. Ethics Education**

...ethics education...should be developed and required for all researchers and student-investigators ...[EOP] should convene a panel to consider appropriate and meaningful training...

10. Ongoing Evaluation of Objections

Discussions of moral objections to syn bio should be revisited periodically ...[in] an iterative deliberative process...particularly if fundamental changes occur in the capabilities of this science and its applications

Recommendations - Promoting Intellectual Freedom & Responsibility

11. Fostering Responsibility and Accountability**

...govt should support a continued culture of individual and corporate responsibility and self-regulation...[EOP] should evaluate and re-evaluate...the effectiveness of current research mechanisms and determine what, if any, additional steps should be taken...

12. Periodic Assessment of Security and Safety Risks**

...At this time,risks posed by syn bio..appear appropriately managed...[EOP] should periodically update this assessment...

13. Oversight Controls

[If Rec 12 review identifies unmanaged concerns] the govt should consider making compliance with certain oversight or reporting measures mandatory for all researchers...

Recommendations - Promoting Democratic Deliberation

14. Scientific, Religious and Civic Engagement

Scientists, policy makers, and religious, secular and civil society groups are encouraged to maintain an ongoing exchange regarding their views ...

15. Information Accuracy

...individuals and deliberative forums should strive to employ clear and accurate language...A mechanism should be created...to fact-check...claims

16. Public Education

Education activities...should be expanded...[EOP] should identify and widely disseminate strategies to promote scientific literacy...amongst all age groups

Recommendations - Promoting Justice and Fairness

17. Risks in Research**

...[EOP] should lead interagency evaluation of current requirements and alternative models to identify mechanisms that ensure that risks of research in synthetic biology...are not unfairly or unnecessarily distributed...

18. Risks and Benefits in Commercial Production and Distribution

...[those using] synthetic biology for commercial activities should ensure that the risks and potential benefits to to the communities and the environment are assessed and managed...and are not unfairly or unnecessarily borne by certain individuals..[EOP] should evaluate current statutory mandates ..and should consider developing guidance materials and voluntary recommendations...

Summary - NY Times Article

- Points out that some recommendations call for “prudent vigilance”, but that synthetic biology already used for malarial drug and biofuel production
- Connection to Venter paper
- More than 50 groups from around the world believe risks should be better understood, regulations developed
- Drew Endy (“one of the most influential researchers in synthetic biology”) and Craig Venter (“whose work precipitated the commission’s study”) view report as good steps for the field

Who is Andrew Pollack?

- Business and science of biotechnology writer since 2000
- Technology writer for NY Times since 1981
- B.S. CEE (Princeton)
- M.S. CEE (MIT)

Summary: Response of FOE & Others

- *“These recommendations give industry a free pass, while failing to ensure that the environment and public health are protected. We need stronger, more transparent regulation for synthetic biology, not less.”*
- Reliance on suicide genes as means to mitigate environmental risk
unsubstantiated and unreliable
- Self-regulation = no regulation
- Long list of worldwide supporters

Friends of the Earth

- [www.foe.org]
- *“Friends of the Earth is a fierce advocate of scientific progress, but people must be put before profits, and we must take precaution to ensure new technologies don’t do more harm than good.”*
- Fight against GMOs, for clean energy solutions (*NOT* biofuels), for global warming solutions

Discussion

Thoughts on 'prudent vigilance' vs precautionary principle?

What does 'prudent vigilance' look like practically?

- what are your (ethical) responsibilities?
- what are the (ethical) responsibilities of others?

Proposal: (bi)weekly discussion group

Format: Up to you! (news & views, state of field, etc)

Suggest working in partners

Times: weds lunch?

YOU HAVE FIVE MINUTES TO ANSWER THE QUESTION
"WHAT IS THE FUTURE OF SYNTHETIC BIOLOGY?"

the world's first

SYNTHETIC BIOLOGY SLAM



TUESDAY, JUNE 14TH
7-10 PM

AT
STANFORD'S HUANG
ENGINEERING CENTER

CONTACT US AT
SYNBIOSLAM@GMAIL.COM
TO PARTICIPATE

BEER, FOOD, AND
MICROPHONE BROUGHT TO
YOU BY SYNBERC

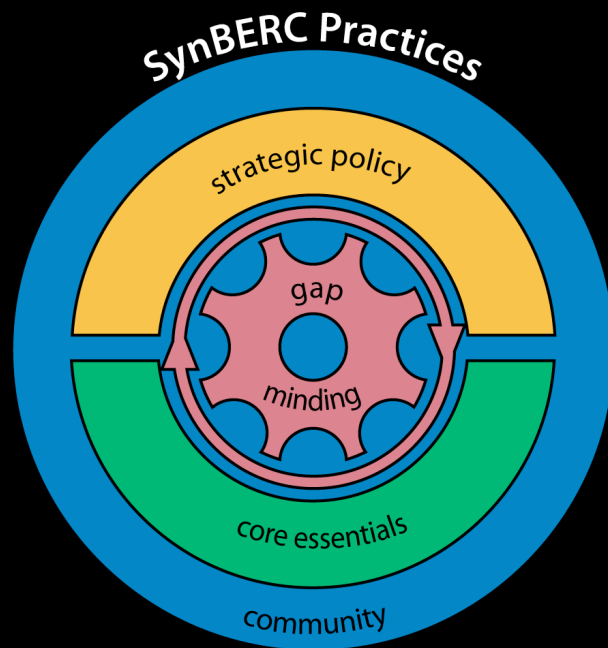
Bay Area Science Festival: Syn Bio Event



Oct 29-Nov 6 2011
Call for Proposals: April 18th

Currently Scoping Forum, Science Cafes, Activities
Let me know if you want to be involved!

SB Practices Working Group



First Meeting 4/6/2011

**15 ppl: Stanford, Berkeley, UCSF,
BioCurious, IDEO**

Next Meeting TBA

**Let me know if you would like
to be involved**