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Dr. Kelvin Droegemeier, Director
White Office of Science and Technology Policy
Via email: MBX.OSTP.WHBioeconomy@ostp.eop.gov

Dr. Droegemeier,

Boston University appreciates the White House Office of Science and Technology Policy's interest in advancing a prosperous U.S. bioeconomy.

BU is home to research leaders in the fields of synthetic biology, infectious disease, and neurotechnology, all of which are critical to the bioeconomy. In responding to your Request for Information, we often provide specific examples for these research fields.

BU's Biological Design Center is at the heart of the fast-growing synthetic biology discipline. Synthetic biology uses basic biological "building blocks" to create fundamentally new cells, organisms, and biological functions not found in nature. The creation of designer biological systems and technologies is transforming products ranging from therapeutics to agricultural solutions, and BU researchers are leading change in the production of biofuels, automating biological design for large-scale applications, and engineering human cells to treat disease.

BU's National Emerging Infectious Diseases Laboratories (NEIDL) is a Biosafety Level 4 facility dedicated to protecting the nation's health and security from threats such as Ebola and Marburg. Following the 9/11 attacks and anthrax mailings, the NEIDL was one of two BSL4 biocontainment laboratories built on an academic campus in order to leverage the unique expertise of university researchers. NEIDL researchers contributed to the effort to diagnose, treat, and prevent Ebola virus infections abroad.

The BU Neurophotonics Center is at the forefront of the advances in neuroscience and photonics (the study of light) that are allowing us to better understand how the brain works in health, as well as brain disease and injury. Combining these scientific disciplines in novel ways is guiding new diagnostic and therapeutic strategies.

Our responses are as follows:

1. What specific actions could the U.S. Government take to reinforce a values-based ecosystem that will guide the transformation and expansion of the U.S. Bioeconomy, in both the short- and long-term? Please consider:

a. Policy or regulatory opportunities and gaps throughout the continuum of basic science translation, product development and commercialization.

In order to support technology transfer between academic researchers and the private sector, the government should act to strengthen patent protection, especially as it relates to patent claims for diagnostic products. The STRONGER Patents Act pending in the U.S. Senate would be an example of this.

b. Scientific areas where research funding could be strategically targeted to stimulate discovery.

The most important thing the federal government can do is focus on basic research, because paradigm-shifting research always comes from undirected scientific work.

The U.S. is currently the leader in synthetic biology. However, other countries in Asia and Europe are not too far behind. In order for the U.S. to maintain its leadership, the federal government must ensure ample funding for synthetic biology from basic research to commercialization. In particular, there is an urgent need for more funding that focuses on the development and applications of synthetic biology to biomedical problems. Most of this funding currently comes from DARPA. However, DARPA funding alone is not robust enough to support a large-scale bioeconomy.

Synthetic biology spans many disciplines, and consequently, many federal scientific agencies. The federal government can lead a coordinated effort to identify research areas that can be widely impactful across different fields (e.g., energy, health agriculture), recognizing that advances in one application area will benefit others. A concerted effort would also allow the U.S. to carefully navigate the expectations that both the American public and our global partners have for ethical conduct of synthetic biology research.

The BRAIN initiative set the stage to capitalize on the explosive advances occurring now in neurophotonics. Policymakers should consider a next generation BRAIN initiative and continue to dedicate funding for neuroscience fields, including neurophotonics, past the currently planned expiration of the BRAIN initiative in 2025.

c. Novel public-private partnership mechanisms.

The government should increase its investment in proof of concept centers, especially in emerging, fast-moving fields such as gene editing, synthetic biology, and regenerative medicine. The government should incentivize the private sector to support proof of concept centers through both private dollars and human capital, such as mentoring, need-validation, and the creation of milestone-based plans.

Further, the federal government should provide funding for the space between academic proof of concept and proof of application/product, bridging the funding gap between what federal research grants and corporate entities support. For example, policies or funds could incentivize industry to secure gap funding in order to drive a better connection between basic research and product development. Earlier funding from industry to academic entities could de-risk and bridge this gap. Alternatively, government or industry (with government incentives) could fund product development and management professionals, tools, platforms, and facilities in academic settings to efficiently move innovations into development.

d. International opportunities;

The federal government should support international engagement with foreign biocontainment laboratories working to address infectious disease. It is in everyone's interest to make sure these facilities are safe and secure, and that the research they conduct is done transparently. Forging international partnerships will allow us to share our biosafety expertise and create research collaborations that reduce the risk of accidental release or purposeful misuse of dangerous pathogens.

2. In what ways can the U.S. Government partner with the private sector, industry, professional organizations, and academia to ensure the training and continued development of a skilled workforce to support the growth of the Bioeconomy? Please consider:

a. Potential needs and solutions at the skilled technical, undergraduate, professional master's program or graduate level.

At the graduate level, training grants, such as those at the National Institutes of Health, are an excellent mechanism for growing the bioeconomy workforce and seeding a holistic training environment for the next generation of scientists. For example, these grants could support interdisciplinary programs that combine biology and computer science and/or engineering, as well as academic initiatives that train students at the intersection of these two fields.

Additionally, the federal government should consider novel mechanisms for supporting graduate student internships in industries at the forefront of bioeconomic development, such as synthetic biology, regenerative medicine, bioinformatics, and neurotechnology. For example, training grants that include short-term work stints in industry for doctoral students will allow them to evaluate whether they wish to pursue private sector or academic work following the completion of their Ph.D.

BU was one of 17 institutions who received an NIH Broadening Experiences in Scientific Training (BEST) grant in 2014. Through the BEST program we developed an evolving Ph.D. curriculum relevant to workforce needs and exposed life sciences doctoral students to a range of careers relevant to the bioeconomy (regulatory science, government, scientific communications, etc.). We are continuing the program past the expiration of the five-year grant.

At the K-12 level, we should strive to expose students to emerging bioeconomy fields well before they reach college or graduate school. For example, it is possible to learn some of the basics of engineering biology in high school, but most schools do not offer the opportunity.

b. Specific needs within basic science, translational research, product development, and commercialization;

The federal government should invest in training programs that educate doctoral students and postdoctoral researchers about the commercialization process. We need a new class of entrepreneurial scientists who can translate discoveries in synthetic biology, neurophotonics, regenerative medicine, and other fields into impactful products, technologies, and services.

In basic science, it is difficult to sustain long-term research lab talent within academic labs because federal funding does not support senior scientists or personnel focused on product development and management. Federal funders should consider broadening the type of scientific personnel who can be supported by a research grant.

With regard to translational research, the federal government should support team science that brings together basic and clinical researchers across and within institutions. Funding collaborative research, including industry as a collaborative partner, will improve the likelihood of translation.

c. Approaches for the development of non-traditional, multi-disciplinary educational backgrounds that address the convergent nature of emerging technologies and integrate core values including safety and security.

The federal government should support training and apprenticeship programs specifically geared towards work in biosafety containment laboratories, such as the NEIDL. These facilities require uniquely trained personnel who have extensive understanding of biosafety procedures and can pass background checks administered by U.S. security agencies. In addition to trained scientists, the labs need building engineers, safety officers, service personnel who are able to repair and maintain specialized equipment, and administrators who can meticulously keep the detailed records required by regulatory agencies. Most universities maintain their own training programs for this work since there are few available commercial offerings, adding to the cost of doing research.

3. In what ways can the U.S. Government partner with the private sector, industry, professional organizations, and academia to establish a more robust and efficient Bioeconomy infrastructure? Please consider:

a. Current infrastructure—from databases to world-class technology and manufacturing capabilities.

To support synthetic biology, the government can help create an environment that is conducive to standards development, building computer infrastructure, and distributed, automated bio-manufacturing

facilities. These efforts may need to be initially subsidized until their wide-adoption helps to justify the initial development costs.

To successfully address infectious diseases, the U.S. needs sustained funding for the maintenance and operation of the biocontainment labs created to increase our understanding of dangerous pathogens. We should view this funding as an investment in critical national infrastructure, just as we do for the nation's road and bridges.

4. Across the spectrum, from basic discovery to practical application, what data policies, information-sharing mechanisms, and safeguards will be necessary for a prosperous U.S. Bioeconomy? Please consider:

a. Scientific, regulatory, manufacturing standards and/or benchmarks and/or best practices around data that should be developed to best accelerate Bioeconomy growth;

It would be helpful to have a dedicated study section at the NIH for the field of synthetic biology in order to properly evaluate synthetic biology standards, technologies, and practices. In addition, the government could substantially support the field of synthetic biology by continuing to streamline the regulatory process for new therapies, particularly those that might involve engineered biological vectors, materials, cells, or combinations.

b. Possible safeguards for technology, data, and emergent products, such as patent/intellectual property protection, data quality and provenance validation, and privacy and security assurances.

The creation of multiple, independent, parallel data collection efforts has the potential to slow the growth of the bioeconomy. Ad-hoc and short-term databases do not allow for robust data sharing and may even pose data security problems.

Fortunately, the NIH has done important work to standardize data policies and information mechanisms. The federal government should continue to support the creation of sustainable, stable, and secure research databases that enable long-term data set storage, data sharing, and querying. Further, the federal government should recognize that investments in cybersecurity will also benefit the bioeconomy.

Again, thank you for the opportunity to provide Boston University's input on advancing the U.S. bioeconomy.

Sincerely,

Gloria Waters

Gloria Waters
Vice President and Associate Provost for Research

cc: President Robert A. Brown
Provost Jean Morrison