PCAST Report: Biomanufacturing to Advance the Bioeconomy

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DRAFT/PRE-DECISIONAL

Working Group on Advanced Biomanufacturing

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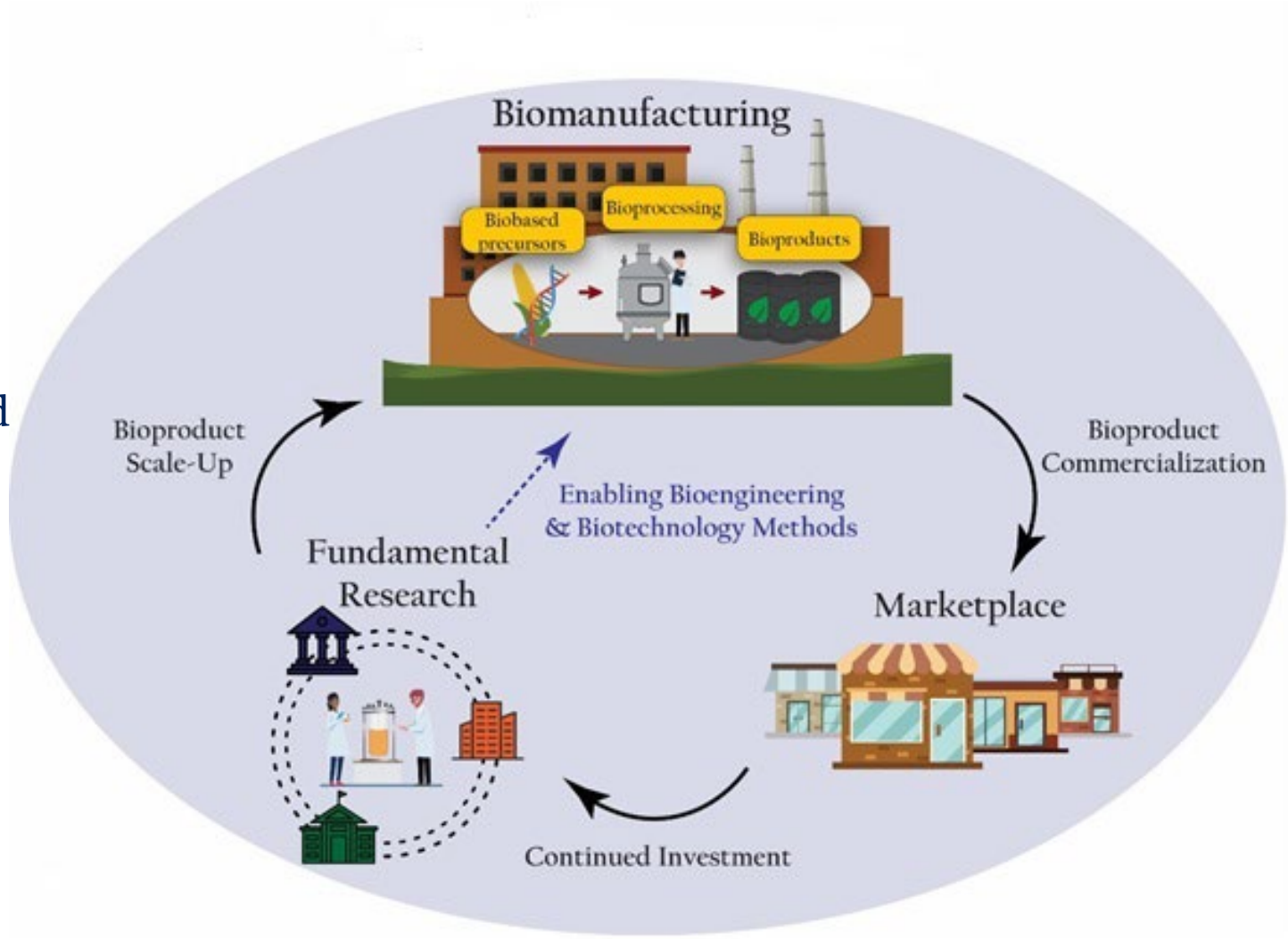
The Bioeconomy

An emerging and rapidly expanding economic sector that represents the portion of the economy based on products, processes, tools, and services derived from biological resources.

The U.S. bioeconomy market share was valued at $959.2 billion in 2016.

The global bioeconomy is estimated to have a future value between $2 and $4 trillion in the next 10 to 20 years.

Biomanufacturing is the engine by which innovative products of the bioeconomy are brought to commercial scale.



Advanced Biomanufacturing

- Executive Order 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy calls on PCAST to issue a report on the bioeconomy with recommendations to maintain global competitiveness.
- Biotechnology offers enormous promise for a new industrial revolution that could transform many American lives and livelihoods, but there are key gaps that are limiting the country's ability to realize the full spectrum of opportunities:
  - **insufficient manufacturing capacity**,
  - **regulatory uncertainty**,
  - and an **outdated national strategy**.
- PCAST has proposed a series of recommendation to meet the challenges in each of these areas.

Biomanufacturing infrastructure hubs

1.1. We recommend that the President direct the **Secretary of Commerce** to establish biomanufacturing infrastructure hubs* with the authorities and resources necessary to successfully scale up from prototype components in a production relevant environment (Manufacturing Readiness Level 6) to low-rate production capability (Manufacturing Readiness Level 8) by expanding the capability and capacity of the Manufacturing USA Institutes and leveraging the Regional Technology Hubs authorized in the CHIPS and Science Act.

* Consistent with the criteria for hubs established in the CHIPS and Science Act, biomanufacturing infrastructure hubs at MRL Levels 6 to 8 will help to fill a number of important roles in supporting the growth of the bioeconomy including physical facilities, continuing education and hands-on training, research and development related to bioproducts/bioprocessing, and touchpoints between regulators and industry.

Biomanufacturing infrastructure hubs

1.2. We recommend that the President direct the **OSTP Director** and the **Secretary of Commerce**, in consultation with the **Secretary of Defense**, the **Director of NSF**, and the **Secretary of Energy**, to develop a strategic plan that A) includes a competitive process for determining biomanufacturing infrastructure hubs' specific foci, funding allocations, and geographic locations and B) directs the creation of a network that connects the hubs established via any of the available innovation hub programs, including the Manufacturing USA Institutes, Commerce's Regional Technology Hubs, the Department of Defense biomanufacturing initiative, and NSF's Regional Innovation Engines. The plan should be completed within 180 days of the publication of this report.

Biomanufacturing infrastructure hubs

1.3. We recommend that the President instruct **NSF**, **NIH**, **DOD**, **DOE**, **USDA**, **FDA**, and other relevant agencies to coordinate with the biomanufacturing infrastructure hubs to form partnerships and funding opportunities with local university and research institutions. These partnerships should focus on bioprocessing and biomanufacturing, establish advanced biomanufacturing research opportunities that leverage or expand the biomanufacturing infrastructure hub network and facilities, and support programs across the spectrum of post secondary training opportunities in this area.

Coordinated Regulatory Approval Process

2.1. We recommend that **EPA Administrator**, **Secretary of Agriculture**, and **FDA Commissioner** establish a standing Rapid Response Team of key agency representatives that meets regularly and frequently to vet new, cross-cutting products and provide recommended regulatory routes for bioproducts to developers. This team should be involved with the continued development of the Unified Website for Biotechnology Regulation that is required by EO 14081. The Rapid Response Team should provide opportunities to cross-train regulatory staff members in ombuds positions that would reside within each agency to act as guides for bioproducts.

Coordinated Regulatory Approval Process

2.2. We recommend that **FDA**, **EPA**, and **USDA** develop streamlined and model pathways for regulatory review and approval of emergent bioproducts of similar type by either: a) drawing from the evolution of pathways as a result of past product review processes, and/or b) creating an open access, searchable library of previously determined routes or pathways for new bioproducts as they are established.

Coordinated Regulatory Approval Process

2.3. We recommend that the President direct the **FDA**, **EPA** , and **USDA** to create a training and information network that links across the biomanufacturing infrastructure hubs and existing or future federally funded advanced biomanufacturing centers (e.g., BioMade, BioFAB, NIIMBL, and other relevant centers), and to assign regulatory scientists as affiliates to the biomanufacturing infrastructure hubs.

A new, data-based strategy for the bioeconomy

3.1. We recommend that the President direct the **National Science and Technology Council (NSTC)** to prepare a long-term (10-year) strategy for the bioeconomy. This strategy should be informed by the reports required by the CHIPS and Science Act and EO 14081. The strategy should be completed and delivered within 18 months to the OSTP Director. The strategy must consider the long-term economic, environmental, and societal benefits and liabilities of the proposed actions and policies as well as national security implications.

A new, data-based strategy for the bioeconomy

3.2 The **OSTP Director** should include research needs of the bioeconomy as a key component of the National Biotechnology and Biomanufacturing Initiative outlined in EO 14081; and the National Engineering Biology Research and Development Initiative and the 5-year coordinated research report designated by the CHIPS and Science Act to be delivered in 2023. These plans should emphasize the fundamental and translational research needed to accelerate the growth of the bioeconomy and other key objectives for international competitiveness.

A new, data-based strategy for the bioeconomy

3.3. We recommend that the **Secretary of Commerce** should direct the **Bureau of Economic Analysis** to establish a satellite account for the bioeconomy as soon as possible and no later than FY 2024. Federal statistical agencies should plan to provide data for the strategy's established metrics and request the resources necessary to do so in their budget requests for FY 2025. The plan should provide the data necessary for the metrics defined by the NSTC strategy and with the cadence necessary to track the bioeconomy.