

To: Dr. John P. Holdren, Director
White House Office of Science & Technology Policy
Bioeconomy Project Team

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

Dear Dr. Holdren and Bioeconomy Project Team:

Submitted via e-mail December 6, 2011

We are pleased to submit the following comments in response to the Notice by the White House Office of Science and Technology Policy (OSTP) published in the Federal Register on 10/07/2011, requesting public inputs to identify and propose solutions to the grand challenges facing America in building and sustaining a vibrant Bioeconomy.

OPPORTUNITY

We believe the biggest of the grand challenges currently facing America's Bioeconomy is not scientific. The greatest, most solvable, grand challenge is: To improve the financing of translational science.

Funding is the commitment of money to develop products. Financing is the delivery of money. Funding is and will be constrained in today's tight economic times. However, all the tools and networks already exist to make the delivery of federal funds much more effective. America must do this now.

More efficiency in delivering government funding is the key catalyst for Bioeconomy innovation. Currently, government funding is not aligned to support the promise or the pace of 21st century translational science. The translational science pathway is horizontal and continuous, with a sequence of clearly defined stages to move products directly toward approval, or down selection for science failure.

Government science funding is vertically siloed among different agencies, and is delayed by interruptions between the agency funding cycles. This funding system lacks the product focus and strategic continuity to ensure that basic research is translated efficiently into approved products. Government funding is also hindered by administrative burdens which make Government-funded research take longer than commercial science. These factors discourage private sector investment, cause or contribute to significant research delays and unrealized opportunities for innovation, increase cost, and prevent the nation from fully benefiting from our remarkable scientific enterprise.

The National Bioeconomy Blueprint is THE unique opportunity to identify, highlight, and deploy tools to align the funding and financing paths with the science development path -- and vastly accelerate bioproduct delivery.

APPROACH: 21st CENTURY BIOECONOMY FINANCING

The United States of America must systematically use 21st century financing tools and networks to immediately and practically accelerate translational science. This will speed up bioproduct delivery and enable exponential growth in jobs and investment across the Bioeconomy.

The alignment of funding, financing and science can readily be achieved under existing federal R&D authorities used as a 21st Century Bioeconomy Toolkit. This includes:

- Pledges of grant and contract funds as debt service for Revenue Bond Financing
- Commercial contracts using Other Transaction Authorities
- Advance Contingent Purchase Commitments for high-priority products
- Additional federal funding acceleration authorities
- Financing Partnership Networks

The federal government has deployed these tools for decades to support large-scale projects including construction of research facilities, housing, economic development, and advanced defense science and

technology. Together these tools can transform the bioeconomy by ensuring that a 21st century financing system is in place to accelerate 21st century science.

IMPLEMENTATION

1. **Revenue Bond Financing** is a well-established financing tool used to speed the creation of high-priority public goods with multiple, complex development stages. Funding pledges are converted to up-front cash via bonds, and the bonds are then paid down over time. This tool is used when the benefits of acceleration (faster product availability, faster economic growth) are larger than the cost of financing.

Taxable revenue bond financing can be applied to translational R&D as follows:

- Government agencies which are funding the development of high-priority bioproducts convert a portion of existing grant and contract funding to cash tranches and commit the tranches to pay debt service covering the principal and interest on taxable revenue bonds
- State and local economic development authorities issue taxable revenue bonds backed by these commitments, and distribute the proceeds to companies with federally funded projects based in their areas
- Companies developing the high-priority products receive the bond proceeds and conduct science using commercial contracts
- Government agencies establish and validate achievement of science milestones, Technology Readiness Levels (TRL's), performance standards, and company performance sureties
- Funds from Government agencies with varied funding missions can be aligned and precommitted to fund R&D stages in a linked path to product approval, tied to science milestones rather than diverse, un-aligned agency administrative requirements
- Private debt and equity capital can be combined with federal funds in capital stacks to fully finance priority bioproducts to licensure and market availability
- Bioproduct manufacturing in America can readily be financed by taxable revenue bonds issued by economic development agencies

The Government can and should immediately set up standardized bond financing vehicles – Innovation Bonds – to speed the translation of science into bioproducts.

2. **Other Transaction Authorities (OTA)** are well-established Government contracting vehicles for R&D. They allow flexible commercial contracts and reduce administrative burden. The Government can and should immediately make OTA's a standard contract vehicle for Bioeconomy translational science.
3. **Advance Contingent Purchase Commitments** are binding Government acquisition contracts, conditioned on successful product approval, for the purchase of high-priority products in development. Advance contingent purchase commitments provide early-stage incentives for private capital to commit and compete to develop bioproducts. For example, the International Financing Facility for Immunisations (IFFIm, www.iffim.org) has been using this model for development and purchase of bioproducts since 2006.

Advance Contingent Purchase Commitments can immediately be applied to Bioeconomy translational R&D as follows:

- Government agencies define Target Product Profiles for high-priority products, and minimum purchase commitments for products achieving approval
- Companies develop technologies through early stages to reach TRL-4 or higher
- Once projects have met science milestones and achieved TRL-4 or higher, Government agencies make advanced contingent purchase commitments

- Government agencies authorize OTA-based commercial contracts to allow conversion of federal funds as pledges of debt service to support revenue bond financing and continuous, linked funding and financing of bioproduct R&D to science failure or product approval and availability

The Government can and should immediately establish and use Advance Contingent Purchase Authorities supported by taxable revenue bond financing in high-priority areas such as vaccines, medical countermeasures, defense and national security biomedical technologies, agri-bioproducts, biofuels, etc.

4. **Additional federal funding acceleration authorities** are available under Congressional authorities to the President, the Department of Defense, and other agencies to help protect the United States against diverse national security threats, including threats to public health from bioterrorism and pandemics. Special, fast-track government contracting and procurement processes, and contingent product purchase commitments, are authorized and have been used to attract private sector product developers to rapidly produce diverse defense and intelligence community priority products. These authorities, as well as advance commitments to next stage funding when major science milestones are met, can and should be used now to help address America's top public health threats.
5. **Financing Partnership Networks** are teams of private companies, Federal science and funding agencies, equity and debt investors, state and local economic development agencies, and strategic product end-users that can and will rapidly be drawn together and catalyzed by the recommended more efficient Federal funding into financing partnerships to push bio products to approval at the speed of science.

IMPACT

The Government can and should make a strong, immediate commitment to solving the grand challenge of improving the financing of translational science. This strategic solution will bring widespread positive impacts to America's Bioeconomy, e.g.:

- Empower Bioeconomy innovation to move at the pace of science, much faster than the pace of administrative procedure
- Accelerate Bioeconomy product delivery, job creation and economic growth
- Establish federal funding as a more effective component in delivering translational bioproducts and portfolios
- Establish strategic funding continuity and make Bioeconomy companies and projects investable
- Attract large new sources of private capital back into the funding of American innovation
- Ensure that American Bioeconomy innovation leadership leads to American Bioeconomy manufacturing leadership

The comments above are submitted by an informal group of scientists, entrepreneurs, executives, life sciences attorneys, contract research managers, venture fund managers, former senior federal officials and advisors, and public policy experts. These individuals have many years of combined experience and service in senior government, industry and academic roles in bioscience research and development and in attracting and managing private capital in the life sciences sector.

Respectfully submitted,
 Dr. Charles Hamner
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