Summary of Recommendations on The US Bioeconomy: Maximizing Opportunities for Economic Growth and National Security with Biology

August 12, 2019

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Center for Health Security

Introduction

On July 16, the Johns Hopkins Center for Health Security and Ginkgo Bioworks convened a meeting in Washington, DC, to solicit stakeholder input on specific ways that national policy can strengthen the US bioeconomy. For the purposes of this meeting, the bioeconomy was defined broadly as the economy built on biotechnology. There currently is no consensus on a definition of bioeconomy, but most accept that it encompasses parts of the energy, agriculture, medical, industrial, and defense sectors. The aims of the meeting were to consider the benefits to the US if its bioeconomy were to be expanded; examine the current health of the US bioeconomy; discuss existing US government programs, policies, and initiatives related to the bioeconomy; and identify priorities for strengthening the US bioeconomy.

The United States already hosts one of the world's most competitive bioeconomy markets and is a leader in biological innovation and education. However, recent advances in biological technologies are catalyzing global investment, spurring innovation, and increasing international competitiveness. As the growth or neglect of the US bioeconomy affects national security, it is critical for the US to actively develop new mechanisms that leverage advantages in biotechnology for its benefit in the face of greater peer competition.

The US Bioeconomy meeting featured participation from members of government, academia, and industry, including subject matter experts from a range of disciplines and sectors: venture capitalists, biotechnology entrepreneurs, defense prime contractors, synthetic biology industry analysts, and defense, health, and agriculture scientists and experts. A list of meeting participants is attached. The meeting provided an opportunity to discuss US policy options, both opportunities and limitations, in a frank, open manner. Comments were not for attribution.

The meeting was supported by the Open Philanthropy Project. The Center for Health Security and Ginkgo Bioworks did not attempt to reach stakeholder consensus on the myriad of topics discussed during the meeting. What follows is the Center for Health Security's synthesis of recommendations made by one or more participants during the meeting.

Government should move toward contracting mechanisms that emphasize cost savings across the enterprise, as well as factoring in nonmonetary benefits of biologically produced materials.

Fuels, specialty chemicals, and other products made using biological processes may be expensive in comparison to products made through more traditional approaches, including petroleum-based nonbiological industrial approaches. However, that higher cost does not include the potential benefits of biologically processed products, including sustainability, reduced logistics costs if the biologically produced products can be produced closer to where they are needed, opportunities to alleviate supply chain constraints or avoid disruptions, and avoidance of environmental contamination and damage. If those factors are included in a cost analysis when comparing products made from biological processes to standard approaches, biologically derived products may be substantially less expensive than traditionally manufactured products. In addition to costs, there are potential national security gains, if the ability to manufacture items

biologically can alleviate supply chain disruption risks. The US government should examine its purchasing strategies with this full range of costs and benefits in mind, and move toward contracting mechanisms that emphasize cost savings across the enterprise, fully accounting for life cycle costs, sustainability, logistics, environmental remediation, carbon footprint, and the availability of the product in the event of traditional supply chain disruptions.

Government should identify ways to recruit and retain talent needed to run innovative biotechnology R&D programs.

There is a well-documented lack of expertise in biotechnology across multiple government agencies, which leads to poor decision making, missed opportunities, and insufficient coordination across government agencies. Important national security consequences may result—for example, a lack of biotechnology expertise in the Committee on Foreign Investment in the United States (CFIUS) could directly affect the health of the US bioeconomy by not appropriately estimating the national security importance of a particular biotechnology.

Rectifying this knowledge gap will require direct action at many levels, to include: drawing talent from the private sector and people with nontraditional backgrounds to positions with expected short tenures in the government; encouraging "open campus" initiatives that draw expertise from regional biotechnology centers to work with government service laboratories or government agency programs; and creating opportunities for promotion for biotechnology experts so that they can move up the career ladder in the government.

In contrast to information security, where there are American National Standards Institute (ANSI) standards for certifications and mechanisms within the government, particularly the Department of Defense (DoD), to make such certifications required for promotion, biotechnology does not have an accompanying ANSI standard or required courses to take to become certified in biotechnology. While there are excellent biotechnology education opportunities in the government, such as at the National Defense University, these training courses should be expanded and standardized to seed expertise in biotechnology at high levels of government.

Retention of biotechnology talent in the US is another urgent problem that can be addressed through financial incentives and green card access. The National Science Foundation tracks the emigration of US PhD-trained researchers to other nations and foreign students who are trained in the US and return to their home countries. In addition to that loss of talent, when US-trained foreign-born scientists return to their home countries, biotechnology companies are not being formed in the US. US-trained graduate students and postdoctoral fellows may also not have the option to stay in the US after their training is completed, another way the US is losing critical biotechnology talent. Green cards for biotechnology researchers, in particular, should be streamlined.

The US can create a good environment for those entering the biotechnology workforce by demonstrating that this area is a US priority. Funding basic research with minimal fluctuations from year to year; funding science, technology, engineering, and mathematics (STEM) education

initiatives; supporting international genetically engineered machine competition (iGEM) teams and advisors; instituting financial incentives to discourage synthetic biology companies and other biotechnology companies from locating offshore; developing the workforce through retraining programs; ensuring that women are targeted for advancement in STEM fields; and encouraging foreign students who receive their PhDs in the US in technical areas to stay in the country by issuing green cards enabling them to work here—all of these are options that demonstrate the US commitment to biotechnology growth and promotion of the bioeconomy.

The US government should initiate the tracking of data around the biotech workforce and company formation as these data compare to other countries.

Data on the US brain drain in science and technology is widely available from the academic perspective through the National Science Foundation (for example, numbers of researchers trained in scientific areas that have left the US), but there is limited data from the industry perspective and others not covered by the NSF efforts. How many additional companies would have been formed in the US if potential founders, after being trained in the US, did not have to go back to their home countries? More effort to quantify the extent of the problem can yield additional options for financial and other solutions to these problems.

The US government should articulate a vision for its bioeconomy and coordinate its efforts to promote and protect the bioeconomy.

Many US agencies are "directionally correct" in their efforts to embrace biotechnology and the bioeconomy, but they are largely doing it independently of other agencies, which leads to duplication and incremental progress. A visionary, broader interagency approach is needed, with leadership and a plan: The current efforts under way at the DoD, National Security Council/ Office of Science and Technology Policy, and Congress are thus timely and should yield long-term strategies.

One important step for the US is to be a good customer, to get companies off the ground, and to embrace its role as a bioeconomy catalyst. Biotechnologies are not generally fostered in the US government, so partnership with the private sector is important. There are many actions that should be taken, including the following:

- Government contracting should be a faster, smoother process for small businesses. A government liaison could partner with small companies to lead them through the process or link them with primes or service laboratories, which can assume a lot more risk than private companies.
- There should be more incentives for government program managers to award contracts and to make the contracting process smoother, easier, and faster.
- Programs like the US Air Force Pathfinder program could be a model for ways to facilitate mutually productive government contracts and value talented workers. In this innovative in-house modernization effort, launched in 2017, the program managers changed their typical acquisition procedures to "think like a start-up," delivering results at a fraction of the price.

- The Committee on Foreign Investment in the United States (CFIUS): CFIUS is an interagency committee authorized to review certain transactions involving foreign investment in the US ("covered transactions"), in order to determine the effect of such transactions on the national security of the US. The US government should do more to anticipate CFIUS concerns and to pay companies to develop their technology in the US.
- Programs put into place to encourage bio-investment, such as "BioPreferred Program," managed by the US Department of Agriculture (USDA), which aims to spur economic development, create new jobs, and provide new markets for farm commodities, require more teeth—stronger incentives for implementation.
- Expansion of SBIR programs for biotech companies are important and successful ways to promote small company development.
- Tax credits that favor the founding of biotechnology companies. Canada has taken this approach with artificial intelligence, and although it may seem to be a slow process, it has been extraordinarily successful.
- Initiatives to create "opportunity zones" for biotechnology and fermentation facilities, which is a designation created by the Tax Cuts and Jobs Act of 2017, to allow for certain investments in lower income areas to have tax advantages and provide education initiatives for retraining veterans in biotechnology.

The US government should consider strategic use of non-dilutive capital, matched by VC investments, to help drive the creation of key biotech companies that would be important to the US bioeconomy.

The government can offer non-dilutive financing to biotechnology companies—where the company founders do not lose equity in their company—which may offset a great deal of risk for future venture capital funders. The government has traditionally had a difficult time picking winners and losers among young companies, particularly as the time scale for government funding tends to be short (in the range of 2-3 years) and success requires a longer term commitment. Partnering with venture capitalists (VCs) can help sustain a technology, because when a VC invests, they are committing to the company's success and growth. A blended USG-VC investment strategy may work best, where milestones are set for US government financial rewards when a company meets challenges. This signals to the investment community that a biotechnology company has drawn government interest. Smaller government grants and seed funding can also provide proof to investors that the technology is worth the investment.

The US government should work to clarify the uncertain regulatory pathway for novel synthetic biology products.

Regulatory science funding is needed, as a clear regulatory environment could help to speed bioeconomy investments and growth. As biotechnology products pose different regulatory challenges than have been experienced before (using living biological organisms for mining, for example), regulatory pathways for such products need to be developed and capture biotechnology risks. Having a regulatory system that appropriately examines real risks stemming from biotechnology products will help avoid public distrust resulting from oversight gaps.

If the US government were more explicit about what kinds of biotechnology-derived products it may need, the biotechnology industry could be more valuable to the government.

There are direct applications of synthetic biology beyond medical countermeasures that offer value to the US economy and defense. Products such as biologically made concrete, cloth, caffeine production, food, and rare earth mining are just a few biotechnologies that may be valuable to the government or to defense. In addition, there are medical benefits, including regenerative manufacturing of organs or human tissue, that may benefit injured warfighters.

There may be more products that could have biology-based solutions, but more communication and knowledge is required to bring those ideas from industry to the government. More biotechnology "knowledge brokers" within the government—people who build networks between the US government, private biotechnology companies, and VC—are needed to identify these opportunities.

Conclusion

The growth of the bioeconomy should be a priority for the US, to take advantage of the benefits that biotechnology will bring across a variety of sectors and for continued national security. DoD and, broadly, US government leadership must embrace biotechnology and the bioeconomy as critical components of the US economy and invest accordingly. The ideas presented above represent a range of practical recommendations for consideration by US government officials in the coming months.

The following members of the Johns Hopkins Center for Health Security contributed to this report: Gigi Kwik Gronvall, Lane Warmbrod, Marc Trotochaud, Anita Cicero, and Tom Inglesby.

Meeting Participants

Jennifer Alton
Pathway Policy

Kavita Berger
Gryphon Scientific

Elizabeth Bernard
Sandhill Consulting

Kenneth Bernard

Patrick Boyle
Ginkgo Bioworks

Richard Bruns
Johns Hopkins Center for Health Security

Sarah Carter
Science Policy Consulting

Linda Chrisey
OUSD R&E Human Systems Directorate

Anita Cicero
Johns Hopkins Center for Health Security

Nancy Connell
Johns Hopkins Center for Health Security

John Cumbers
SynBioBeta

Diane DiEuliis
NDU

James Diggans
Twist Bioscience

Peter Emanuel
US Army Futures Command

Robert Fisher
FDA

Sarah Glaven
US Naval Research Laboratory

Jimmy Gollihar
US Army Research Laboratory

Gigi Gronvall
Johns Hopkins Center for Health Security

Chris Hassell
HHS/ASPR

Richard Hatchett
CEPI

Andrea Hodgson
The National Academies of Sciences, Engineering, and Medicine

Orin Hoffman
The Engine

Tom Inglesby
Johns Hopkins Center for Health Security

Nathan Khosia
Lockheed Martin

Andy Kilianski
Department of Defense/JPEO-CBRND

Brett Lambert
Northrop Grumman

Monique K. Mansoura
MITRE

Megan Palmer
Stanford University

Wallace Patterson
Air Force Research Laboratory

Edward Perkins
US Army Corps of Engineers

Scott Plevy
Synlogic Therapeutics

Melissa Rhoads
Lockheed Martin

Michelle Rozo
US Department of State

Marc Salit
Joint Initiative for Metrology in Biology

Zach Smith
Ginkgo Bioworks

Dahlia Sokolov
House Subcommittee on Research & Technology

David Stenger
US Naval Research Laboratory

Dimitria Stratis-Cullum
US Army Research Laboratory

Leonard Tender
Center for Bio/Molecular Science and Engineering,
US Naval Research Laboratory

Alexander Titus
OUSD (R&E)

Marc Trotochaud
Johns Hopkins Center for Health Security

Gary Vora
US Naval Research Laboratory

Lane Warmbrod
Johns Hopkins Center for Health Security

Ian Watson
OSTP

Renee Wegrzyn
DARPA

Misha Wolfson
Ginkgo Bioworks

Adam Woomer
Lockheed Martin

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Center for Health Security

621 E. Pratt Street
Suite 210
Baltimore, MD 21202

Tel: 443-573-3304
Fax: 443-573-3305
Email: centerhealthsecurity@jhu.edu
www.centerforhealthsecurity.org