

Mon 12/5/2011 4:29 PM

Response to RFI: Building A 21st Century Bioeconomy

INTRODUCTION

This set of recommendations is in response to the October 11, 2011 Request for Information (RFI) from the White House Office of Science and Technology Policy (OSTP) titled *Building a 21st Century Bioeconomy*. The stated purpose of the RFI is “to solicit input from all interested parties regarding recommendations for harnessing biological research innovations to meet national challenges in health, food, energy, and the environment while creating high-wage, high-skill jobs.”

Biomedical Development Corporation is a small business located in San Antonio, TX.

We have recommendations on behalf of entrepreneurial companies located in areas where there is very little venture capital. Accordingly, these companies develop entrepreneurial approaches to research and development, manufacturing, and marketing.

Cognizant of the fiscal constraints facing the U.S. government at this time, **none of the following recommendations require new government spending**. At most they would require small shifts in funding from programs that are generally delivering less economic value. Furthermore, we believe that **most of these recommendations can be immediately implemented without the need for new legislation**. To the extent that any of these ideas require some legislative tweaks these would not require an appropriation and would likely garner bipartisan support.

RESPONSES TO SELECT REQUESTS FOR INFORMATION

What are the barriers preventing biological research discoveries from moving from the lab to commercial markets? What specific steps can Federal agencies take to address these shortcomings? Please specify whether these changes apply to academic labs, government labs, or both. (Q5)

The single greatest barrier to moving biological research discoveries from the lab to commercial markets is the low funding priority assigned by the National Institutes of Health (NIH) to technology transfer and translational research. Nearly all of the nearly \$30 billion received by the NIH each year goes to hypothesis driven basic research by academics. While this research sometimes serves as a foundation for future clinical and commercial applications, NIH funding almost always ends long before private investment in the research can commence without undue risk. Furthermore, the amount of funding available for basic research significantly outweighs that available for the translation of early stage research into useful products.

What specific changes to Federal Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs would help accelerate commercialization of federally funded bioeconomy related research? (Q6)

Adopt a more commercial and entrepreneurial (rather than academic or multi-national corporate) review process for the NIH SBIR program and recognize that all new jobs are important to our economy; not just “high wage, high skill jobs”. Further, high wage, high skill jobs generate new opportunities and jobs across the economy. For example, commercializing a new technology often results in jobs across all segments including manufacturing, sales, marketing and distribution.

With regard to the current SBIR/STTR review process at NIH, we have several observations and suggestions.

Observations:

1. Reviewers generally approve “cutting edge science” and/or “something they would like to use in their labs” rather than “the best commercial opportunities.”

2. Reviewers often view the selling of Intellectual Property (i.e., licensing patents) as an endgame instead of developing and selling products, which has a greater impact on the creation of jobs in the United States.
3. Reviewers typically do not appreciate that a small business can work a lot faster than a multinational corporation with its multi-layers of decision making, risk aversion and lack of entrepreneurial determination.
4. Reviewers do not take into account that unique, novel products are often difficult for multi-national corporations to integrate into their established structure.
5. Reviewers generally do not recognize the value of products that can be manufactured profitably in the United States and exported:

Suggestions:

1. Special consideration should be given to federally funded bioeconomy related research that can be commercialized in the near future in order to generate sales and jobs in the United States as quickly as possible.
2. Special consideration should be given to federally funded bioeconomy related research that will be converted to products that will be manufactured by the small companies in the United States.
3. Special consideration should be given to federally funded bioeconomy related research that small companies in the United States will market and sell in the United States and abroad.

Thank you for the opportunity to provide input.

--

Phyllis B. Siegel
C.E.O.
Biomedical Development Corporation

