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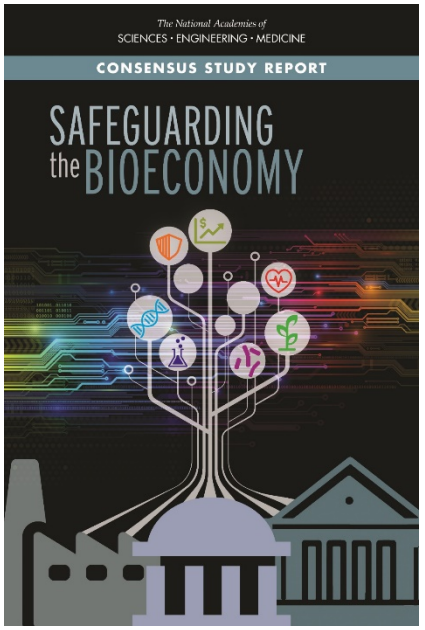
Safeguarding the Bioeconomy



BRIEFING TO DOE-BER ADVISORY COMMITTEE

MAUREEN C MCCANN

16TH APRIL 2020

BOARD ON LIFE SCIENCES • BOARD ON AGRICULTURE AND NATURAL RESOURCES • BOARD ON SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY • BOARD ON HEALTH SCIENCES POLICY • FORUM ON CYBER RESILIENCE

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Impetus for this Study

2009 –*A New Biology for the 21st Century*

- Described the growing power of biology, the intersections of biology, biotechnology, computing, and engineering
- Pointed to the deep ties between research innovation and economic benefits.

2012 – National Bioeconomy Blueprint Released

- Proposed strengthening R&D efforts, advancing products to market, reducing regulatory barriers, developing a 21st-century bioeconomy workforce, and fostering key public–private partnerships

2012-2019 – Rapid Changes in the Life Sciences, Policy, and Industry

However, little was done to holistically examine the value of the U.S. bioeconomy or assess the risks that relate to the bioeconomy.

As a result, concerns about the national strategic thinking and the ability to protect the U.S. bioeconomy remained.

Questions posed by ODNI, the sponsor

How do we **define** the bioeconomy?

How can we **measure** the U.S. bioeconomy?

How can we measure U.S. bioeconomic **leadership** and where the US currently leads?

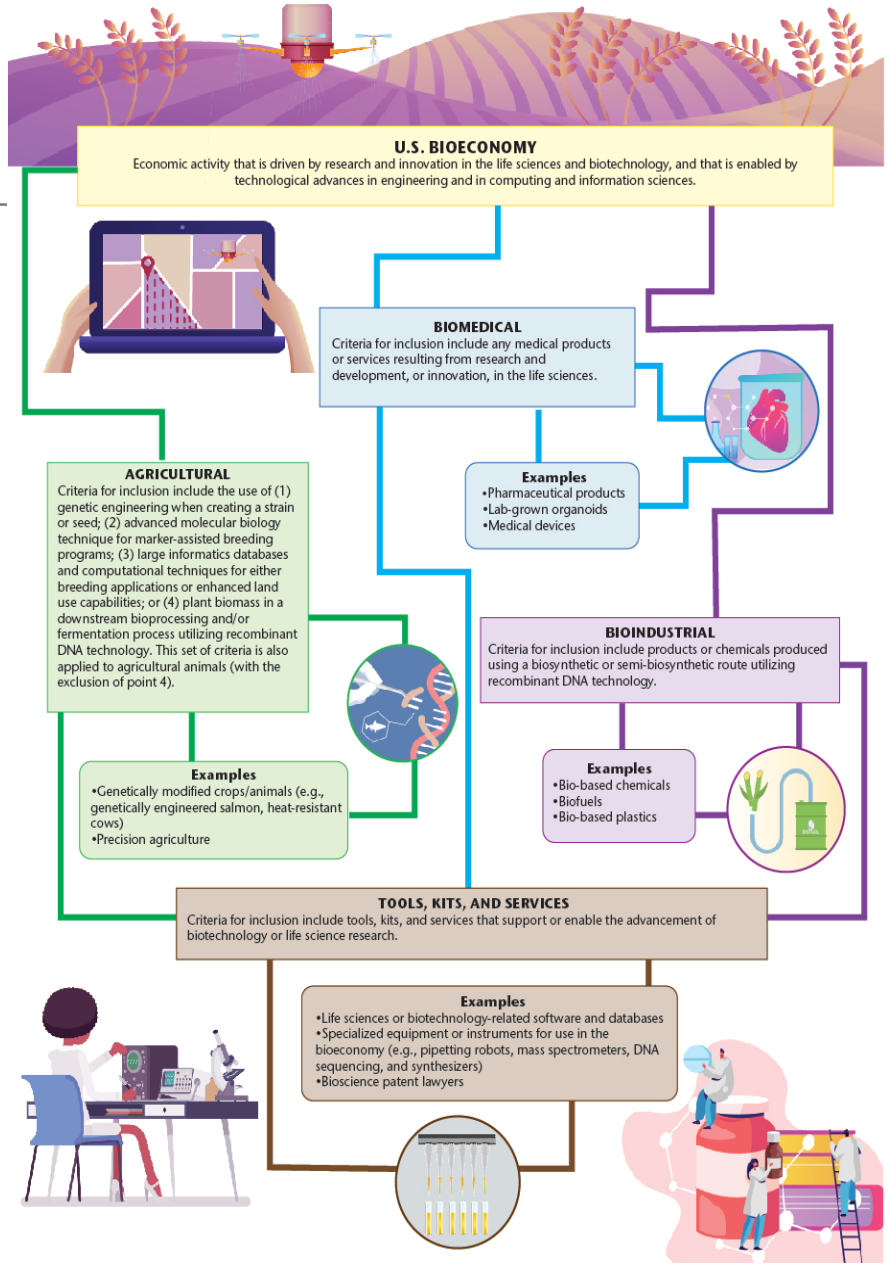
What **security risks** are associated with the U.S. bioeconomy?

What are the specific **cybersecurity/data** concerns?

In what ways can we **forecast** the bioeconomy?

Themes

- Transdisciplinary integration drives the bioeconomy
- Need to measure, track, and analyze the bioeconomy
- Balancing security considerations with openness
- Importance of coordination and collaboration
  - Across disciplines, sectors, agencies, and countries



Getting to a Definition: Context

Challenges

- Activities span many sectors
- In order to measure, need to identify which activities to include and exclude
- Definitions and strategies vary with countries' technological capacities, natural resource bases, and economic comparative advantages

No international consensus on the definition of a bioeconomy

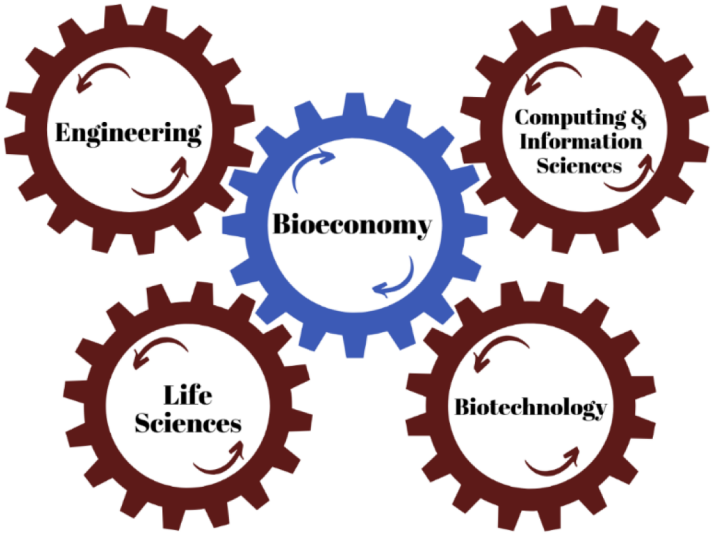
More than 40 countries have strategies for promoting their bioeconomies which can be cataloged in terms of 3 visions:

- Biotechnology vision
- Bioresource vision
- Bioecology vision

Defining the U.S. Bioeconomy

Criteria for a definition:

- enable assessment and strategy development
- guide the metrics and data collection efforts for economic assessments
- be flexible enough to allow for the future inclusion of new developments



Recommendation 1: For purposes of demarcating the scope and reach of the U.S. bioeconomy and establishing a uniform framework for valuing the bioeconomy and its assets, the U.S. government should adopt the following definition of the U.S. bioeconomy:

The U.S. bioeconomy is economic activity that is driven by research and innovation in the life sciences and biotechnology, and that is enabled by technological advances in engineering and in computing and information sciences.

Understanding the Ecosystem of the U.S. Bioeconomy

As the pace of scientific discovery has accelerated and discoveries have evolved into practical applications for commercial products and services, the United States has realized the benefits of a national innovation ecosystem capable of transforming research discoveries into economic and societal benefits. This ecosystem is essential to the continued realization of such benefits to the United States.

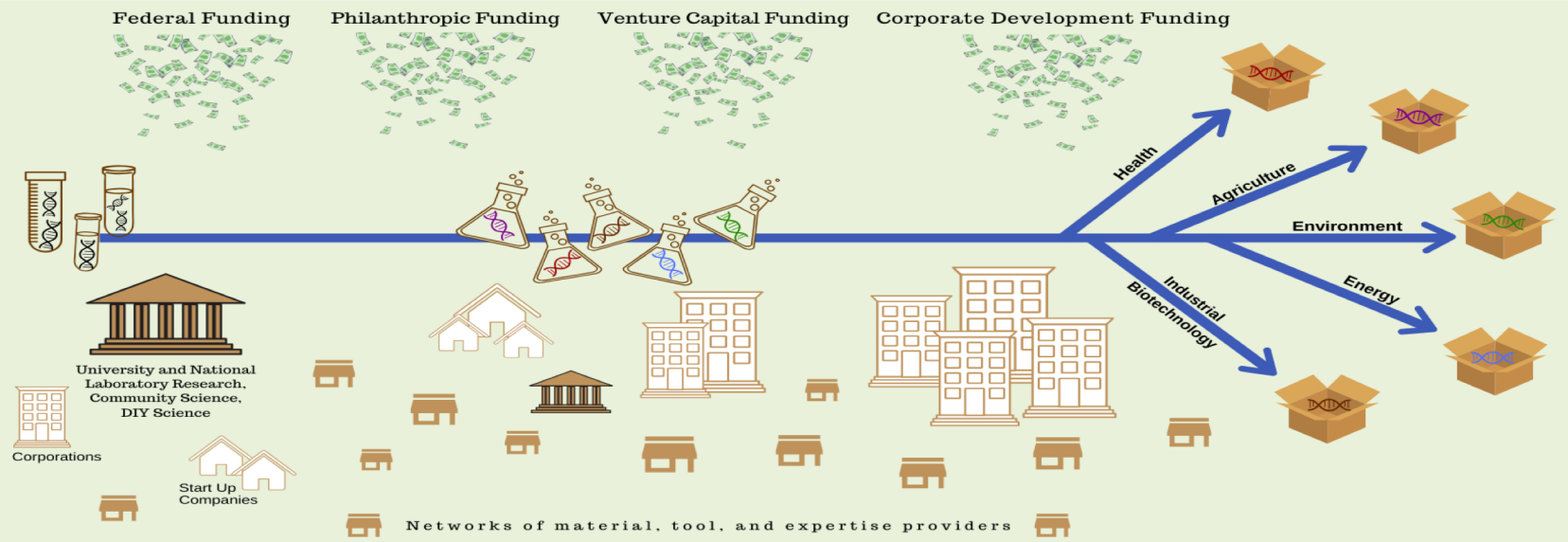


FIGURE 5-1 Advances in fundamental biological knowledge and in a number of enabling technologies are creating commercial opportunities with application to many sectors of the bioeconomy.

Measuring the U.S. Bioeconomy

Challenges

- Tied to basic science and its commercialization (innovation)
- Cross-cutting
  - Metrics commonly used to classify, collect, and report economic data fail to capture bioeconomic activity
  - Data on the bioeconomy have substantial gaps
- Innovations in the bioeconomy often replace existing products the benefits of such substitution may not be visible in in traditional economic statistics

Past Studies – not in alignment with this committee's definition

- Focus on industry activity (replacing petroleum-based activity with bio-based)
- Focus on biomedical activity (pharma, medical device, health care)

How can we value public databases?

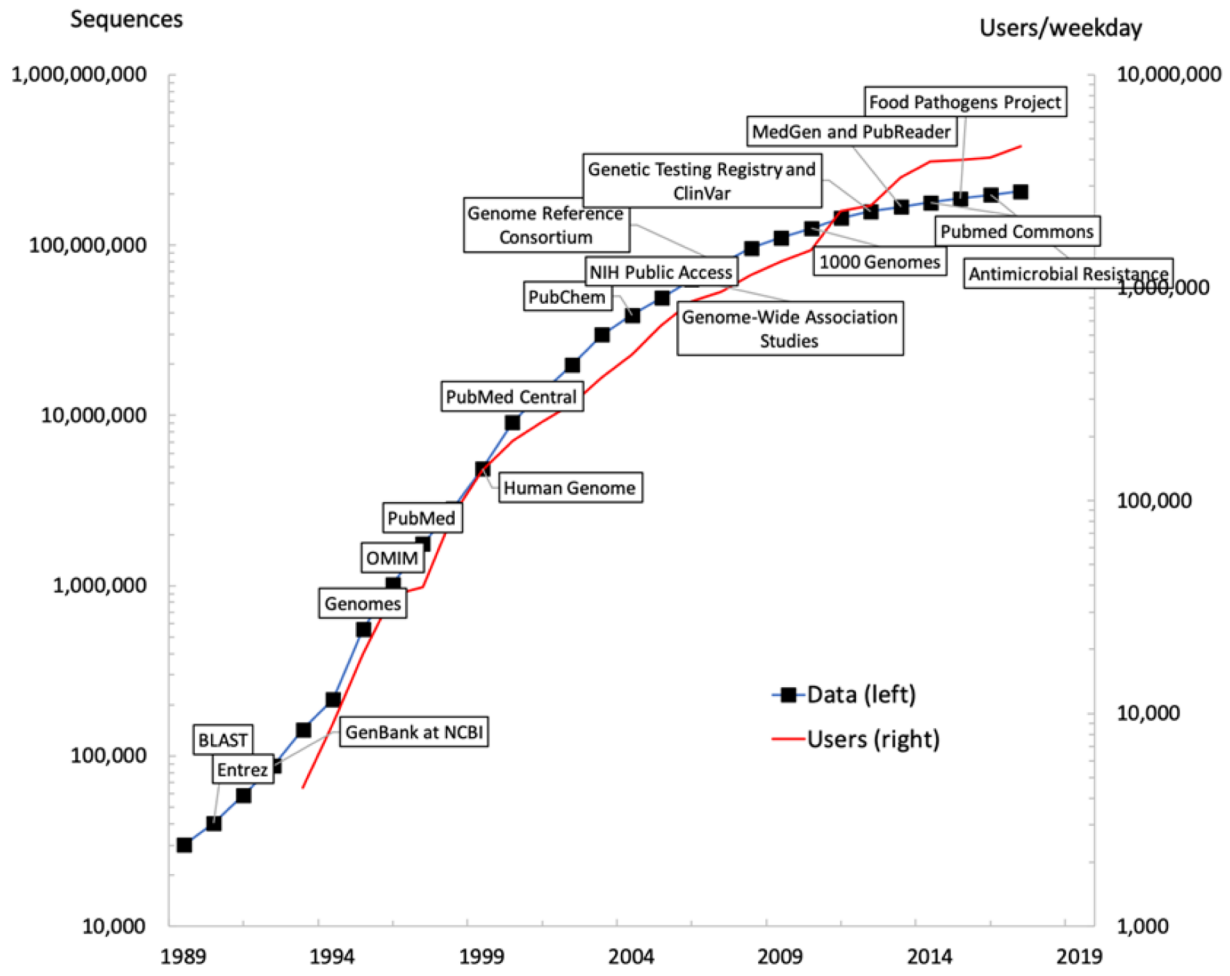


FIGURE 3-4 National Center for Biotechnology Information: Data (sequences) and users. SOURCE: Based on statistics reported at https://www.nlm.nih.gov/about/2019CJ.html#Budget_graphs (accessed May 4, 2019).

Case Study: Synthetic Biology

A key feature of synthetic biology is that its potential to engineer living organisms not only is an important driver of fundamental research but also (through the functions and synthesized products of these organisms) has direct relevance for immediate commercial application.

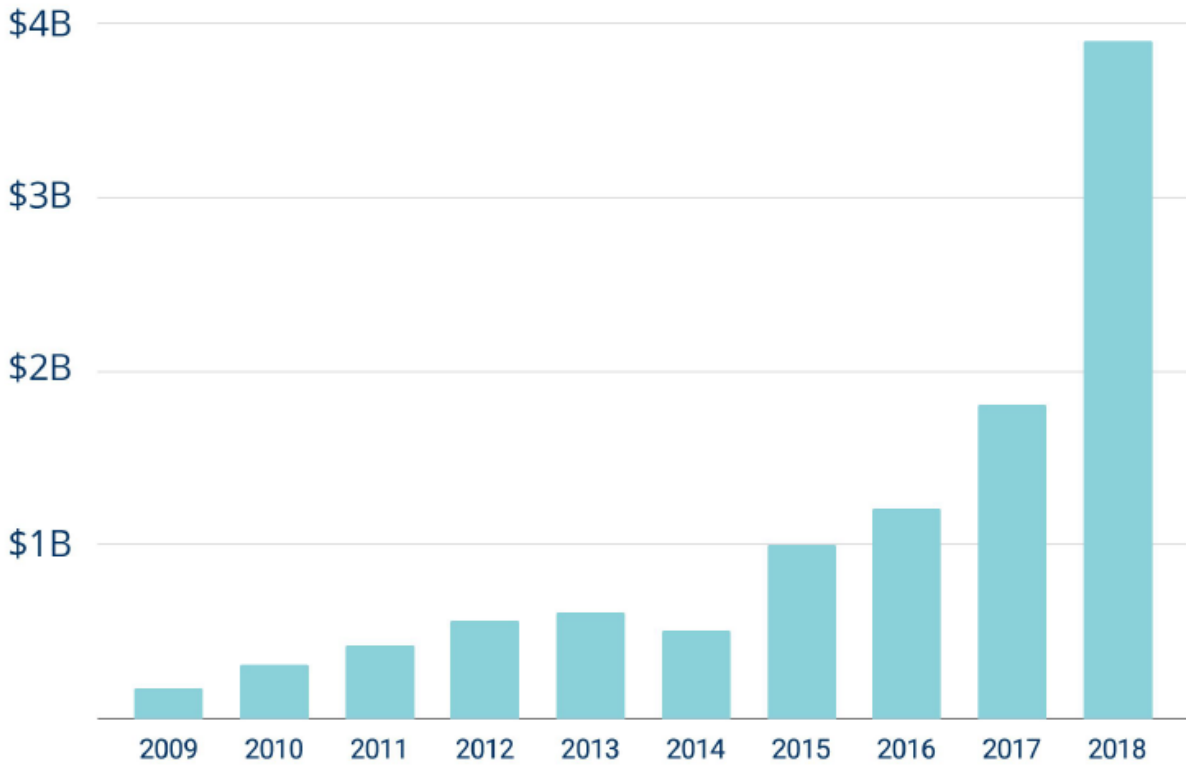


FIGURE 3-12 Funding for synthetic biology companies, 2009–2018.
NOTE: 2018 ≅ $3.8 billion.
SOURCE: Cumbers, 2019. Presentation to the committee January 2019.

Framework for Valuing the U.S. Bioeconomy

1. Set boundaries for the definition; identify primary segments of interest
2. Identify subsets of the primary segments to be included (covering equipment, services, and intangible assets*)

The following 6 segments were used as an approximation, as best as can be determined from available data:

- genetically modified crops/products;
- bio-based industrial materials (e.g., bio-based chemicals and plastics, biofuels, agricultural feedstocks);
- biopharmaceuticals and biologics, other pharmaceuticals;
- biotechnology consumer products other than drugs, (e.g., genetic testing services);
- biotechnology R&D business services, including laboratory testing (kits) and purchased equipment services (e.g., sequencing services); and
- design of biological data-driven patient health care solutions (i.e., precision medicine inputs), exclusive of patient care services per se and drugs counted elsewhere.

*see report for specifics on valuing intangible assets

Improving Valuation Efforts: Need Better Data

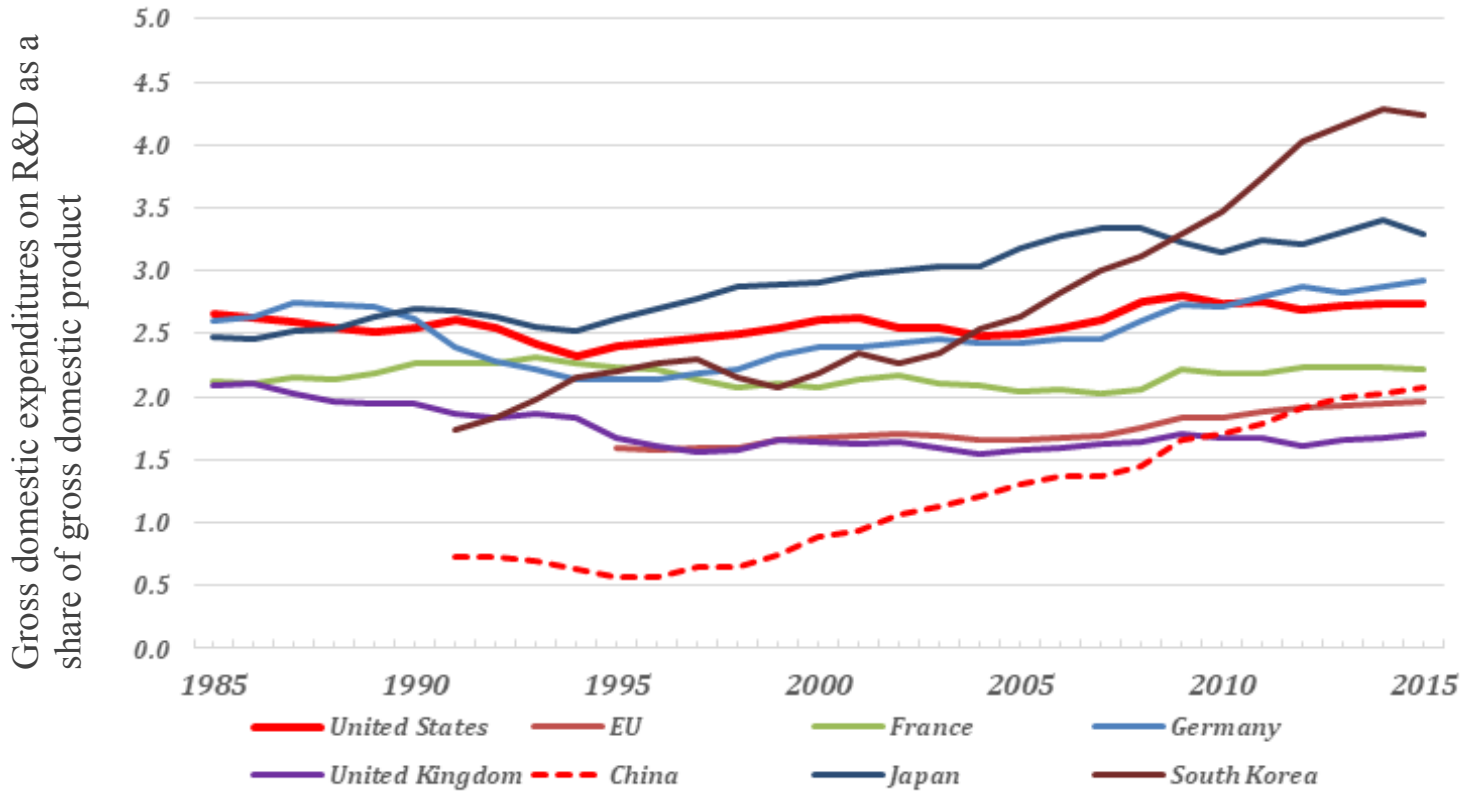
Recommendation 2: The U.S. Department of Commerce and the U.S. National Science Board should expand and enhance data collection efforts relevant to the economic contribution of the U.S. bioeconomy as defined by this committee.

This includes:

- Obtaining input from partners in science agencies and from nongovernmental bioeconomy stakeholders
- Updating and revising the North American Industry Classification System (NAICS) and the North American Product Classification System (NAPCS)
  - OTE study aimed at richer characterization of the permeation of biologically based products, processes, and services
- Development of bioeconomy satellite account linked to central national accounts
- Undertake new data collection efforts and analysis of innovation in the bioeconomy for the *Science and Engineering Indicators* report; need better indicators of leadership

Comparing Investment in Innovation

- The United States continues to lead the world in total investment in innovation.
- However, not relative to the size of its economy.



Other Metrics Demonstrating U.S. Leadership

Scientific Output in the Bioeconomy

- U.S. lead in the production of publications in the biological and medical sciences

International Patents

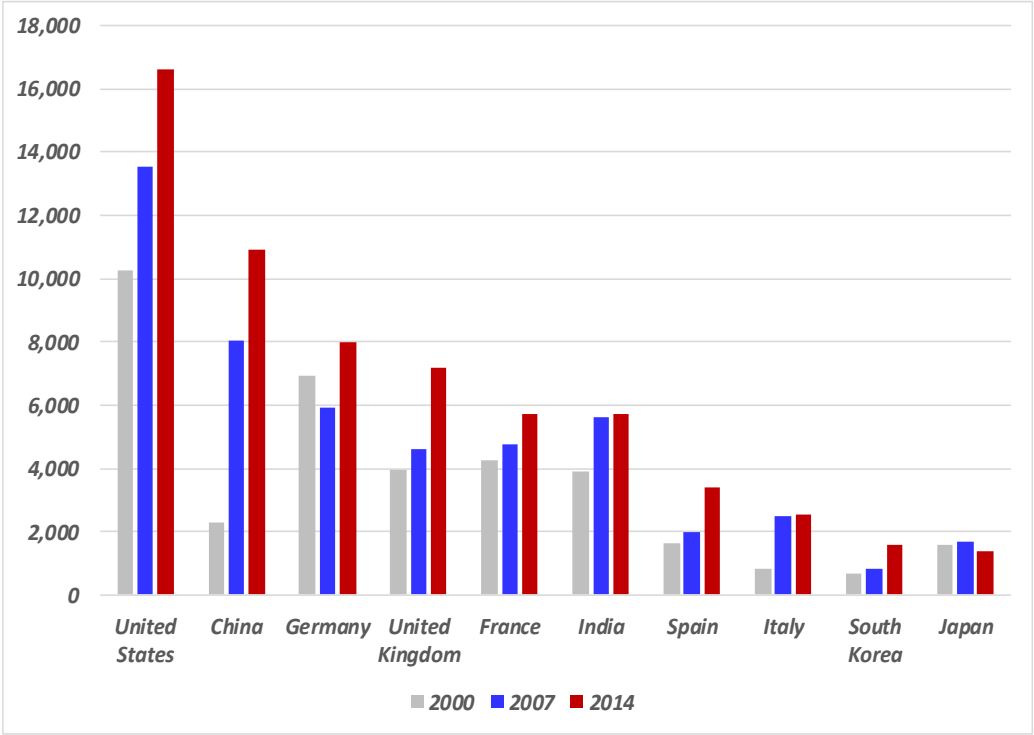
- United States leads world in patents
- Between 2001 and 2014 – there is a relative decline

National Patents

- China surpassed U.S. between 2011-2012

Scientific Training for the Bioeconomy

- United States leads world in training
- 30–34 % are students on temporary visas, majority are Chinese



Number of doctoral degrees in physical and biological sciences, mathematics, and statistics

U.S. LEADERSHIP CASE STUDY: SYNTHETIC BIOLOGY

Synthetic biology is an area in which evidence of U.S. leadership exists in innovation, entrepreneurship, and scientific and economic success.

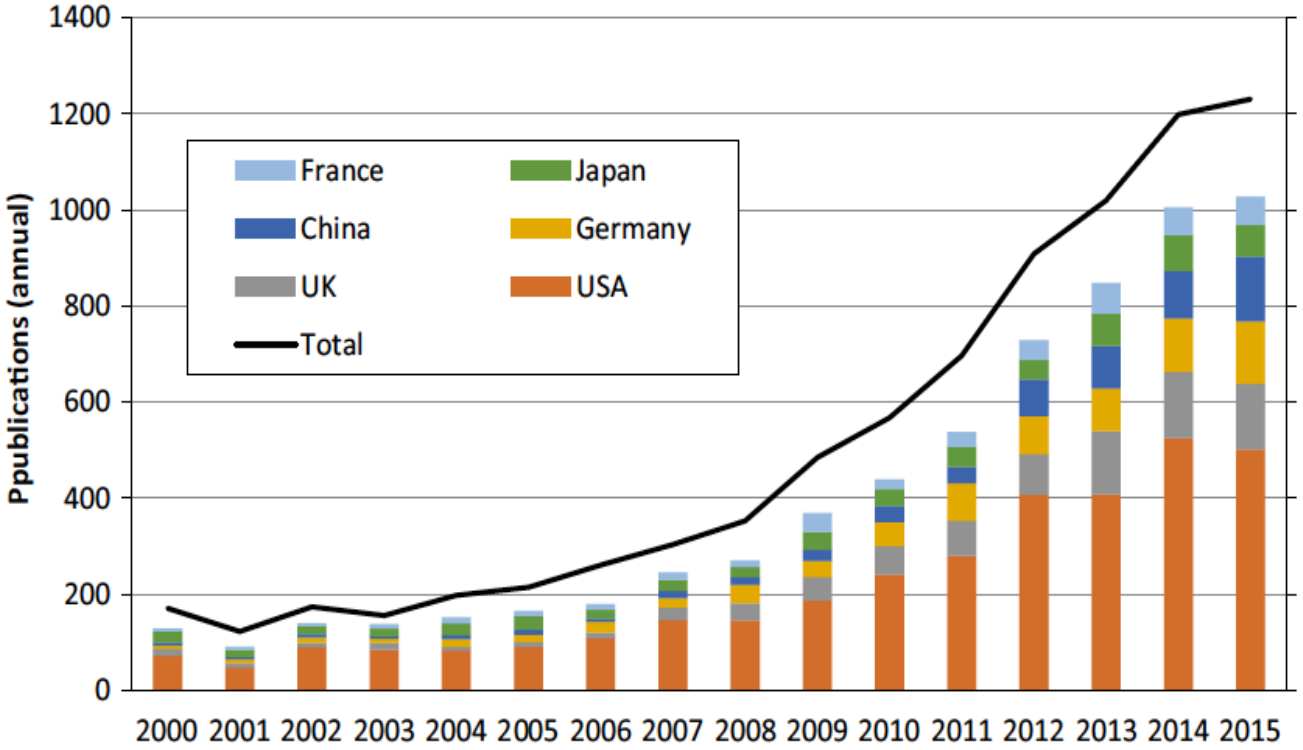


FIGURE 4-17 Synthetic biology publications, worldwide and by leading countries by author affiliation, 2000–2015. NOTE: Line graph depicts worldwide annual publications. Bar chart depicts annual publications for the six leading countries by total publication output. SOURCE: Shapira et al., 2017.

U.S. Bioeconomy Leadership Relies on Investment, Openness, and a Skilled Workforce

- Demonstrated general U.S. leadership in areas built on R&D in the life sciences
- Leadership built as a result of, and not despite, open scientific borders
- Continued leadership will involve
  - careful analysis of the policies and ecosystem undergirding the bioeconomy
  - continued commitment from the federal government to world-leading investment in sciences

Recommendation 4: To maintain U.S. competitiveness and leadership within the global bioeconomy, the U.S. government should prioritize investment in basic biological science, engineering, and computing and information sciences. In addition, talent development, at all levels, to support these research areas should be a high priority for future public investment.

Risk: Failure to Promote the U.S. Bioeconomy

- Insufficient U.S. government R&D investment
- Asymmetric research constraints
- Inadequate workforce
- Ineffective or inefficient IP environment
- Ineffective or inefficient regulatory environment
- Lack of public trust or conflict with public values

Risk: Failure to Protect the U.S. Bioeconomy

- Constrained access to international data
- Use of datasets to the detriment of individual privacy or national security
- Cyber risks associated with the bioeconomy
- Economic attack – theft and infiltration
- State involvement in business activities
- Trade barriers
- The bioeconomy as a component of critical infrastructure
- Traditional biosecurity and biosafety risks
- Risks from global climate change

Failure to Protect: Data & Cyber

Constrained access to international data

Use of datasets to the detriment of individual privacy or national security

Cyber risks associated with the bioeconomy

- The bioeconomy is vulnerable to the same cyber vulnerabilities present in any other sector – viewed as fundamental cybersecurity risks.
- Among the security vulnerabilities that derive from cyber intrusions are risks related to the cyber-physical systems that result in unwanted or dangerous biological outcomes, risks related to datasets, and vulnerabilities due to reliance on open-source software.

Recommendations Related to Data & Cyber Risks

Inadequate cybersecurity practices and protections expose the bioeconomy to significant new risks.

Recommendation 6*: All bioeconomy stakeholders should adopt best practices for securing information systems from digital intrusion, exfiltration, or manipulation.

Recommendation 7: To protect the value and utility of databases of biological information, U.S. science funding agencies should invest in the modernization, curation, and integrity of such databases.

Recommendation 8*: Bioeconomy stakeholders should pursue membership in one or more relevant information sharing and analysis centers (ISACs) or information sharing and analysis organizations (ISAOs), or consider creating a new sector-based information-sharing organization for members of the bioeconomy.

*Shortened for presentation

Failure to Protect: Economic Attack – Theft and Infiltration

Theft or misappropriation of trade secrets, confidential documents, or proprietary products

Illicit transfer of knowledge and technology via academic misconduct

- Such as violations of the terms and conditions, unauthorized dissemination of proposals, and theft of nonpublished research information

Recommendation 4-1: The U.S. government should continue to support policies that attract and retain scientists from around the world who can contribute to the U.S. bioeconomy, recognizing that open academic engagement has been strongly beneficial to the U.S. scientific and technological enterprise, even as it inherently offers potential benefits to other countries as well. Policies intended to mitigate any economic and security risks posed by foreign researchers in U.S. research institutions should be formulated by U.S. security, science, and mission agencies working closely together, and through ongoing engagement with a group of recognized scientific leaders. Having this group able to be fully briefed on the threat environment will greatly facilitate these discussions, since access to classified, proprietary, or other nonpublic information may be needed.

Failure to Protect: State Involvement in Business Activities

- State directed economic programs, the acquisition of U.S. biotech companies by foreign entities to gain access to IP
- Concerns that state-directed investment undermines the principles of open trade and distorts global markets

Recommendation 5: The U.S. government should convene representatives from its science and economic agencies who can access relevant classified information to provide security agencies with subject matter expertise so as to (1) identify aspects of bioeconomy global value chains that are vital to U.S. interests and to which access must be ensured, and (2) assist the Committee on Foreign Investment in the United States (CFIUS) in assessing the national security implications of foreign transactions involving the U.S. bioeconomy.

Strategy for Safeguarding the Bioeconomy

Need for Coordinating Mechanism

Given the lack of obvious lead government agency for the bioeconomy, a mechanism through which the science, economic, and security agencies could bridge the gaps in communication and coordination is needed.

Recommendation 3*: The Executive Office of the President should establish a government-wide strategic coordinating body tasked with safeguarding and realizing the potential of the U.S. bioeconomy.

- Presided over by senior White House leadership,
- Representation from science, economic, regulatory, and security agencies
- Responsible for relevant foresight activities and informed by input from a diverse range of relevant external stakeholders.

*Shortened for presentation

Designing an Approach

Recommendation 3-1*: The coordinating body should develop, adopt, and then regularly update a living strategy with goals for sustaining and growing the U.S. bioeconomy. This strategy should be

- Informed by an ongoing, formal horizon-scanning process
- Identify and raise awareness of means through which the U.S. government can advance the bioeconomy (ex. procurement of bio-based products)

*Shortened for presentation

Opportunities for International Engagement

Recommendation 9: Through such entities as the World Trade Organization and the Organization for Economic Co-operation and Development, as well as through other bilateral and multilateral engagements, the U.S. government should work with other countries that are part of the global bioeconomy to foster communication and collaboration.

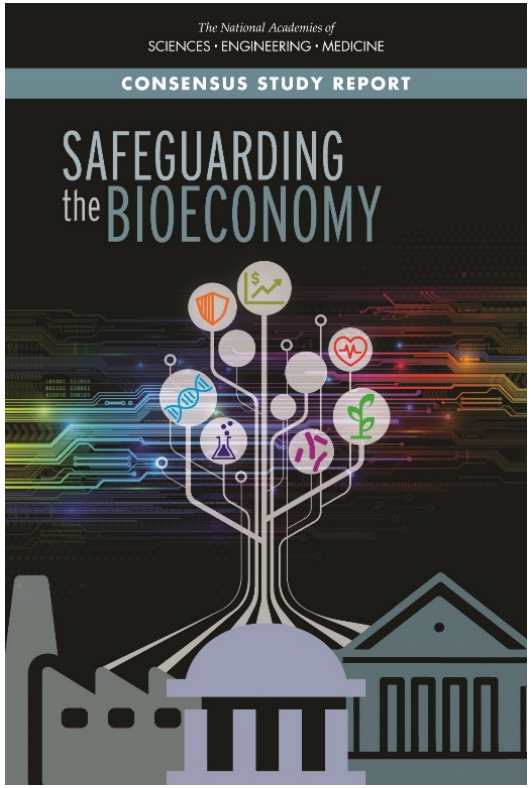
The goals of such international cooperation would be to:

- drive economic growth
- reinforce governance mechanisms within a framework that respects international law and national sovereignty and security
- create a level playing field.

Horizon scanning and foresight methods for growing the bioeconomy

- Approach: scenario planning or issue identification processes, or both?
- Scope: broad or narrow?
  - Defining the bioeconomy vs. tracking specific lines of development or policy issues
- Process: machine processing or expert opinion?
  - In the near term, horizon-scanning activities are likely to be human-driven; however, tools for automated data gathering are advancing and could be used to feed into a meta-review.
- Timeframe: near term or far term?
  - Combining horizon-scanning and foresight approaches will enable the identification of both near-term developments (foresight) and longer-term developments (horizon scanning).

Acknowledgements



- Fellow committee members
- National Academies staff
- Reviewers, speakers, and members of the public

Please visit nationalacademies.org/bioeconomy for more information or contact Andrea Hodgson, ahodgson@nas.edu.

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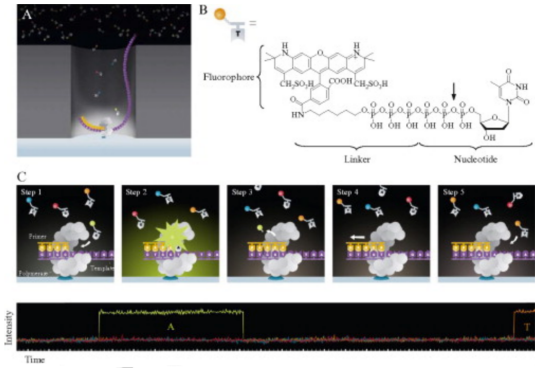
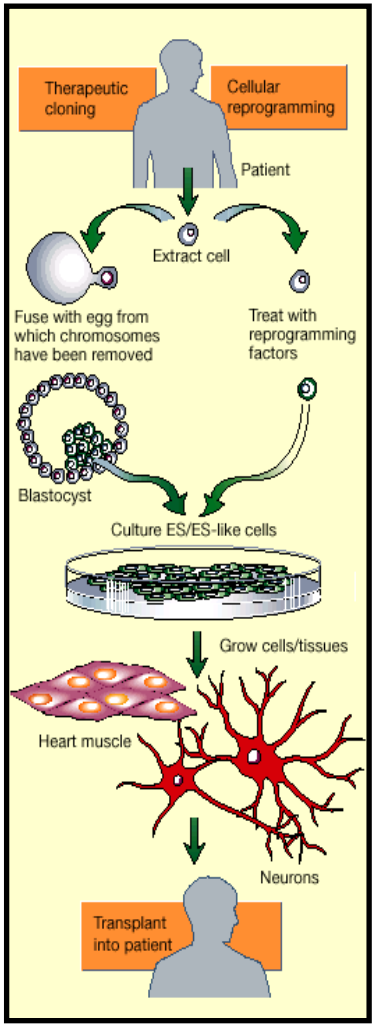
Discovery accelerates technology that accelerates discovery

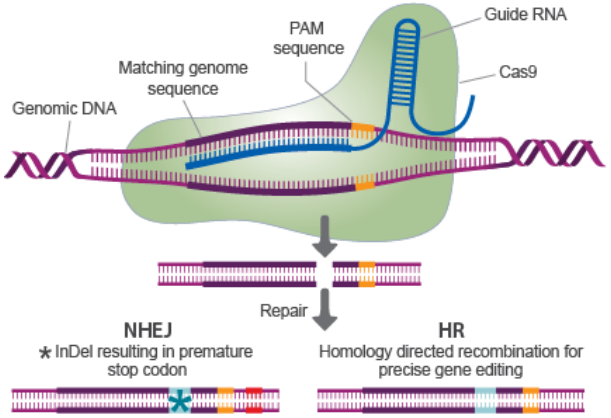
DNA sequencing technologies are moving toward real-time, single-molecule



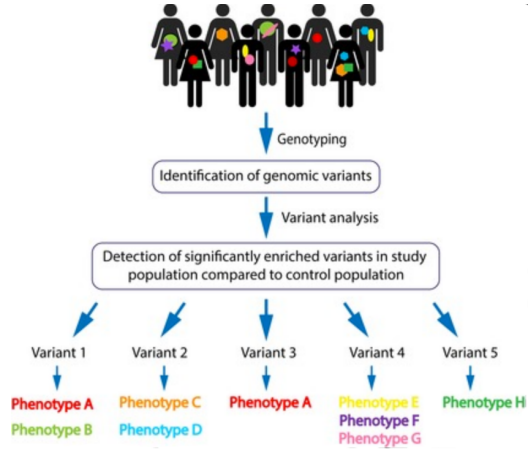
Fully differentiated cells can be reverted to an embryonic stem cell fate



Gene correction via CRISPR/Cas editing



Advances in deep-sequencing technologies have enabled genome-wide association studies (GWAS)



Reflections on BER's potential engagement

- Assess the research and economic value of the databases and tools that BER supports
- Evaluate research outputs through the lens of value to, and security of, the bioeconomy
- Develop policies and strategies for resource protection
- Support science that identifies/measures risk or promotes resilience
- Look over the horizon!