The United States National Bioeconomy Blueprint

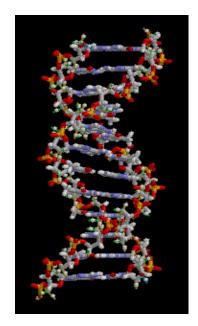
Presented at the 2017 Bio Future Forum Seoul, Korea By Robbie Barbero, Ph.D. Chief Business Officer, Ceres Nanosciences Former Assistant Director, White House Office of Science and Technology Policy

The U.S. bioeconomy rests on two pillars

BIOMASS



BIOSCIENCES



We are now in an era where biology is technology...

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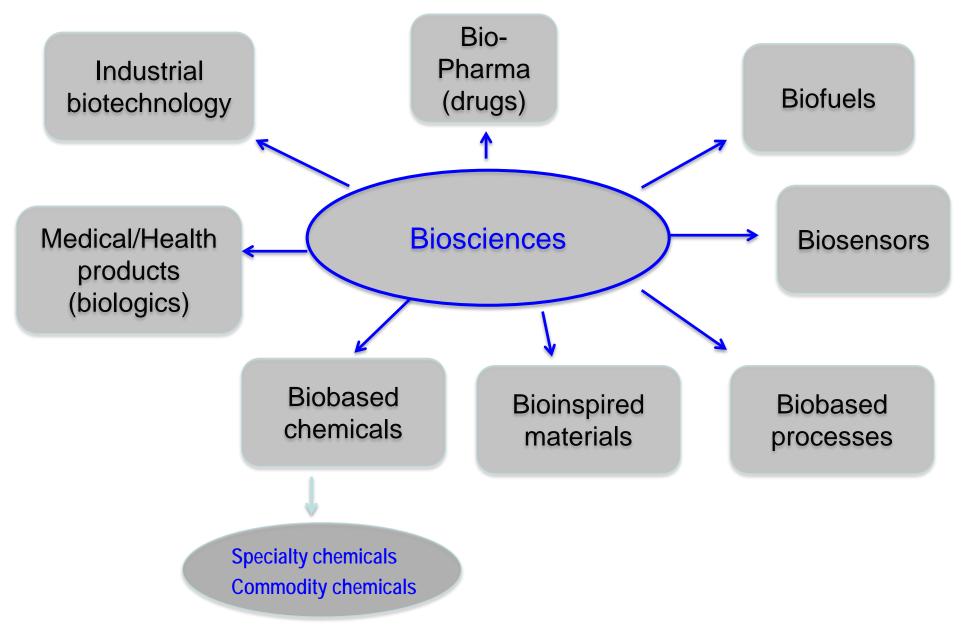


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...with multiple applications



United States Government biosciences effort is large and diverse

More than 20 R&D agencies across 8 Cabinet-level departments and 4 independent agencies

Department of Agriculture (USDA)

- Agricultural Research Service (ARS)
- National Institute of Food and Agriculture (NIFA)
- Forest Service (FS)
- Animal and Plant Health Inspection Service (APHIS)

Department of Commerce (DOC)

- National Oceanic and Atmospheric Administration (NOAA)
- National Marine Fisheries Service (NMFS)
- National Institute of Standards and Technology (NIST)

Department of Defense (DOD)

- Air Force Office of Science Research (AFOSR)
- Defense Advanced Research Projects Agency (DARPA)
- Defense Threat Reduction Agency (DTRA)
- Office of Naval Research (ONR)
- U.S. Army Medical Research and Materiel Command (USAMRMC)

Department of Energy (DOE)

- Office of Science
- National Laboratories
- Office of Energy Efficiency and Renewable Energy (EERE)
- Advanced Research Projects Agency-Energy (ARPA-E)

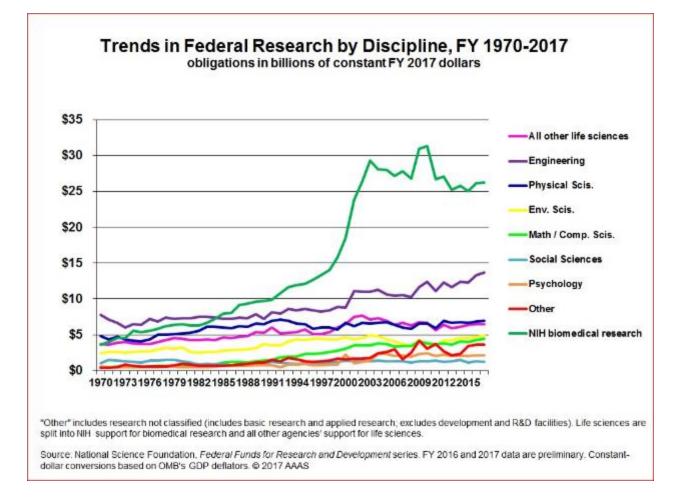
- Department of Homeland Security (DHS)
- Department of the Interior (DOI)
 - Fish and Wildlife Service (FWS)
 - Geological Survey (USGS)
- <u>Health and Human Services Department</u> (HHS)
 - Centers for Disease Control and Prevention (CDC)
 - Food and Drug Administration (FDA)
 - National Institutes of Health (NIH)
 - Food and Drug Administration (FDA)

Veterans Affairs Department (VA)

Independent Agencies

- National Aeronautics and Space Administration (NASA)
- National Science Foundation (NSF)
- Environmental Protection Agency (EPA)
- Director of National Intelligence (DNI)
 - Intelligence Advance Research Projects (IARPA)

U.S. Gov't spends >\$30 billion on biosciences R&D



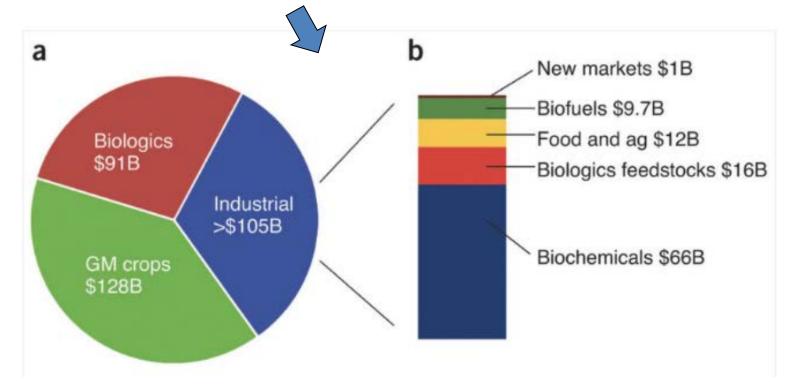
 And, when you include funding from foundations, philanthropists, state governments, private research institutes, and industry that number is much larger.

The U.S. bioeconomy is large and diverse

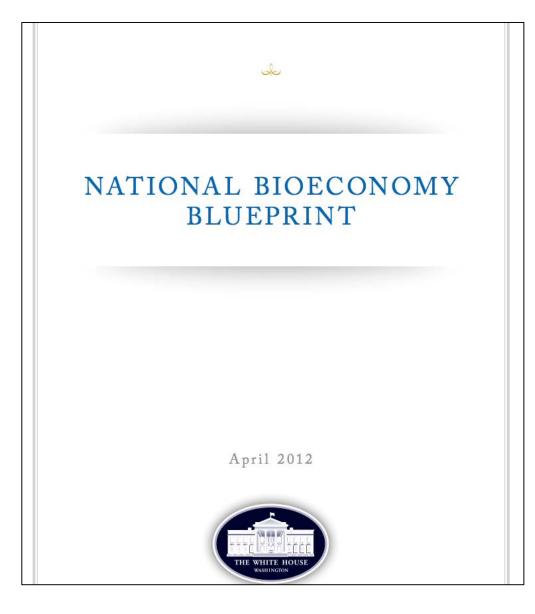
In 2012

- >\$324 Billion in revenues
- = 2% of overall U.S. GDP
- Contributed to more than 5% of U.S. economy's overall growth

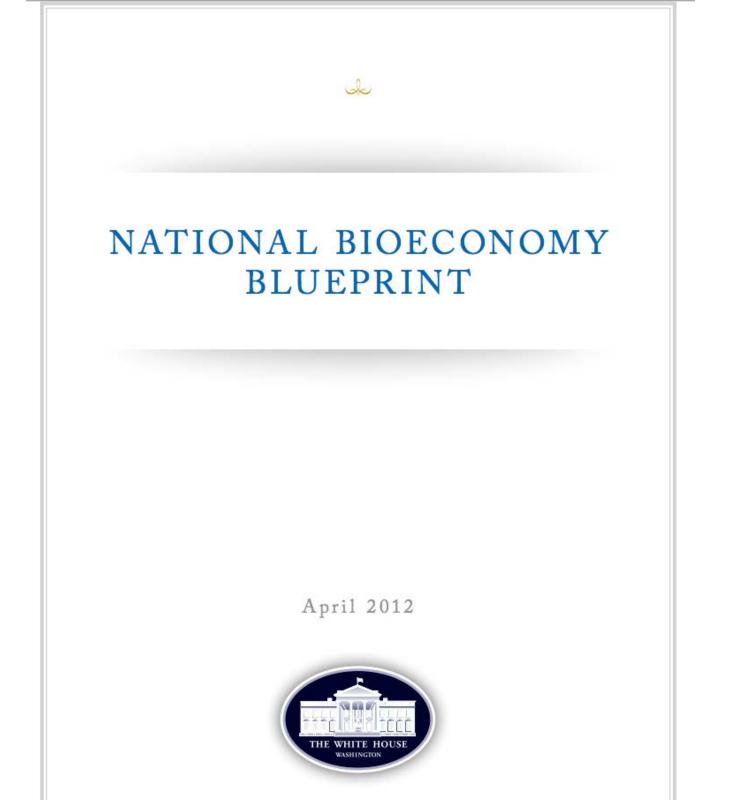




Ok, fine, but why develop a national bioeconomy strategy?



- Lay out strategic objectives that will help realize the full potential of the U.S. bioeconomy
- Signal to industry, investors, and researchers a commitment to biological research as a driver of the future bioeconomy
- Underscore the potential of biological research to address national challenges in health, energy, environment, food
- Provide guidance to S&T agencies about where to focus efforts





Support R&D investments that will provide the foundation for the future U.S. bioeconomy

- Expand and develop essential bioeconomy technologies
- Integrate approaches across disciplines
- Implement improved funding mechanisms



Facilitate the transition of bioinventions from lab to market, focusing on translational and regulatory sciences

- Update SBIR programs
- Accelerate transfer of government-owned inventions*
- Enhance entrepreneurship at universities
- Utilize federal procurement authority to create and grow new bio-markets

Objective 3

Develop and reform regulations to reduce barriers, increase speed and predictability of regulatory processes, and reduce costs while protecting human and environmental health

- improve regulatory processes and regulations
- collaborate with stakeholders

Objective 4

Update training programs and align academic institution initiatives with student training for national workforce needs

- Enable employer-educator partnerships
- Re-engineer graduate education programs



Identify and support opportunities for development of public-private partnerships and precompetitive collaborations – where competitors pool resources, knowledge, and expertise to learn from successes and failures

What came AFTER the National Bioeconomy Blueprint?

More than \$6.5 billion in new R&D funding (public and private) for bioeconomy-related activities, including:

- 2013 BRAIN Initiative (neurotechnologies) \$1.5B public-private funding from 2014-2016 AND \$1.5B over 2017-2026 (21st Century Cures Act)
- 2015 Precision Medicine Initiative \$1.4B over 2017-2026 (21st Century Cures Act)
- 2016 Cancer Moonshot \$1.8B over 2017-2026 (21st Century Cures Act)







What came AFTER the National Bioeconomy Blueprint? (continued)

More than \$6.5 billion in R&D funding (public and private) for bioeconomy-related activities, including:

- 2015-2017 Modernized the U.S. Biotechnology Regulatory System
- 2016 Advanced Regenerative Manufacturing Institute (multicellular tissues and workforce development) - \$290M public-private funding
- 2016 National Institute for Innovation in Manufacturing Biopharmaceuticals (cell-based therapeutics and workforce development) -\$90M
- 2017 DOE Agile Biofoundry (synthetic biology) -\$40M to achieve a 50% reduction in time-to-scale up for chemical biomanufacturing



National Strategy for Modernizing the Regulatory System for Biotechnology Products

Product of the Emerging Technologies Interagency Policy Coordination Committee's Biotechnology Working Group





So HOW did the United States develop a national bioeconomy strategy?

- Objectives developed and refined
 - National needs/societal challenges (e.g., National Academy of Sciences reports)
 - Administration priorities
 - Agency input
 - Public input
- Research trends, economics, etc.
- Foundational technologies selected
 - Potential to significantly and broadly change biology and the economy
- Early achievements solicited from agencies
- Clearance through official USG process
- Release the document
- And, continue to work on the priorities!

One useful framework for filling in the details

the proposal?

What should we do? (A does B to accomplish C) If your goal requires multiple individuals and How likely is that that a organizations work given set of actors will together over an be willing and able to extended period of time, take the action is there a forum where proposed? that collaboration can occur? If an organization is If an organization is able but not willing to willing, but not able to act, can you address act, can you (or Source: their concerns by someone else) relax Policy Entrepreneurship at the White providing additional House: Getting Things Done in Large the relevant evidence or modifying **Organizations** constraint?

Thomas Kalil

And, some things that might be possible if we make the right investments

- Advances in biomedical sciences & "big data" & artificial intelligence will drastically improve healthcare
 - But, will be critical to protect privacy and security
- Ensuring sufficient safe, secure, sustainable, affordable food, water, and energy for all, while reducing GHGs
- Fashioning materials from abundant elements to substitute for current uses of scarce ones
- Understanding the brain and curing its ailments
- Controlling infectious and vector-borne diseases
- Defeating cancer
- Facilitating graceful aging
- Cellular therapeutics
 - Beyond small molecules and biologics
- Personalized organs and tissues on demand

Credit to Dr. John Holdren, Former Director of White House OSTP, for assembling most of this list

Thank you!

For more information:

- <u>rbarbero@ceresnano.com</u>
- Twitter: @robbiebarbero