

**Executive Office of the President
Interagency Committee on Synthetic Biology**

Monday, March 7, 2011

6:00 p.m. – 7:00 p.m.

**Arizona State University DC Center
1834 Connecticut Ave., NW, Washington, D.C.**

1. Purpose

On Monday, March 7, 2011, the Interagency Committee on Synthetic Biology will hold a hearing to explore citizens' views about research and development of synthetic biology— an area of scientific inquiry and technological development which harnesses techniques and methodologies from a variety of fields including genetics, molecular biology, information technology and nanotechnology, to design and develop complex biological systems that do not occur in nature.

2. Witnesses

- Virginia: Esha Maharishi and Becky Baik
- Maryland: Michael Nguyen and Brianna Buch
- District of Columbia: Monica Liu and Kaylee Yocum

3. Overarching Questions

- How do you define synthetic biology? How is it different from genetic engineering? Metabolic engineering? How much time do we have to deliberate over this definition in order to determine what to do about synthetic biology in terms of funding, regulation, and monitoring? Years? Months? Weeks? Or is it already too late? How will your response change if there were (a) major scientific breakthrough like creation of synthetic life, (b) major human casualties like from an accidental release of a synthetic virus, and (c) major global economic crisis like sustained spike in price of crude oil?

4. Background

The Executive Office of the President is developing a strategy document that it wishes to present to Congress, which proposes to accelerate, with appropriate attention to social, environmental and ethical risks, the pace of current research and development in certain areas of synthetic biology.

Following considerations have contributed to this decision:

- The Presidential Commission for the Study of Bioethical Issues concluded that the likelihood of creation of life through research and development in biology and genetics still remains remote. With the moral and ethical issues surrounding the creation of life

being temporarily set aside, the commission found it realistic to expect that over time research in synthetic biology will lead to new products for clean energy, pollution control, and more affordable agricultural products, vaccines, and other medicines.

- The failure of the 111th Congress to enact comprehensive legislation in the areas of energy and climate change makes the prospect for a bi-partisan consensus and legislation on these issues extremely unlikely in the foreseeable future.
- A National Survey conducted by the Woodrow Wilson Center for Scholars show that by two to one, Americans believe synthetic biology should be allowed to move forward with a focus on uncovering possible effects on humans and the environment.
- Responding to continuing economic malaise, declining tax revenues, rising healthcare costs, and political pressures to reduce the federal budget deficit through deep cuts in spending, the President is pivoting his budgetary strategy from stimulus spending to a cut-and-invest agenda where he is proposing to slash spending in some domestic programs to both reduce deficits and make room for increases in education, infrastructure, clean energy, innovation and research to promote long-term economic growth and global competitiveness.

In the past three weeks citizens groups from the States of Virginia and Maryland and the District of Columbia had deliberated with each other and with experts in the field about the prospects, potentials, uncertainties and challenges associated with the research and development of synthetic biology. They had a chance to listen respectfully to each other, review publicly available information, and obtain answers to their questions directly from experts in the field. Reflecting on these deliberations they have formed a set of recommendations about how the research and development of these emerging areas of science and technology should or should not be governed.

5. Questions for Witnesses

Witness from Virginia:

- Research and product development must be carried out in a way that is safe for researchers, the public and the environment. The Federal government regulates these activities to maximize safety. At the same time, it is thought by many that such regulations slow or impede research and may have a chilling effect on investment in research that is heavily regulated. In the case of products intended to promote and protect health, there may also be a personal and public cost to slowing their development. Is it possible to measure the burden or slowing of such research? And, if so, can the opportunity cost of delayed product commercialization be balanced against the potential benefits? Should such considerations be factored into the regulatory process?

Witness from Maryland:

- As synthetic biology advances technologically and scientifically, and becomes easier and thus a more commonly used “toolkit” for biological science, it can be expected to leave the relatively controlled environment of formal academic, industrial or government biolabs and be practiced more widely in less controlled and supervised places (the “Do-It-Yourself” or DIY phenomenon). What are the dangers of DIY biology and what restraints or controls (if any) would you accept as necessary and appropriate for DIY activities that would not unduly constrain innovativeness?

Witness from District of Columbia:

- What do you think should be the role of the general citizenry as we continue to make advances in synthetic biology? If, when and how should they engage with those who fund, regulate, shape, research, develop, publicize and critique this emerging field of science and technology? Do you think participatory processes and citizens deliberations with experts and stakeholders can make useful contributions to this process? Why or why not?

OFFICIAL TESTIMONY

Synthetic biology is the engineering of biological systems and processes. Using this definition, genetic engineering and stem cell research are not separate from synthetic biology, but rather subcategories. Synthetic biology includes creating organisms from a bank of parts, altering living organisms, and creating new organisms from scratch.

We choose to give a very broad definition in order to appropriate funding for research that may overlap different fields, some of which may not be covered under a more narrow definition of synthetic biology. Because this is an emerging field, it is likely that breakthroughs will occur along blurred lines, and with broad funding, research that overlaps these fields will be facilitated.

Though it is important to have a preliminary definition of synthetic biology, it should be fluid and open to change as new research and findings arise. The preliminary definition given should be used to determine the scope of funding and to provide a guideline for policy-makers.

As the Presidential Commission for the Study of Bioethical Issues has already made recommendations regarding synthetic biology, it is evident that some actions have been taken without a specific definition. However, the preliminary definition can and should be used for all future actions. Past actions should be brought into line with any new definitions, if possible. For example, if appropriations have been made for synthetic biology in the past, the appropriations should be rectified at the next available opportunity.

Though providing funding for basic and applied research will lead to many possible benefits, there are also significant risks that need to be considered. For example, the release of engineered organisms could have myriad unexpected effects, such as the destabilization of ecosystems. Furthermore, synthetic biology could be weaponized. For these reasons, at least at first, we should impose strict regulations on synthetic biology. Of course, we expect that regulations will have a detrimental effect on the rate of progress in the field. It would be very challenging to measure the slowing of research in a quantitative way. We do, however, have good intuition about how certain regulations will affect the speed of research, and can make qualitative judgments about the impact of regulations.

Some might argue that regulators should be blind to the benefits of the research they are regulating if they are to make good decisions. However, the benefits of synthetic biology are too great to ignore, and policymakers should consider the negative impacts of the regulations, however well-intentioned they may be. We must try to balance risk and benefits. For example, let's say that in our extreme over-cautiousness, we halt research in synthetic biology. Other countries, however, beyond the legislative reach of Washington, could easily continue ground-breaking and potentially dangerous research. Without a knowledge base in synthetic biology, we would not only lack the ability to be competitive, but also the ability to defend against dangers from outside.

As we move inexorably towards a future in which artificial organisms will be increasingly significant, questions such as these will continue to be important, and will no doubt be revisited countless times before they are resolved.

Executive Office of the President: Inter-agency Committee on Synthetic Biology Maryland Group Testimony

Members of the citizen panel include Brianna Buch, Ritu Dwivedy, Michael Nguyen and Kate Shipman. The group held deliberations on Wednesday, March 2nd. The testimonies below solely reflect the opinions of group members.

An Evaluation of Overarching Questions

A definition would be useful in order to determine policy, but it is not necessary. Synthetic biology has been in effect for a long period of time, yielding promising results without any catastrophic instances; synthetic biology research has not been hampered due to a lack of a definition. Regarding funding, federal, and legal issues a definition of synthetic biology would be useful, however, there is no time to excessively deliberate on a definition. Waiting for a concrete definition instead of furthering research and regulation can have possible detrimental effects in the field.

We adhere to the definition put forth by the Presidential Commission for the Study of Bioethical Issues, namely “to apply standardized engineering techniques to biology and thereby create organisms or biological systems with novel or specialized functions.” With this understanding, we believe the defining factor of synthetic biology to be the novelty of the biological parts, devices and systems produced. Synthetic biology itself is not a new field of science, but the applications of it are. Rather, synthetic biology is an extension of previously existing fields. It is on the extreme end of the biological engineering continuum which includes genetic and metabolic engineering.

Should an advance such as synthetic life, or a catastrophe or a crisis occur, our definition of synthetic biology does not need to change. However, the regulations and safety precautions will need to be reevaluated.

Response to Questions Concerning “Do It Yourself” (DIY) Synthetic Biology

We believe that DIY synthetic biology comes with its share of dangers and that restrictions should be placed on “garage research labs.” First off, it’s very expensive to do research on one’s own. If people want to do research themselves, they must adhere to stringent regulations that are on par with current research regulations for regularly functioning research labs. Even if people wanted to do DIY synthetic biology, it’d be incredibly difficult because of the high degree of funding which is necessary in order to carry out biological research.

One danger of DIY synthetic biology is the possibility of accidental introduction of biohazards to the environment and the creation of an invasive species. One way to prevent the harmful effects of a potential invasive species is the requirement of a suicide gene and/or the inability of the organism to live outside of lab conditions.

Potential forms of regulation for DIY synthetic biology include gaining research approval before experimentation and the monitoring of purchase of materials; an ideal state for DIY synthetic biology would allow for heavy regulation with licenses and permission necessary to buy materials and execute research.

Recommendation- Washington DC Citizenry

Prepared by Akaash Gupta, Peter Hansen, Monica Liu, and Kaylee Yocum

We, as the group of citizens representing Washington DC, are here to present our recommendations to the panel of intergovernmental agencies assembled here today. We agreed upon the following definition for the field of synthetic biology, which we will use when referring to this field: The creation of a novel species by manipulating genetic information. This shows the key difference between synthetic biology and genetic engineering, which is that genetic engineering does not result in the creation of a novel species. In addition, our group views metabolic engineering as a subset of genetic engineering, so this definition applies for both fields. This definition is a working definition, so as more research becomes available, a better and more specific definition can be developed. In terms of funding for synthetic biology, we have time to deliberate over this description of synthetic biology because funding is based on individual projects, so a general definition is not necessary to determine whether these projects acquire funding. We believe that the government should not stop funding for synthetic biology because we do not have a definition. Although it is true that a more refined definition will be needed for regulation and monitoring, more research needs to be done in order to come up with a better definition, so funding should continue, even in the absence of stringent regulation and monitoring tools. Based on our deliberations, we came to the conclusion that we as a country have several years before an official definition is required. We also discussed various scenarios that could change our definition. If there was a major scientific breakthrough in the field, the definition would not change, except to further refine it. If a synthetically created organism was released into nature, causing human casualties, the definition would need to be broader to ensure that more projects are covered by regulation. A major economic crisis, like a spike in oil prices, would not change our definition, but would cause focus to shift in the field to projects that could alleviate the problem. The definition of synthetic biology is not permanent, and we have the time to refine the definition to cover these scenarios.

For synthetic biology to be a successful and accepted research path, the public must be educated on the breakthroughs and issues that occur. In addition, scientists and policy experts should make an effort to reduce reliance on media coverage of synthetic biology to ensure that the public gets reliable and unbiased results. Citizens should have an opportunity to interact with experts and have a hand in making decisions, especially if a piece of legislation is to be considered. At the present stage, however, general deliberations are more likely to be more beneficial for the education

of the public than the policies themselves, but a basic level of education should be required for the public to participate in these discussions. Prior to participating in these discussions, the citizens who wish to participate should be given reading on background information of synthetic biology as well as the policies currently in place and the proposed policies to be put in place. Experts in the scientific aspect of synthetic biology and policymakers should be designated discussion leaders for these deliberations. These discussion leaders should ensure that reading material is placed online in an easily accessible location so that all public participants can arrive at deliberations prepared. The meetings would allow the public to feel involved in the process of policymaking, and some of the ideas presented at such meetings should be taken into account. Findings from these meetings should be released to the general public in a publication following each meeting. Otherwise, the public should be able to access accurate information about developments in synthetic biology through an annual “State of the Sciences” address and public service announcements. Though we appreciate the availability of open deliberations on the topic of synthetic biology, we worry that until we begin discussing specific projects and piece of legislation, the deliberations are purely educative. More targeted, in-depth discussions would help involve the public in decision making and foster a sense of political activism.

Synthetic biology is a rapidly burgeoning field of science with great potential for success, but also great potential for disaster. In order to promote the success and mitigate the disaster, we must ensure that the best possible policies be enacted. These suggestions presented here are our basic recommendations in the pursuit of synthetic biology research. These recommendations are not final, and any policy that is set in place should be revised and monitored to ensure that it is kept up to date on the developments in this area of research.