December 6th, 2011

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[redacted]

Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Re: OSTP Request for Information: *Building a 21st Century Bioeconomy*

Dear Office of Science and Technology Policy,

I am a Postdoctoral Scholar in the Department of Bioengineering at Stanford University and serve as the Deputy Director of the Practices Thrust of the NSF Synthetic Biology Engineering Research Center (SynBERC). This response to the OSTP's Request for Information on *Building a 21st Century Bioeconomy* focuses on the role that synthetic biology and its practitioners can play in shaping the bioeconomy. Synthetic biology tools and techniques - when developed alongside an understanding of their societal ramifications - offer tremendous potential to accelerate the development of a bioeconomy that improves livelihoods in the US and abroad. Specifically, the recommendations herein focus on **critical needs to develop people, programs and places for addressing gaps in creating sustainable biotechnological solutions for economic, social and environmental needs.** These recommendations reflect views collected and developed via my continued interactions with SynBERC-affiliated researchers and partners in academia, industry and other organizations, in particular members of the SynBERC-supported Synthetic Biology Practices Working Group (SBPWG). The SBPWG, which I lead, is a diverse group of synthetic biology community members interested in advancing best practices for the responsible development of biotechnology. We strongly support your efforts to develop a national bioeconomy blueprint and urge you to consider integration of these recommendations and approach us for additional consultation.

SynBERC, the SBPWG, and the synthetic biology community at large, strive to enable predictable, reliable, sustainable and cost efficient engineering of biological systems. Synthetic biology tools and techniques – including standardization of parts and processes for genetic engineering, creation and characterization of novel biological functions, and design of synthetic organisms – can drive the industrialization of biology for existing and new application areas. Developing these technologies in concert with an advanced understanding of the factors affecting how technologies manifest in the world will inform design and implementation that is more efficient, effective and well-matched to areas of need and opportunity.

Synthetic biology is now starting to deliver on its promise. For example, recently we have seen the development of a bacterium with a synthetic genome by the J. Craig Venter Institute, the

production of an antimalarial drug precursor via engineering of yeast metabolic pathways by Amyris Inc., the distribution of free-to-use sequence and functional expression information for collections of standard genetic elements by the BIOFAB, and the use of standard genetic parts to design and build living systems by over 160 undergraduate teams at the yearly international Genetically Engineered Machine (iGEM) Competition. Yet these and similar achievements continue to raise many challenging questions about how biotechnology can be effectively channeled to create economic, social and environmental value. For example:

- What application areas are most economically viable for developing and deploying biology-based alternatives to current manufacturing platforms?
- What are appropriate criteria for evaluating safety and efficacy of new 'intrinsic containment' strategies – such as the use of non-natural genetic codes – across various application areas?
- What property rights structures for uses of genetic functions might best support innovation?
- What are effective and appropriate strategies for proactively identifying and responding to potential dual-use biotechnologies in early stages of research design and implementation?

Answering these types of questions – and many others – requires a **systemic promotion of interdisciplinary training, research and development efforts**. I outline three critical areas for which we can develop support for interdisciplinary inquiry – **education (people), research (programs), and venues (places)** – but emphasize that all three areas are inherently coupled and mutually reinforcing.

People: Interdisciplinary Education and Training in Bioengineering and Interacting Disciplines

Effective development of a bioeconomy will require technology leaders able to cross traditional disciplinary boundaries to address opportunities and confront challenges which have non-technical dimensions. Until biotechnologies establish more rigorous standards of practice, much of the emerging bioeconomy workforce will continue to train in American research universities, largely at the graduate level. Currently there is little exposure within university training to practices in technology development beyond academic labs that could equip practitioners to effectively frame their work with a translational focus. We cannot expect researchers to inform their design to meet anticipated needs for production and scale-up, or provide advice on high-level policies for biotechnology, without themselves or their mentors receiving training or exposure to real-world criteria and practices.

We advocate promotion of university programs in bioengineering that leverage existing expertise in industry and government, and increase interactions with other disciplines. We would also encourage opportunities for students in other disciplines, such as law, business and social sciences – to learn about biotechnology. A bioeconomy blueprint should encourage and facilitate the restructuring of relationships to prepare students to creatively, strategically, and responsibly develop biotechnologies.

While there is no single solution, there are many existing strategies that can be further developed to bridge educational gaps:

Professors in Practice: University faculty positions targeted at veterans of industry and government that can provide complementary teaching and research project advisement alongside traditional academics
Internships / Co-ops: Undergraduate and graduate fellowships / programs requiring internships in industry and/or government
Interdisciplinary Programs: Graduate fellowships / programs targeted at interdisciplinary research (e.g. bioengineering alongside economics, law, ethics, risk management, etc.)
Design Courses: Undergraduate and graduate design courses in which teams of students from across disciplines work on projects solicited from, and advised by, industry clients
Short-Courses in Topics of Practice: Workshops engaging practicing scientists and engineers on topics complementing their work, such as science and technology policy
Bioengineering for Non-Bioengineers: Outreach programs introducing bioengineering principles to students outside of bioengineering to engender future interdisciplinary research opportunities
Professional Societies and Accreditation: Creation and support for organizations developing professional standards and accreditation in bioengineering practice
International Students: Visa and immigration reform allowing the US to attract and maintain the best young minds from around the world

There is also a complementary need to develop appropriate metrics and critical success factors to be used to evaluate the effectiveness of these programs in preparing students for diverse career paths.

Programs: Funding Interdisciplinary Research and Facilitating Industry and Government Partnerships

Solutions to pressing challenges in biotechnology development often remain unaddressed because they fall between interdisciplinary boundaries and require input from partners outside academic institutions. Many barriers exist to effectively pursuing interdisciplinary work within universities, including the simple fact that most academic researchers, as outlined above, are never trained to frame interdisciplinary problems. They are therefore not likely to value, nor engage in, interdisciplinary pursuits independently, or inspire their students to do so. Furthermore, many of these potential research problems don't fit squarely within current funding programs, disciplines, or academic departments. We recommend promoting research funding programs, and institutional restructuring, which incentivizes collaborations between researchers with complementary disciplinary expertise, and partners from industry and government. These programs would examine biotechnology development from a comprehensive engineering systems perspective. We also recommend exploring opportunities for facilitating public-private partnerships, including evaluating successes and challenges within existing programs (such as NSF ERCs) designed to engage industrial partners in framing projects towards a translational focus. Specifically, there is a need to evaluate the effectiveness of these programs for developing 'horizontal' technology platforms versus 'vertical' application areas for biotechnology.

Places: Venues for Interdisciplinary Collaborative Research Programs

Enabling interdisciplinary and translation-oriented research requires venues which co-locate heretofore disparate researchers and partners to effectively collaborate to frame and work on projects. Venues would ideally bring academic, industry and policy practitioners together to rapidly prototype the development of biotechnologies as well as the practices and policies

coupled to their successful translation. The BIOFAB, located at the Joint BioEnergy Institute (JBEI), provides one example of an innovative approach in which a professional team of researchers are piloting the development and dissemination of free-to-use sequence and functional expression information of standardized genetic architectures. The BIOFAB team must confront not only technical challenges, but also challenges relating to standards, property rights, business models, industry partnerships, and security. The National Labs provide fruitful places to build upon existing expertise in mounting large coordinated projects, and should therefore be examined for missed opportunities to build partnerships with industry, and create closer ties with policy experts.

Through promotion of coordinated efforts enabling interdisciplinary training, research and development across these three critical areas – people, programs and places – I strongly believe we can more effectively realize a *21st Century Bioeconomy*.

Please feel free to contact me for clarification or further comments.

Sincerely,

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Acknowledgments: Members of Synthetic Biology Practices Working Group (SBPWG) made significant contributions to this letter, including notably Joshua J. Wolf, Andrew Chang and Jay W. Vowles, all in the Department of Bioengineering at Stanford University.