

*Submitted on behalf of Jennie Hunter Cevera, Ph.D., Executive Vice President, RTI International*

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### **Grand Challenge**

*Human Proteome and Metabolome* – this is needed to advance our understanding of both wellness and the onset of disease. The Genome was only the guide, but the proteome and metabolome will decipher the how, when and why. This could also help reduce health care costs since a more rational approach to individual medicine would be an outcome.

This basic, applied and translational research program should be integrated and supported by NIH, FDA and NIST. Investments would also be made to industry to produce the new tools in the “toolbox” such as more sensitive mass spectrometry and computational analysis for complex data sets.

### **Focused Research**

The Federal government should provide funding mechanisms for development or proof-of-concept research, as well as public-private partnerships to promote innovation and commercialization. Currently funding agencies are top heavy on basic research and lean on “team science,” or applied, interdisciplinary research. Study sections often align on their agendas, rather than the funding agency roadmaps. Priority needs to be given to the research and outcomes that support agency priorities and roadmaps.

The critical technical challenges that prevent high throughput approaches from accelerating bioeconomy research include the lack of advanced analytical tools and the funding for “tool box” development. There is a need for integrated research programs that bring together physics, mathematics, biology and chemistry under one umbrella, or within a single framework. Priority should be given to exploring chemical “whispering” at the sub-cellular level and on developing “omics” and bio-imaging capabilities. These types of multidisciplinary funding efforts could revolutionize predictions of protein functions of genes.

Barriers that prevent biological research discoveries from moving from the lab to commercial markets include a lack of understanding of how and why development science and technology functions; a lack of teamwork in universities; a lack of integration on sponsored research with business development; sparse outreach interaction with industry to identify needs and research gaps; a system that promotes based on publications rather than patents; a lack of trained industry people working in universities; and the need for savvy people in the research trenches to ask the right questions about potential applications of basic research.

Increasing funding for SBIR and STTR might encourage more university and government laboratories to reach out and partner with industry. Also bringing back the ATP program at NIST would make a positive difference since these awards are larger than SBIR or STTR.

The Department of Defense does significant research resembling “biology on the edge,” but it is selective in what it releases. Perhaps here is where another grand challenge could play a role by creating more public-private partnerships for drug discovery.

The challenge to existing private-sector models for financing entrepreneurial bioeconomy firms is that very few firms are willing to invest in early stage technology. Perhaps if the government offered matching funds – a kind of “grand angel” that could partner with venture firms within established parameters – then more early technologies might get past the valley of death and make it to the market.

## **Work Force Development**

To better prepare scientists and engineers for private-sector bioeconomy jobs, universities could require internships in industry and partner more with industry on solving their problems. If government funding agencies matched industry dollars for graduate and post-doctoral fellowships to focus on moving ideas or hypotheses from concept to proof-of-concept, and on to product or process, we would have much faster returns on the investment of obtaining graduate degrees and post-doctoral fellowship experiences.

Community colleges are becoming more and more popular for high school students to attend rather than four-year degree programs. Programs that focus on “real world” or hands-on experience the entry of graduates into the workforce in industry and ensure they have the skills needed to hit the ground running, instead of requiring extensive company training. Many entry-level positions require at least a 2-year associate’s degree. Absent an internship, these new employees need at least six months additional training. If there were a way to tailor community college applied technology programs to real manufacturing scenarios (mock FDA trials, etc.), it could save time and money for the biotechnology industry. Private industry could design the curriculum and training programs for students and also provide guest lecturers.

For government and industry to successfully partner with academia and encourage successful entrepreneurship by faculty, graduate students and post-doctoral students, universities will have to adjust their approach and develop a culture of entrepreneurship. They should consider embracing “team science,” doing away with tenure, and moving toward performance-based promotions for faculty. Faculty members should lead, and students should follow. Change is needed to become more competitive in the global economy.

## **Reducing Regulatory Barriers**

The FDA is woefully underfunded and has not been able to keep up with the emerging bioeconomy. Genetic tests seemingly take forever to get approved, yet they could make a huge difference in choosing the right drug for cancer, etc. Please read the Personalized Medicine Coalition’s recently issued *Case for Change* report.

The federal government is unlikely to improve the predictability or transparency of regulatory processes until the regulatory system is overhauled and equipped with additional financial and human resources, including internships from the drug industry.

Our regulatory systems are based on many prior experiences that covered biochemistry and physiology. Today the shift is toward “omics” and sub-cellular chemistry, yet the regulatory guidelines are not well suited for the type of medicine and practice towards personalized or individualized medicine.

The FDA for years has focused on single compounds and yet the data and evidence for therapies that involve more than one compound to cure a disease is growing along with evidence associated with diet and exercise. It would be great to have a program that integrated wellness and disease research and healthy lifestyle promotion. NIH mainly focuses on disease, not on health or wellness. Perhaps it is time to create a new federal agency that focuses on wellness and well-being.

## **Public-Private Partnership**

Some public-private partnerships have worked well in the past (TMT and Novartis). A grand challenge that unites public and private institutions in dealing with obesity in this country might make a huge impact in both the bioeconomy and the healthcare and the food industries.

Obesity causes diabetes, cancer and heart disease, which in turn leads to a less healthy workforce for America. Companies today are spending a fortune on healthcare for employees, many of

which are on high cost medication to deal with chronic diseases that could have been avoided if employees ate better and exercised. T

The bioeconomy is a two-way street: high paying jobs provide a higher tax base, but if the workforce is not healthy, it can cost companies more money and slow down productivity.