

**Office of Research
Center of Excellence for Regenerative Health
Biotechnology**

13706 Innovation Drive
Alachua, FL 32615

November 28, 2011

The White House
Office of Science and Technology Policy
bioeconomy@ostp.gov

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

Dear Sirs,

I strongly support President Obama's initiative to develop a National Bioeconomy Blueprint.

The University of Florida's Center of Excellence for Regenerative Health Biotechnology (UF CERHB, <http://cerhb.ufl.edu/>) is a biomedical translational research support center with the mission to stimulate promising research and facilitate first-in-man studies, leading to commercialization of technologies that will provide treatments for human diseases, as well as create new companies and high-wage jobs.

We are positioned at the interface between industry and academia to provide expertise, training programs, and drug manufacturing services to the biotechnology industry and to biomedical research institutions.

Established with state and federal funding (US Dept. of Commerce EDA), our 23,500ft² cGMP biopharmaceutical development operation (Florida Biologix[®], <http://www.floridabiologix.ufl.com>) offers a wide range of affordable biopharmaceutical manufacturing and testing services. We have manufactured over 50 product lots since 2007, including cell and gene therapies and proteins expressed in mammalian cells, and provide aseptic filling, product testing, and regulatory support. Products made in our facility are suitable for Phase I and II human clinical trials, offsetting common barriers of bringing laboratory discoveries to the clinic, such as the high operating cost of cGMP compliant manufacturing and regulatory expertise. Client sponsors include Florida companies, start-up companies, multi-national and foreign companies, domestic private and public companies, academic scientists, and the NIH.

The UF CERHB Education and Training Center (http://cerhb.ufl.edu/education_index.html) was established as a biotechnology education resource to prepare a technical and knowledge-based workforce to support the growth of the biotechnology industry. We have brought together elements needed for a fully integrated biotechnology education program. Developed with deep industry involvement, our curricula are focused on fundamental science applied to biotechnology product development, manufacturing process development, analytical technology development, regulatory compliance, and commercialization. Hands-on STEM-based curricula with a focus on Industrial Biotechnology were developed at the college and high School levels (funded by NSF).

In anticipation of these new course offerings, the UF CERHB submitted a 3-year curriculum in industrial biotechnology to the Florida Department of Education, which approved the coursework for both academic and Career and Technical Education (CTE) credit in December, 2006. Offered for the first time in the Fall of 2007, the program now spans the state with over 900 students currently enrolled. Teacher training programs were also developed by the UF CERHB to provide district certification for teaching the CTE component of the secondary program, and to assist teachers in the preparation of teaching science and its tools, as a means of discovering, developing, and testing products for use in humans and commercial sale. An industry-recognized credentialing exam was created and is administered by the UF CERHB (funded by US DOE OVAE/Florida DOE), as a mechanism for graduates of the secondary program to demonstrate mastery of bio-industry based skills and knowledge for employment, or for statewide articulation into post-secondary A.S. degree biotechnology programs. We have found that framing basic science concepts in the context of their application to product development and careers in the biotechnology industry engages the students at a level that motivates them to succeed.

To address immediate and emerging workforce needs, hands-on curricula in Industrial Biotechnology were developed (funded in-part by WorkForce Florida, Inc.) for entry-level and incumbent workers. Additional courses continue to be developed as the industry grows and matures in Florida. An Advisory Council has been assembled comprised of leaders from industry, workforce boards, and economic development agencies from across the state. Industry focus groups, a needs assessment, and surveys have been conducted to determine the needs of Florida companies. Based on this input, highly relevant short courses that combine classroom and wet lab training have been developed, each of which leads to an industry-recognized certificate. These courses were rolled out in 2007, and we now have over 300 graduates. Furthermore, a novel Masters Program titled “Science Master’s Program in Translational Biotechnology” was established in 2010 (funded by NSF). It is a two-year program that is interdisciplinary (biosciences and business), is research intensive, has industry involvement, and includes a formal internship at a company. Students will graduate with a major (Master of Science in Medical Sciences) and a minor in business administration (Graduate Business Minor), well prepared for immediate employment in mid-level industry positions

UF CERHB has established an extensive support and participation network including companies, research institutes, professional societies, industry organizations, chambers of commerce, materials and equipment suppliers, business development boards, community colleges, school districts, regional workforce boards, and international research collaborators. These partners are motivated to work with UF CERHB to implement the programs and services statewide, nationally, and internationally. I feel that we have built high quality programs that can be replicated throughout our country, and may serve President Obama’s initiative well.

Establishing active private-public partnerships that support and accelerate innovation to move biological research discoveries from the laboratory to the clinic and market is critical. The three suggestions below are made in this context:

- 1) Establish private-public resources at the local, state, and federal levels using the successful UF CERHB model as a template.

- 2) Establish public-private partnerships that can facilitate first-in-man studies by establishing programs to support the manufacture and testing of novel candidates, before venture funding is made available. More funding is needed to ensure that technologies can reach their full potential, but rigorous evaluation of the technology, its market potential, competing technologies, business model, and medical need should be conducted as a condition for funding, and this can be ensured/administered by a center such as ours.
- 3) Provide additional funding for programs that better prepare scientists and engineers for private-sector bioeconomy jobs, beginning in high school and at all post-secondary levels. The majority of Ph.D., MS, BS, AS, and high school graduates will accept jobs outside of academia, yet very few students are exposed to the job and career profiles available to them in the life sciences industry. The education and training these students receive in the basic sciences can be applied and focused to enable them to succeed in industry. Furthermore, with an understanding of drug development, regulatory compliance, quality systems, and manufacturing technologies, these students are more attractive to companies for hiring. Companies benefit too since, once hired, these students can contribute productively to a company in a shorter timeframe, and with less mistakes.

The active leadership by a University in working with high schools, community colleges, workforce boards, economic development agencies, and the industry sector has proven effective. The cornerstone of transferring discoveries to the marketplace is the merging of academic scholarship and research with an understanding of the regulatory processes as they apply to product development, manufacturing, and clinical testing. Designed to facilitate industry growth, our models for affordable biopharmaceutical manufacturing and testing services, and statewide opportunities for workforce and professional training support the state's initiative to promote commercialization and are integral pieces in the infrastructure for building a domestic bioeconomy that is competitive globally.

I would be happy to discuss these ideas further and invite you to visit UF CERHB.

Sincerely,

Richard Snyder (electronic signature)

Richard O. Snyder, Ph.D.
Director

cc: Dr. Winfred M. Phillips
Senior Vice President for Operations
Chief Operating Officer
University of Florida