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CLYDE L. BRIANT
Vice President for Research

December 6, 2011

The Honorable John P. Holdren
Director
Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Dear Dr. Holdren:

Brown University appreciates the opportunity to comment on the Office of Science and Technology Policy's (OSTP) Request for Information (RFI) on the National Bioeconomy Blueprint. We believe this is a vital and timely national effort complemented by local efforts around the country.

We are witnessing the development of a successful bioeconomy right here in Providence, RI, spurred primarily by the research and the people emerging from our 12 institutions of higher education as well as through the involvement of the area's affiliated teaching and research hospitals. While there is already a significant amount of activity in the bioeconomy field, we are poised in Rhode Island to encourage greater progress in years to come if we make decisions wisely. The focus for this expansion is the Jewelry District in downtown Providence, formerly the world capital of jewelry manufacturing. This district which includes hospitals, Brown University's medical school and several of its research buildings, many emerging companies, and, importantly, developable land is in the process of being transformed into a Knowledge District with a locus of bioengineering, life sciences, health care, and green technology research. Where workers once made watchbands, scientists from Brown University and colleagues at other universities are now conducting research that will not only change lives but influence our understanding of the nature of life itself. They are investigating causes and processes of aging in human cells; examining the relationship of protein modification and abnormalities in cell structure to the development of disease; exploring links between cancer and chronic irritations caused by asbestos and other pollutants; and seeking affordable, universally accessible vaccines against AIDS, tuberculosis, West Nile Virus, and other infectious diseases.

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Biological research is the very foundation from which the bioeconomy must build its success, and any blueprint must incorporate an aggressive and robust research portfolio to bolster efforts to expand the bioeconomy. Earlier this fall, Brown University helped host a technology showcase to launch a Life Sciences hub for the state of Rhode Island. At the showcase, thirteen Rhode Island-based life science companies were selected to make brief presentations to a room packed with more than 250 attendees, more than 30 percent of who represented industry. Several other companies presented at the poster session. Over fifty licensable and/or collaborative projects were presented at poster sessions. The research that underlies these companies and promising technologies was performed at institutions across the state and with federal, state, and private funding. The event attracted entrepreneurs from Rhode Island and the region, venture capitalists, and scientists who were drawn together to learn about promising lifescience opportunities in RI and the emerging biomedical local and regional ecosystem.

Brown University is home to many of Rhode Island's leading biological sciences research initiatives. Two sites for the National Children's Study, an important and long term NIH-funded effort to improve the health and well-being of children, are led by Brown faculty in collaboration with Women and Infant's Hospital. Brown, in partnership with IBM, built a unique platform and public-private partnership, the Ocean State Consortium of Advanced Resources (OSCAR). OSCAR, with over fifty partner organizations, is a social infrastructure serving all sectors, disciplines and organizations and builds capacity to address RI's most challenging problems across health, energy, environment, and education. For example, OSCAR supports an effort, *Greening the Knowledge District,* that assesses the energy use and recommends strategies for sustainable development of the emerging Knowledge District where much of our growing bioeconomy activities are occurring and will continue to expand. OSCAR also supported regional partners in a successful application for a Broadband Technology Opportunity Program (BTOP) that will not only connect researchers regionally to accelerate their efforts but also this award will provide an estimated 200 jobs in the region.

The RFI on the National Bioeconomy Blueprint asked about six specific areas. Brown's comments in the areas relevant to the University's work are below.

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Grand Challenges

We believe there is not just one bioeconomy; it has many layers from international trade and commercialization, to regional efforts, to the local university. Addressing grand challenges requires an interdisciplinary approach, with input from individual researchers to large multidisciplinary centers. We recommend that grand challenges be identified through a fully interactive process involving Federal agencies, academia, and industry (similar to the process used to establish the National Academy of Engineering Grand Challenges for Engineering). Also, we recommend exploiting existing networks, such as the Rhode Island Life Sciences hub and OSCAR, to coordinate university, industry and non-profits to maximize the impact and address grand challenges. With its small size and existing collaborative networks, Rhode Island represents an ideal location for pilot projects within the bioeconomy blueprint.

Research and Development

Under this theme the RFI posed questions about priorities for high-impact research and innovation in a time of constrained Federal budgets. Brown University believes that traditional life sciences and basic research must be included in the bioeconomy blueprint. These provide the foundation for future innovation and train the future bioeconomy workforce. We recommend complementary approaches that include both single agency and multidisciplinary, multi-agency programs. For example, at Brown a National Institute for Environmental Health Sciences Superfund grant (initial award in 2005 and renewal in 2009) has supported a number of investigators from the traditional basic biology and engineering departments, and also has engaged researchers from the social sciences in support of its mission to address and resolve the scientific, engineering, and societal issues arising from the reuse of hazardous waste sites in Rhode Island. From this umbrella grant, our faculty have successfully competed for single-investigator funding opportunities from NSF, NIH, EPA, and state funding.

Also at Brown, our National Science Foundation-funded Institute for Computational and Experimental Mathematics is located in the same building as our Public Health Department and within proximity to the Rhode Island hospital system's core research facilities, as well as Brown's new Alpert Medical School building and a core molecular biology research facility in Knowledge District. This location leads to potential collaborations on issues such as gerontology research that brings together the extensive experience and expertise in clinical, basic science, and community-based research and Brown University and its teaching hospitals. Rhode Island, with its small scale and

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population and collaborative environment, is a great national platform for longitudinal studies to probe genetic and environment causes and determinants of health and disease. Additional multidisciplinary programs that support formal collaborations like this one would be high-impact and further accelerate ongoing federal efforts like the National Children's Study.

The Science of Massive Data initiative at Brown University is another program that supports the abovementioned multidisciplinary studies, as well as research on critical technical challenges that will accelerate bioeconomy-related research such as the specific question of how to deal with the overwhelming amount of DNA sequence information available to scientists. The explosion of data and data sources presents a grand research challenge in data-centric analyses, modeling, visualization, and information fusion. Tackling the data challenge will accelerate the learning curve, advance technologies and open new discipline-based pathways to explore data and translate it into innovative ideas and solutions. This Brown initiative develops partnerships between academia, government, and industry to advance innovative data-driven technologies and drive novel research and education models (including workforce development) to close the data to knowledge gaps.

Moving Life Sciences Breakthroughs from Lab to Market

<u>Barriers preventing translation of research discoveries to commercial markets</u>

The Bayh-Dole Act very effectively provides a legal framework for innovation at US universities to be captured, developed and turned into commercial products. By enabling academic institutions to control their intellectual property resulting from university funded programs and by providing universities with the legal authority to enter into exclusive licenses, the Act has been spectacularly successful at stimulating the development and commercialization of countless products. Especially at a time when economic forces are requiring large companies to scale back or even eliminate their internal research and development endeavors, products and technologies acquired by licensing are becoming increasingly important and even critical components for the commercial enterprise. Indeed, a significant proportion of drugs, medical devices and other commercial products developed over the last 20 years were based on developments and inventions made at research universities in the United States.

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Moreover, the number and magnitude of alliances between research universities and industry has increased over the last 20 years, thereby augmenting and leveraging the government's funding of basic research. These relationships are often based on patented inventions from university research.

Barriers that can prevent biological research discoveries from moving from the laboratory to commercial markets and that could represent areas to implement significant improvements include the following:

Education and training – University faculty often lack working knowledge about intellectual property and therefore do not recognize the potential commercial implication of their own work. The implementation of dedicated educational programs for students and faculty to teach and reinforce innovation and commercialization values would launch a mechanism to create a culture of innovation. Such programs would improve the wide capture of valuable intellectual property by stimulating disclosures and creative thinking on commercial development and focused, practical translational goals. At Brown, our masters program in Innovation Management and Entrepreneurship is one way we are educating students in this important area.

Collaborative agreements – Critical to a successful program for the translation of basic research discoveries from the academy into the public sector is the implementation of practices that reflect that discoveries from universities are very often early stage. Accordingly, agreements for commercialization often need to be flexible to ensure rapid and effective translation into the public sector. Risk-sharing and co-development types of structures should be considered that serve the function of being more palatable to industrial partners from the financial perspective, while mitigating the risk of licensing early stage innovations. If the technology results in a successful outcome the university and inventors can enjoy in the upside.

Bridging the development gap and lack of risk capital – Early stage technologies often encounter the so-called "development gap". In this case the mechanisms and initial insights might have been established in the academic laboratory using government funding, but additional proof of concept work is required before capital can be attracted for a start-up and/or a licensing partner to be brought on board. Funding for such translational work is sorely needed. Further, because early-stage investment in such programs is difficult to secure, government funded "venture" funds, perhaps with a longer-term horizon than traditional venture capital would be very advantageous.

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Suggested changes to SBIR and STTR programs for acceleration of commercialization of federally-funded research

The SBIR and STTR programs have been quite successful in providing critical funding for early stage companies to launch programs, expand their capabilities and develop products. Several concrete suggestions to improve the successful commercialization include the following: (a) allowing such grants to fund "pre-companies" – that is, to fund translational proof of concept work either at a university or contract research organization (CRO) in advance of a company being formed. (b) using a portion of funding under the SBIR/STTR program so that it is paired with outside (independent) business expertise. Thus, early stage companies would be treated to business review, assistance with focus on business/commercial goals and critical path, and ultimately have better access to capital.

Challenges associated with private-sector models for financing entrepreneurial bioeconomy firms

One of the principal challenges with currently available private-sector financing models is that the expected rates of return are sufficiently high that so-called "singles" and "doubles" (i.e. programs that might lead to innovative products, though not blockbusters) are not attracting investment. Although programs might be innovative and potentially satisfy market needs, they might not be big enough winners to be within the investors' rate of return spectrum. In addition, bio-science technologies take a long time to develop to fruition, so funding needs to have a long-term horizon. The Federal government should consider implementing programs to mitigate risk such as matching funding from the private sector (angels and/or venture capital funding).

Workforce Development

Brown University believes training for scientists and engineers should explicitly foster skills needed for the bioeconomy workforce. These skills include the ability to work in diverse teams that straddle expertise areas and disciplines, innovative thinking oriented around solving real-world problems, and communication with non-scientists. The National Science Foundation Integrative Graduate Education and Research Traineeship Program (IGERT) is an example of a Federal graduate training program that encourages mentorship, career development, hands-on experience with innovation, and translating research discoveries to solutions for societal challenges. These best practices should be

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expanded beyond the frontier interdisciplinary programs that IGERT supports to graduate training across the life and physical sciences and engineering.

Brown currently holds two IGERTs and a PIRE (Partnerships for International Research and Education) and so can attest first-hand to the value of these programs in developing the next-generation workforce of scientists and engineers. Two of these grants (the IGERT "Reverse Ecology: Computational Integration of Genomes, Organisms, and Environments," and the PIRE, "Millennium Village PIRE") are collaborations with the Marine Biology Laboratory (MBL) at Woods Hole, thereby providing our students opportunities to work with a diverse team of world-class scientists at both Brown and MBL. The second IGERT, "Development and Inequality in the Global South," draws on the University's strengths in social sciences to address key issues facing the world's growing population.

The Rhode Island EPSCoR is another positive workforce development program. It is led by a team of University of Rhode Island and Brown researchers and is focused on promoting collaboration and cooperation among the Rhode Island's institutions of higher education, including the Rhode Island School of Design (RISD). RI EPSCoR seeks to align its efforts with the needs of the state to increase research competitiveness, especially in marine life science and affiliated sciences. It does this with investments in infrastructure (specifically shared equipment) and education at the undergraduate and graduate student level.

Also, scientists and engineers in both academia and industry will need appropriate awareness of the interdisciplinary research questions central to the bioeconomy. It will be critical to train biological scientists with highly-developed quantitative skills as well as physical scientists and engineers with appropriate awareness of challenges in the life sciences. Also, programs that support network creation, workshops, travel, and summer programs for researchers are useful to raise awareness across scientific communities about science at the interface between disciplines. Fellowships that allow students to spend part of their graduate careers working in industry or other sectors help create networks between academia and industry, foster real-world learning, and provide students with greater understanding of workforce opportunities beyond the lab.

To promote commercialization of research breakthroughs, we recommend the government provide supplements to research grants if appropriate commercialization opportunities can be developed. For instance, the latest Department of Commerce i6 Green Challenge is a worthy initiative to spur the creation of proof-of-concept centers.

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We applaud funding for these types of centers but recommend that government and matching funds be available to support the development of commercial ventures, not just research teams from not-for-profit organizations. To help technologies get to the marketplace, proof of concept centers must be able to fund new commercial ventures once the innovation has "transferred" from the not-for-profit university laboratories.

To accelerate the commercialization of technologies within Rhode Island, Brown provided seed money to start the Rhode Island Center for Innovation and Entrepreneurship (RI-CIE), a collaborative state-wide effort to cultivate technology entrepreneurship. It helps Rhode Island-based entrepreneurs, researchers, and existing companies create, grow, and evolve new and sustainable technology ventures; promote commercialization of research and technology rising out of academic inquiry; and contribute to the state's economic benefit. RI-CIE has held over 200 educational and networking events in two years drawing over 5,000 attendees. RI-CIE supports an active network of close to 50 early-stage ventures. During the last two years, companies supported by RI-CIE have raised $8 million in public and private investment or grants. However, long-term support for RI-CIE is difficult to secure given the narrow focus of many federally commercialization programs.

Reducing Regulatory Barriers to the Bioeconomy

Brown University strongly encourages a streamlining of the regulatory requirements associated with Federal funding to universities through a revision of OMB Circular A-21. This action is timely and important, not just in reducing the burden faced by our researchers and staff, but also in recognizing the duplicative and wasteful nature of the current compliance environment.

We specifically call attention to the Council on Government Relations (COGR) and Association of American Universities (AAU) recommendations for elimination, or appropriate revision, of the current effort reporting requirements. At Brown, the burden associated with effort reporting spreads across a number of departments and divisions, involving both staff and faculty. In the central administration, 1.75 FTE's are dedicated to monitoring 31,000 effort reports annually costing approximately $145,000.

COGR and AAU have pointed out the duplicative nature of subrecipient monitoring. Entities funded by the Federal government, and subject to OMB Circular A-133 and to various compliance assurances (e.g., participation of human subjects, use of animals) are nonetheless required to also monitor each other when collaborating on research

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through subawards. At Brown, the labor intensive work of seeking audit reports, F&A agreements, and subrecipient profile questionnaires from over one hundred subawardees (who are already providing the identical information to their own auditors) is a tedious, labor intensive effort for no substantial benefit to the government or to the research partnership.

In order to assure the most effective and productive investment of Federal research dollars the duplicative and wasteful use of those resources, as well as those of university partners in the research enterprise, must be resolved. The substantial costs of effort reporting, and the redundant oversight required by subrecipient monitoring, should be eliminated. The government should conduct a careful review and reconsideration of excessive and repetitive financial reporting mechanisms such as ARRA, FFATA, and the proposed DATA Act (H.R. 2146), among others, as these mechanisms promise extraordinary additional data gathering and reporting burdens with very little real benefit for the government or the public.

Public-Private Partnerships

As mentioned above, the scale and collaborative environment of Rhode Island fosters successful public-private partnerships. Many of our most successful endeavors, like the Ocean State Consortium for Advanced Resources (OSCAR) and the Rhode Island Center for Innovation & Entrepreneurship (RI-CIE) described above, have at their core a public-private partnership. OSCAR and RI-CIE are excellent examples of regional collaborations of higher education, private industry, state and city leadership and members of the local communities. Both of these examples effectively draw leadership, funding, and human resources from the community to support their efforts and are making major contributions to the innovation ecosystems. Sustained, multi-year federal funding vehicles for the basic operations of these types of initiatives can significantly improve their effectiveness to act as catalysts for multi-institutional, public private partnerships.

These public-private partnerships also can be an effective means for the government to learn about barriers to commercializing technologies. OSCAR and RI-CIE have and will continue to play a major role in providing input and advancing discussions on policies and regulation related to intellectual property management, data transmission, patient safety, and privacy issues.

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Thank you again for the opportunity to comment on the RFI for the National Bioeconomy Blueprint. Brown University looks forward to a strong partnership with you in this endeavor and we are happy to provide further details or clarifications on any of our suggestions.

Sincerely,

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