

5 December 2006

## Response to “Synthetic Genomics: Options for Governance”

On December 4, 2006 a draft report on the governance of synthetic genomics was circulated. Entitled “Synthetic Genomics: Options for Governance,” the stated goal of the Sloan funded report is “to formulate governance options that attempt to minimize safety and security risks from the use of synthetic genomics while also allowing its development as a technology with great potential for social benefit.” Our response outlines strengths of the report and notes where more work is needed.

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The authors of this response are affiliated with the Synthetic Biology Engineering Research Center (SynBERC). For more information please see the last slide of this briefing and visit the SynBERC website at [www.synberc.org](http://www.synberc.org).

OVERVIEW Contents of this Response

I. STRENGTHS Challenges that the draft report identifies (3 slides)

II. LIMITATIONS Challenges that the draft report insufficiently addresses (3 slides)

III. NEXT STEPS Continuous Collaboration (1 slide)

## I. STRENGTHS Challenges that the Report Identifies

The report identifies three kinds of security challenges associated with synthetic genomics. This recognition of multiple kinds of problems is the report's principle strength.

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### 1. TECHNICAL INNOVATION

First is the expansion of dangers and risks connected to the intensification of synthesis technologies. The report frames these trends as technical issues of safety.

### 2. POLITICAL ENVIRONMENT

Second are changes associated with contemporary political environments, particularly new potential malicious users and uses, and increased access to know-how through the internet.

### 3. UNCERTAINTY

Third the report recognizes that there is a horizon of emergent challenges, which by definition cannot be fully known in advance.

## I. STRENGTHS Challenges that the Report Identifies

### 1. TECHNICAL INNOVATION

The first set of security challenges concerns intensification of existing dangers related to DNA synthesis. Recent innovations in synthesis technology vastly expand the capacity to produce ever larger specified sequences of DNA more rapidly, at lower cost, and with greater accuracy. These innovations raise the stakes of the so-called “dual-use” problem (the idea that technologies can be used both constructively and destructively) expanding existing fields of danger and risk. The relation between technical innovation and the expansion of danger has long been identified in the world of genetic engineering. Previously, these trends have been framed as issues of **safety**, which can be addressed through technical solutions. The report carries this framing forward.

### 2. POLITICAL ENVIRONMENT

The second kind of challenge that the report identifies concerns new political environments within which technical innovations are currently developing. These environments are characterized by two sets of distinct challenges: (1) a new range of potentially malicious actors and actions (i.e. terrorists/terrorism) must now be taken into account by those seeking to govern scientific domains, and (2) the internet and other new media provide global access to technological know-how and scientific knowledge; such global access cannot be addressed using existing models of nation-specific regulation. The report’s diagnosis equivocates as to whether new political milieus merely intensify existing challenges, or whether they produce qualitatively new problems that would require qualitatively new solutions. It is probably both. Either way, these challenges cannot be adequately dealt with through an existing frame of **safety**; but require a shift to a **security** framework. The significance of this shift will be explained in the “limitations” slides below.

## I. STRENGTHS Challenges that the Report Identifies

### 3. UNCERTAINTY

The third kind of challenge that the report identifies concerns uncertainty. By definition all scientific research is characterized by a measure of uncertainty with regard to whether its experiments will work and what it will discover. Likewise, the significance of research relative to security and ethics is undetermined. While some risks are presently understood, we lack frameworks for confronting a range of new risks which fall outside of previous categories. Such frameworks would need to be characterized by vigilant observation, forward thinking, and adaptation. Challenges related to uncertainty should be framed in terms of ***preparedness***. Unfortunately, while the report identifies the challenges associated with uncertainty, it fails to offer suggestions for response.

## II. LIMITATIONS Challenges that the Report Insufficiently Addresses

While *identifying* a range of security challenges the report addresses these challenges in only one frame.

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### 1. SAFETY

At the level of proposed solutions, the report works strictly within a **safety** framework, confronting dangers with technical safeguards. However, many of the most significant challenges related to synthetic genomics cannot be resolved in this way.

### 2. SECURITY

Whereas a **safety** framework operates within a logic of technological safeguards, a **security** framework additionally concerns challenges related to political environment. The options for governance proposed by the report, insofar as they address **security** matters, fold them into screening and licensing technologies.

### 3. PREPARED- NESS

While recognizing challenges related to uncertainty, the report offers no concrete proposals for developing frameworks for confronting such challenges. In distinction to **safety** and **security** such proposals will require a framework of **preparedness**.

## II. LIMITATIONS Challenges that the Report Insufficiently Addresses

### 1. SAFETY

As a technical term, “safety” means addressing dangers through safeguards and procedures. Framing the challenges of synthetic genomics as matters of safety, the report recommends development of screening and licensing techniques for controlling who has access to DNA synthesis, and the promotion of “best practices” among scientists. The emphasis is on prevention and protection.

These measures are valuable as far as they go. However, given the kinds of problems identified in the report, it should be clear that they are not sufficient. The report acknowledges that rogue scientists have ready access to the know-how if not the materials and technologies of DNA synthesis; what’s more, these scientists may not form part of the community that would adhere to best practices. Neither challenges related to new political environments, nor challenges introduced by uncertainty can be adequately addressed through the introduction of technical safeguards.

### 2. SECURITY

Whereas a **safety** framework operates within a logic of technological safeguards, a **security** framework additionally concerns challenges related to political environment. As noted, a strength of the report is that it *identifies* such challenges, namely, the ways in which, in a post-9/11 world, potentially malicious users and uses of synthetic genomics are more widespread and diversified (politically, geographically, culturally, etc.) than in past, and therefore cannot be addressed through existing regulatory mechanisms.

The options for governance proposed by the report, designed in a frame of **safety**, offer little for dealing with challenges of **security**.

## II. LIMITATIONS Challenges that the Report Insufficiently Addresses

### 3. PREPARED- NESS

A third way of framing challenges is ***preparedness***. As a technical term, preparedness is a way of thinking about and responding to significant problems that are likely to occur (e.g. a bioterrorist attack or the spread of a deadly virus), but whose probability cannot be feasibly calculated, and whose specific form cannot be determined in advance. In the face of uncertainty, a logic of preparedness highlights the need for vigilant observation, regular forward thinking, and ongoing adaptation. As with matters of ***security***, the report *identifies* challenges of ***preparedness***, but offers no concrete proposals for dealing with such challenges.



## III. NEXT STEPS

### COLLABORATION

As part of the emerging field of synthetic biology, synthetic genomics represents an innovative assemblage of multiple scientific sub-disciplines, diverse forms of funding, complex institutional collaborations, serious forward-looking reflection, intensive work with governmental and non-governmental agencies, focused legal innovation, imaginative use of media, and the like. It is to the credit of the report's authors that in preparing these governance proposals they invited the active participation of individuals from across this assemblage. The report's strengths are due in large part to this process.

The next step, however, demands movement beyond the "report" model of collaboration, wherein formal interaction ceases with publication. We maintain that the next challenge is to design and develop **continuous** forms of collaboration. To date, work on governance in science has consisted either of intensive, short term meetings aimed at producing guidelines or regulations, or standing committees whose purpose is limited to protocol review or rule enforcement.

What is needed today is mutual reflection on the significance of work being done in synthetic genomics, the environments within which that work is being done, and what problems might be on the horizon. The aim of such collaborative reflection would be to identify challenges and opportunities in real time, and to redirect scientific, political, ethical, and economic practice in ways that would, hopefully, mitigate future problems and actualize possible benefits.

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## SynBERC

The Synthetic Biology Engineering Research Center or SynBERC ([www.synberc.org](http://www.synberc.org)) is a multi-institution research effort to lay the foundation for synthetic biology, which aims to design and assemble biological components into integrated systems to accomplish specific tasks. Engineered biological systems have enormous potential to solve a wide range of problems in human health, industrial processes, and renewable energy and the environment.

## HUMAN PRACTICES

If successful in realizing its defining goals, SynBERC is likely to play a formative role in vital areas of contemporary life, such as energy, medicine, and security. As such, a major thrust of the SynBERC initiative examines synthetic biology within a frame of human practices, with reciprocal emphasis on ways that economic, political, and cultural forces may condition the development of synthetic biology and on ways that synthetic biology may significantly inform human security, health, and welfare. It includes both applied research modules under Kenneth Oye of MIT; and fundamental research modules under Paul Rabinow of the University of California at Berkeley ([www.synberc.org/thrusts](http://www.synberc.org/thrusts)).

## MORE INFORMATION

For more an expanded discussion of this response please contact Paul Rabinow, at [rabinow@berkeley.edu](mailto:rabinow@berkeley.edu), or Gaymon Bennett at [gaymon\\_bennett@yahoo.com](mailto:gaymon_bennett@yahoo.com)