Societal Issues arising from Synthetic Biology: What Lies Ahead

A Department of Energy & Alfred P. Sloan Foundation Workshop Report

Workshop Objectives

- Workshop organized by DOE and Alfred P. Sloan Foundation hosted by the Woodrow Wilson Center
- Bring together synthetic biologists, policy makers, ethicists and social scientists to look forward and anticipate with a broad view what might happen to applications of biology in the

Workshop Structure & Methodology

- Prior distribution of paper on systemic risks, disruptive technologies and implications for governance
- Participant response to pre-workshop questions
- Are there lessons learned from the introduction of past technologies that may be pertinent to synthetic biology?
- Have you experienced or encountered any situations or conversations that presented you with any challenges arising from synthetic biology and society?
- What urgent ELSI research needs, arising synthetic biology, can you suggest?

- Plenary presentations: synthetic biologist, historical perspective on ELSI research
- Presentations of DOE and Sloan Foundation grantees working on societal impacts of synthetic biology
- Focused breakout groups:
  - likely first uses of synthetic biology and attendant societal issues
  - legal, public policy, and communication issues that may be expected to arise from synthetic biology research and applications
- Gap analysis: knowledge gaps that could contribute to a research agenda going forward

Meeting Synopsis

- Breakout session 1:
- What are the potential uses and applications of synthetic biology?
- What are the potential game changers (both inside/directly related to the science and technology, and outside)?

- Breakout session 2:
- Legal and economic:
  - controlling information like material? biopiracy
  - intellectual property - SB as a 'thing' vs. a toolkit
- Societal and public policy issues:
  - provision of objective information about underlying science needed
  - input from wide range of communities
  - initiatives required to bridge gap between communities of scientists, journalists, ethicists, those working in public policy
- Public understanding and engagement:
  - common understanding of what SB is needed
  - open discussion of potential benefits and risks
  - paternalistic approaches to engagement not meaningful

Meeting Synthesis

- Definitional issues: What constitutes synthetic biology and who belongs to the community of synthetic biology practitioners?
- Public engagement/communication to multiple publics, including religious groups, challenges articulated by practitioners
- What might a game changer look like in synthetic biology? New fuels, applications to human microbiome, environmental release, first success/first failure
- How should synthetic biology be regulated? How should it be funded? Can welfare concerns be part of the regulatory process? Regulatory and IP laws/approaches and their economics and social impacts need to be studied.
- How can ELSI be meaningfully used? Embedded or integrated? Measurable contributions? How can communication be fostered?

Gap analysis

- What important issues or questions do you think still need to be addressed in the field of synthetic biology as they relate to societal issues?
  - Legal and Economic
  - IP related
  - Public Policy
  - Public Engagement and Communication

Legal/Economic

- Anticipatory/adaptive governance and/or regulation - how to govern a fast-moving technology whose future directions, risks and impacts cannot be predicted in advance

- How to incorporate social, ethical, religious concerns into governance or regulatory structures?

- What should government involvement look like? Who should make decisions about what research directions to pursue? How should the DIY bio community be monitored/ regulated?

- How do we assess and frame progress (with metrics) in overcoming issues?

Intellectual Property

- Are there IP-related issues peculiar to synthetic biology and can (or should) the current patent system be altered to address them?
- What IP regimes for new "disruptive" technologies have worked "best" (in terms of technology dissemination, economic return, fairness) in the past and can we learn from them for synthetic biology?
- Is "open source" biology a better business model than alternatives involving more restriction?
- Does the current IP regime affect synthetic biology research in a way that promotes innovation or constrains it?
- How can the apparent historical conflicts between life scientists' approach to IP and ownership and engineers' approach to IP and ownership be resolved to the benefit of society?

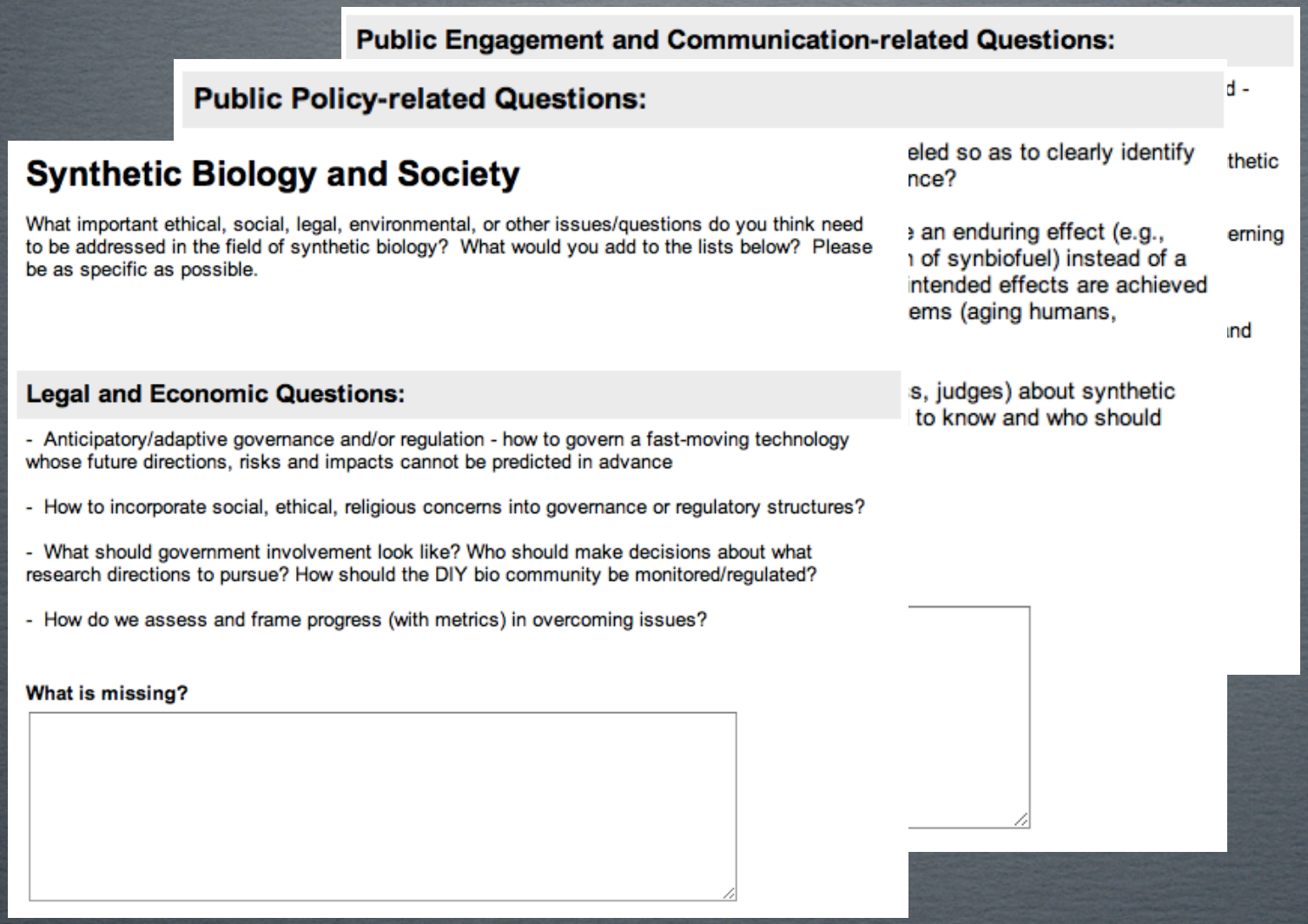
Public Policy

- Should the products/outcomes of synthetic biology be tagged or labeled so as to clearly identify their method of manufacture? How important is this for public acceptance?
- For potential synthetic biology applications that are intended to have an enduring effect (e.g., changing human microbiome, an environmental application, production of synbiofuel) instead of a short-term applications (flu vaccine, etc.) - how might one ensure the intended effects are achieved and unintended consequences are benign (or limited) in changing systems (aging humans, ecosystems etc.)?
- How best can we educate decision-makers (policy-makers, Congress, judges) about synthetic biology and more generally the culture of science? What do they need to know and who should influence the development of this "curriculum"?
- Can we come up with a clearer definition (of synthetic biology?)

Public engagement and communication

- How can the case for synthetic biology ELSI be forcefully, convincingly, persuasively stated - why it matters, why it is important?
- What are creative mechanisms for engaging both the "public" and the social and ethical synthetic biology communities in dialogue about opportunities/needs/values?
- How can the risk assessment process better engage the publics' differing views/values concerning risk? Can we foster an interdisciplinary "deep dive" on ethical and conceptual assumptions/ foundations of risk estimation and evaluations?
- With regard to synthetic biology communications what should be communicated to whom (and why) and who decides?

Please Add to this List



Public Engagement and Communication-related Questions:

Public Policy-related Questions:

Synthetic Biology and Society

What important ethical, social, legal, environmental, or other issues/questions do you think need to be addressed in the field of synthetic biology? What would you add to the lists below? Please be as specific as possible.

Legal and Economic Questions:

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What is missing?

On-line survey at: http://www.synbioproject.org/events/archive/what_lies_ahead/

Questions?
Comments?