The U.S. Bioeconomy: Charting a Course for a Resilient and Competitive Future

A Bioeconomy Strategy

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SCHMIDT FUTURES

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About This Project

To seed the next wave of innovation in synthetic biology and the bioeconomy, Schmidt Futures launched the Task Force on Synthetic Biology and the Bioeconomy in October 2021 as part of a program to advance transformative biobased and bio-enabled applications in areas such as energy, chemicals, advanced materials, environmental remediation, agriculture, electronics, and health. Task Force members were subject matter experts from a wide range of disciplines, including physics, science policy, regulatory policy, biosecurity and safety, national security, risk assessment, ethics, computer science, and synthetic biology; venture capitalists and industry leaders from both small and large companies; and leaders from biotechnology consortia. This report uses the term engineering biology in the broadest sense to include synthetic biology, biotechnology, genome editing, and other academic approaches to generate purposefully designed biological systems.

In an interim report released December 1, 2021, Schmidt Futures focused on identifying research needs for translating promising engineering biology discoveries to biobased production and assessing infrastructure needs to support the U.S. bioeconomy. Since the release of that document, Schmidt Futures has continued exploring topics such as talent and workforce development, policy modernization, and catalytic actions to spur innovation. Bringing everything together, this document presents a strategy composed of three parts: a rationale and recommendations; a set of strategic actions that if implemented would enact the key aspects of the recommendations; and a series of case studies to provide additional context to the concepts discussed. In October 2021, the Office of Science and Technology Policy released a Request for Information to inform an upcoming National Strategic Plan for Advanced Manufacturing, including biomanufacturing, indicating that this is a priority area. The next month, the President's Council of Advisors on Science and Technology identified biomanufacturing as one of the President's priorities for national competitiveness. Combined, these two actions signal the Administration's interest and intent to address the U.S. bioeconomy in a strategic manner. Given this, the strategy in this document may serve as a starting point for such a national plan, one designed with the intention of moving toward a vibrant, U.S. circular bioeconomy.

Certainly, other organizations have developed roadmaps that support funding research that would aid in developing a vibrant bioeconomy. What makes this effort different is its timeliness, but more importantly, its emphasis on taking a system-of-systems approach that simultaneously addresses the research and development activities needed to expand end-to-end bioproduction capacity on the scale necessary to evolve the U.S. bioeconomy toward a circular bioeconomy, works to develop a well-trained bioeconomy workforce, and enables a policy environment that incentivizes and supports a circular bioeconomy and accelerates the transition to a net-zero carbon economy.

This document argues for actions the federal government and other stakeholders can take to bolster the growing bioeconomy in three sections. The first section provides context, laying out the case for why supporting the bioeconomy is imperative as a means of transitioning to a net-zero carbon economy; catalyzing equitable and inclusive regional economic development using sustainable, home-grown resources; securing leadership in an increasingly competitive global bioeconomy; and creating more resilient supply chains and addressing national security concerns. In addition, this section offers recommendations for specific actions the nation should take to achieve the desired outcomes described in the first section. The second section provides a strategy for implementing these recommendations. Though the recommendations and strategy focus largely on federal actions, they have implications for actions at the local, state, and regional levels, and opportunities for action by industry and philanthropic entities. The final section includes illustrative case studies that bring together various concepts, opportunities, and barriers that relate to the recommendations.

To develop the recommendations and create the strategy, the Task Force members met regularly to debate a range of topics and developed several novel research products that informed the recommendations made. Information gathering included interviews of more than 65 experts, literature reviews, and input from meetings and webinars. Schmidt Futures would like to acknowledge and thank the many individuals who contributed to this effort (see Appendix A), in addition to the Task Force members who dedicated their time to participate in this effort.

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** Denotes the Task Force members who contributed to both the interim report and this final document.*

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Executive Summary

In the nearly 50 years since the first genetic engineering experiments, the United States has become the world's biotechnology powerhouse, with the resulting biobased and bio-enabled economy—the bioeconomy—generating at least 5.1 percent of U.S. GDP or more,[1] with more than half of the total generated outside the biomedical sector, including the agricultural and industrial biotechnology sectors. Within the next two decades, a well-developed bioeconomy will transform manufacturing processes to use the more than a billion tons of sustainable biomass and other sources of biogenic carbon in the United States rather than petroleum to make the products of modern society. Doing so will reduce the nation's dependence on fossil fuels, revitalize U.S. manufacturing and employment across the nation, create a more resilient supply chain, address concerns regarding national competitiveness and national security, improve the nation's health and environment, and contribute significantly to the goal of creating a net-zero carbon economy. If fully utilized, those billion tons could be used by a thriving bioeconomy to generate 25 percent of the nation's liquid transportation fuels and 50 billion pounds of bio-based chemicals, as well as cut carbon dioxide emissions by 450 million tons and support 1.1 million U.S. jobs.

Indeed, the world will transition to a bioeconomy within the next two decades, and the question is whether the United States will lead the way or relinquish its current leadership position. However, decentralized leadership and a corresponding lack of a strategic vision, inadequate talent development, insufficient investment in both fundamental research and the activities that turn discovery into public benefits, and international competition put the United States at risk of forfeiting its world-leading position and squandering the entrepreneurial drive and capital market interest that is trying to expand the bioeconomy. Without concrete action to address these concerns, the nation's economy, its national security, the health of its residents, and its opportunity to move to a net-zero carbon economy that creates good-paying jobs and keeps them in the country are in peril.

Schmidt Futures, a philanthropic initiative of Eric and Wendy Schmidt, convened a Task Force to chart a course for achieving the promise of platform technologies such as engineering biology and artificial intelligence to contribute to what has recently been projected to become a future bioeconomy worth somewhere between $4 trillion and $30 trillion dollars globally, according to the most recent projections.[2] The Task Force deliberated on the roadblocks and focused on identifying opportunities for translating basic science research into products for the general public by enabling large-scale production of exciting bioeconomy products such as:

- A new generation of plastics that degrade to harmless compounds in seawater and soil or that can be more easily recycled or reused
- Biologically produced, carbon-neutral cement and carbon-negative commodity chemicals
- Alternative sources of food protein that are more available to the global population, use less water and land, and produce fewer greenhouse gas emissions
- Soil microbes that reduce fertilizer use, improve the health of soils, and remove carbon dioxide from the atmosphere
- Field crops engineered to sequester more carbon in the soil while producing useful grains, as well as plants resilient to climate change, including salt- and drought-resistant crops
- Textiles, dyes, and other performance materials whose production slashes carbon dioxide emissions and reduces toxic waste
- Personal care products developed using ingredients that are not sourced from threatened and endangered species
- Lubricants made from locally available and sustainable biomass and biogenic carbon instead of petroleum
- Compostable dining ware and food storage containers made from tapioca, potato starch, and grass fibers
- Soy-based roof coating that helps reduce urban heat
- Medicines made without relying on petrochemicals

This document makes recommendations for public and private action that fall into four broad categories: addressing foundational science and technology challenges; building a national infrastructure for bioproduction scale-up capacity; developing a well-trained workforce to power the bioeconomy; and enabling centralized leadership and a policy environment that incentivizes and supports a circular bioeconomy. Bringing everything together, this document presents a strategy composed of three parts: a rationale and recommendations; a set of strategic actions that if implemented would enact the key aspects of the recommendations; and a series of case studies to provide additional context to the concepts discussed (see Figure ES1). Collectively, the recommendations and strategy could be implemented in ways that do not harm the environment on a net basis and also advance equity in society, particularly as it relates to improving economic competitiveness and revitalizing underserved communities. In addition, the recommendations and strategy address the fact that most life sciences research funded by the federal government today in the United States is curiosity and discovery driven rather than application driven. As a result, the "non-academic" challenges, which arise in the transition of discovery to application and limit the ability to realize bioproduction goals are underfunded, underexplored, and underdeveloped in the United States. In addition, because other countries are investing in solving these challenges and developing the necessary workforce and regulations that support these activities, U.S. companies are taking their technologies overseas for production and commercialization, a situation that if continued, promises to yield the same "innovate here, produce there" outcome that did so much damage to the U.S. manufacturing sector in the 1980s and the people it employed.

Bringing everything together, this document presents a strategy composed of three parts: a rationale and recommendations; a set of strategic actions that if implemented would enact the key aspects of the recommendations; and a series of case studies to provide additional context to the concepts discussed.

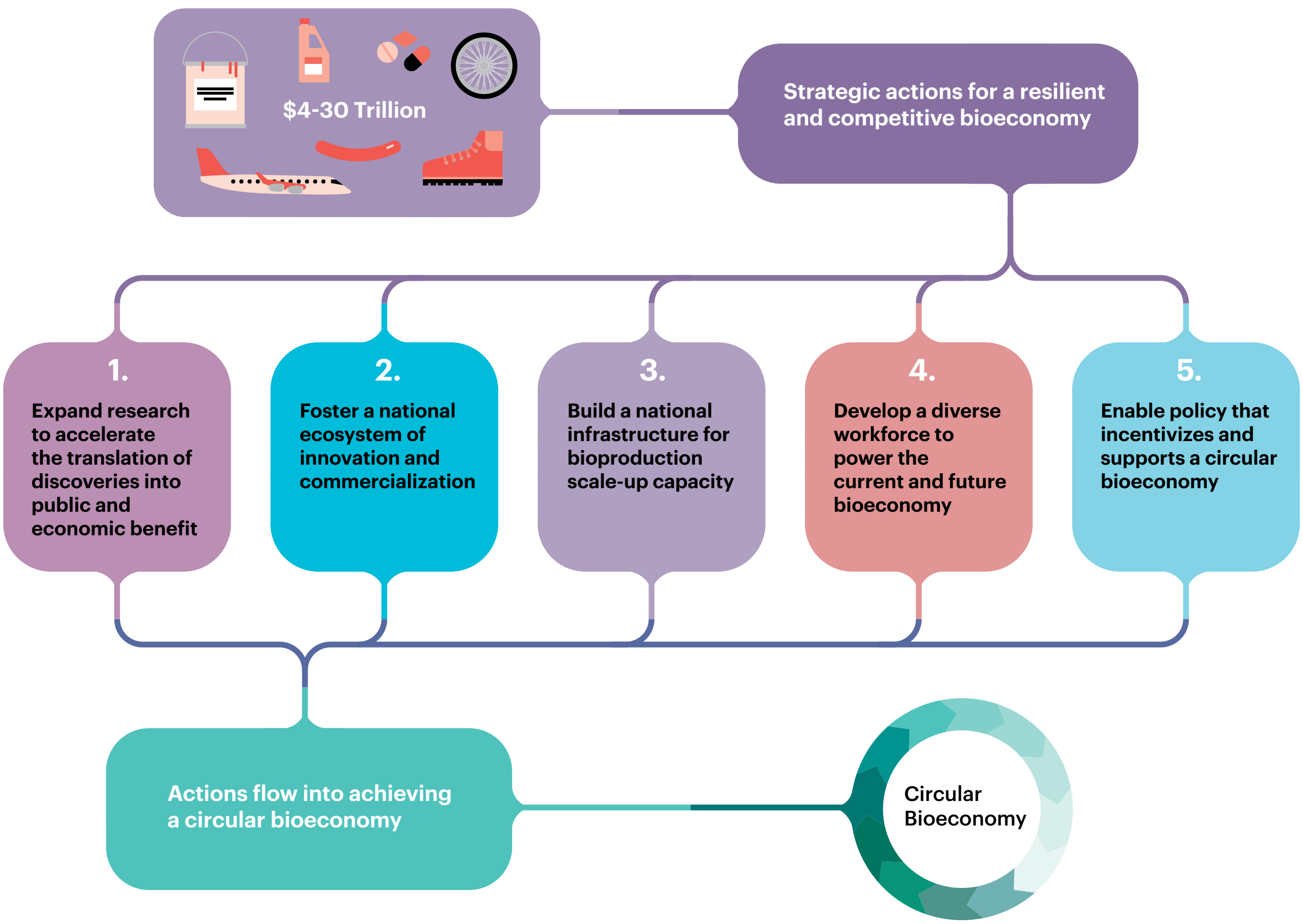

FIGURE ES1 Strategic actions for a resilient and competitive bioeconomy.

Summary of the Recommendations

In addition to the recommendations that follow, many of the recommendations of recent reports by the National Academies and others are directly relevant and should be considered when taking actions to advance the translation of bioeconomy-related discoveries to public and economic benefit.[3]

A Coordinated U.S. Bioeconomy and an Informed Strategy are Needed

To remain globally competitive, the U.S. government through a National Science and Technology Council interagency effort should develop and periodically update a national bioeconomy strategy focused on providing scalable solutions to advance the bioeconomy in a coordinated way, identifying the Department of Commerce as the "home."

More Fundamental R&D is Needed to Translate Discoveries to Market

To secure global leadership in biobased science and scale-up manufacturing, the U.S. government should establish and fund a 5-year, at least $1.1 billion Bioproduction Science and Engineering Initiative (BSEI) that expands budgets and remits of relevant science and technology funding agencies focused on advancing foundational science and technology development for current and future bioproduction and is focused on addressing unmet research needs that hinder the translation of innovative technologies.

New Distributed Bioproduction Testbed Infrastructure is Needed

Given the value of maintaining resilient domestic supply chains and creating manufacturing jobs, the U.S. government should invest $1.2 billion in an extensive and flexible bioproduction infrastructure—one that can process multiple feedstocks using multiple organisms to produce multiple products by multiple mechanisms at multiple scales—over two years to expand domestic bioproduction capacity in an equitable and strategic manner. Additional funding for maintaining and sustaining these investments will be needed over time.

A Well-Trained, Diverse Workforce is Needed

The federal and state governments should provide incentives that bring industry and learning institutions of all relevant types (e.g., community colleges, Historically Black Colleges and Universities, Tribal Colleges and Universities, Hispanic Serving Institutions, 4-year institutions, and others) together to build bioproduction science curricula/certification programs that will provide opportunities for a diverse workforce that is trained with high-demand skills and competencies for immediate industry employment.

Regulatory Agencies Need More Resources

Congress should provide EPA, FDA, USDA and the other agencies (e.g., Fish and Wildlife Service, NOAA, and OSHA) involved in oversight of the ever-evolving biotechnology products being developed with sufficient funding to enable agility and efficiency while protecting human health and the environment, and to develop the requirements needed for assessments of unfamiliar, novel, and/or complex biotechnology products.

Financial Incentives & Measurement Tools are Needed

The federal government should explore and use all appropriate financial incentives to drive growth of the bioeconomy and enable better measurement capacity to track its growth and the success of policy interventions.

Data Sharing Mechanisms are Needed

Recognizing the importance of federally funded and industry generated data for advancing the bioeconomy, Congress should provide funding for the modernization of relevant existing databases and creation of data-sharing mechanisms to spur continued progress, such as creative new public-private partnerships with the goal of reducing the time it takes to successfully scale new products from several years to months.

Introduction

Key Takeaways

National action now will enable the U.S. bioeconomy to lead history's fourth Industrial Revolution, one as pivotal as the invention of the steam engine, the age of science and mass production, and the rise of digital technology.

A future global bioeconomy will be worth somewhere between $4 trillion and $30 trillion dollars. However, concerted action and a national strategy is imperative to ensure the U.S. does not miss out on this historic opportunity to expand the domestic bioeconomy in the face of stiff international competition, and to provide sufficient investment in the infrastructure and training necessary for rapid and safe commercialization of bioeconomy products.

A well-developed bioeconomy will reduce the nation's dependence on fossil fuels, revitalize U.S. manufacturing and employment, create a more resilient supply chain, address concerns regarding national competitiveness and national security, improve the nation's health and the environment, and contribute significantly to the goal of creating a net-zero carbon economy.

Definitions

Bioeconomy	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.
Biogenic carbon	Carbon that is stored in biological materials, such as microbes, plants, and soil.
Bioproduction	Biobased production, including biomanufacturing, that uses biological systems, including plants, microbial consortia, individual living cells, and or parts of living cells (known as cell-free systems), to produce commercially important products from biomass feedstocks in a broad range of economic sectors including health, nutrition, agriculture, and industrial applications.
Biotechnology	The use of biological processes for industrial, agricultural, biomedical, and other purposes, especially the genetic manipulation of microorganisms, plants, and animals for research purposes and to generate useful products.
Circular bioeconomy	An economy that forgoes the traditional linear economic model of "take-make-consume-throw away" for one that uses the power of biotechnology, design for bioproduction, and machine learning/artificial intelligence to create an economic system in which waste products serve as inputs to create highly valued products and materials, that are used as long as possible, and reused without drawing down limited resources or generating wastes that are disposed into the atmosphere, landfills, or rivers, lakes, and oceans.
Engineering biology	The design and construction of new biological entities, such as enzymes, metabolic pathways, cells, microbes, plants, and animals, or the redesign of existing biological systems.
Net-zero carbon economy	An economy that achieves no net emissions of greenhouse gases by balancing its greenhouse gas emissions with steps to either remove them from the atmosphere or eliminate their emissions in the first place.
Sustainable biomass	Biomass that does not affect food production for domestic consumption or export, does not lead to deforestation or land degradation, and maintains environmental quality.

Introduction

In the nearly 50 years since Herbert Boyer and Stanley Cohen conducted the first genetic engineering experiments, DNA has become a foundational platform technology that the United States has capitalized on to become the world's biotechnology powerhouse. Today, this platform technology contributes 5.1 percent or more of the nation's GDP and is powering the creation of hundreds of thousands of good-paying jobs in the U.S. bioeconomy. Much of this economic activity is the result of heavy public and private sector investment in discovery science that has produced life-saving advances in biomedicine; a more resilient agricultural system through developments such as drought-tolerant corn and wheat and the discovery of soil microbes that reduce fertilizer use and improve soil health; options for using enzymes, microbes, plants, animals, sustainable biomass, and biogenic carbon to produce fuels, chemicals, and a number of household and personal care products; and even the ability to turn atmospheric carbon dioxide into cement and other products.

Having seen the scientific and economic potential that biotechnology offers, the rest of the world is increasingly interested in harnessing this technology for their own economic, national security, and societal benefits. As a result, international competition is increasing, and other countries are creating, implementing, and adopting long-term strategies to develop their own bioeconomies as a means of providing a wide range of jobs for all educational levels while capitalizing on the potential to develop long-term solutions for human and environmental health challenges. While there is great potential for global collaboration within the bioeconomy, it is important to recognize that the countries that lead in this space will be able to set the norms and standards that ensure further development of the bioeconomy occurs in a safe, responsible, and equitable manner while maximizing the benefits to their own citizens and economies.

> Decentralized leadership and a corresponding lack of a strategic vision, inadequate talent development, insufficient investment in both fundamental research and the activities that turn discovery into public benefits, and international competition put the United States at risk of forfeiting its world-leading position and squandering the entrepreneurial drive and capital market interest that is trying to expand the bioeconomy.

U.S. policymakers need to recognize, though, that continued investment in discovery-driven science is essential but not sufficient to maintain the nation's competitive advantage and leadership position in the global bioeconomy. Indeed, the nation must increase its support for the research and development activities that enable laboratory discoveries to become products and processes that benefit both people and the planet while creating jobs and growing the U.S. economy as a whole. The United States also needs a strategic vision to guide these activities. Enacting this vision will require examining and strengthening the nation's approach to scientific investment and economic development, creating new education pathways that lead to good-paying bioeconomy jobs that are accessible to everyone, and adjusting existing policies and crafting new ones to remove barriers and incentivize investment in the bioeconomy.

In fact, decentralized leadership and a corresponding lack of a strategic vision, inadequate talent development, insufficient investment in both fundamental research and the activities that turn discovery into public benefits, and international competition put the United States at risk of forfeiting its world-leading position. Without action to address these concerns, the nation's economy is in peril of losing a critical opportunity to capitalize on its substantial investment in biology as a fundamental and transformative platform technology (see Case Study 1). The nation will lose the opportunity to insulate itself from the supply chain disruptions resulting from natural and man-made disasters, as illustrated by the supply chain shocks triggered by recent events such as the extreme weather that hit Texas in 2017 and 2021, the COVID-19 pandemic, and the war in Ukraine.

Moreover, without immediate action, the United States will lose its opportunity to lead the world in utilizing biotechnology to move toward a net-zero carbon economy that creates good-paying jobs, keeps those jobs in the country, and makes a major contribution to mitigating the effects of climate change on our society and on the planet's ecosystems. Indeed, the United States has all the necessary resources—a science and engineering knowledge base, commercial and venture capital interest, plentiful renewable raw materials, an energized and innovative workforce that wants to address the perils of climate change, and consumers demanding products that are less harmful to the environment—to jump-start a concerted national effort to position the bioeconomy as a powerful economic driver that protects rather than harms the environment.

Our game-changing expertise at using DNA as a platform technology can lead the global transition of using renewable biomass and other environmentally benign resources to replace the role of petroleum products and other non-renewable materials in driving economic activity. Should the nation seize this opportunity by capitalizing on its global leadership in genetic engineering, molecular biology, and biotechnology, and its strong position in artificial intelligence, the result will be transformative. National action now will lead to yet-to-be-imagined opportunities and enable the U.S. bioeconomy to lead history's fourth Industrial Revolution, one as pivotal as the invention of the steam engine, the age of science and mass production, and the rise of digital technology (see Box 1).

BOX 1.

The Bioeconomy's Transformative Effects

- Enable the nation to reach its goal of establishing a net-zero carbon emissions economy by 2050
- Lead to a healthier and more sustainable nation and planet
- Address the existential challenge of increasing food and water security
- Reduce the nation's dependence on foreign resources, reduce its balance of trade deficit, and strengthen and add resilience to the nation's supply chains
- Revitalize urban and rural economies and create economic opportunities for marginalized communities
- Capture the lion's share of what is projected to be a $4 to $30 trillion global industry[4] that will affect almost all human endeavors and wellbeing
- Enable access to whole new classes of molecules that are currently not accessible through traditional chemistry, driving entirely new applications and opening up new and yet-to-be-imagined opportunities for economic growth

BOX 2.

Benefits of Transitioning to a National Bioeconomy

- Create 1.1 million high-paying and intellectually satisfying jobs[5]
- Keep $260 billion dollars a year of economic activity from going overseas[6]
- Contribute to the prosperity of rural, urban, and underserved and marginalized communities across the nation by using locally produced biomass for regional bioproduction
- Replace the transportation fuels that long-haul air travel and shipping might require even after electrification of the nation's transportation sector
- Produce chemicals and bioproducts from renewable biomass, biogenic carbon, and waste feedstocks rather than from traditional chemical manufacturing, and produce entirely new materials that nature can make economically
- Create a dependable, economic, resilient and distributed domestic supply chain for producing all biobased products
- Increase access to and improve the nutritional value of food and improve soil health while reducing agriculture's greenhouse gas footprint, nitrogen runoff, and pesticide use
- Use marsh lands and forests more efficiently to improve their carbon- and water-holding capacity
- Create salt-tolerant, drought-tolerant, and disease-resistant crops to increase the resilience of agriculture
- Produce genome-edited livestock that are disease resistant, heat-tolerant, and whose food products have improved nutritional profiles
- Develop large-scale, low-energy-use DNA-based data storage to better capture the tremendous growth in data generated by human activity
- Reduce annual U.S. carbon dioxide emissions by 450 million tons, nearly 10 percent of the nation's emissions, or more, while also creating the possibility of developing biological processes that remove carbon dioxide from the atmosphere
- Improve soil health and biodiversity leveraging a combination of no-till agriculture, bio-derived crop nutrients, specific and selective pest management and genotypes of crops that increase soil content of carbon at the end of the growing season

The U.S. Department of Energy (DOE) projects that the United States could sustainably produce more than 1.3 billion tons of biomass a year—without negatively affecting food, animal feed, export demands, and the environment—while transitioning to low-carbon input agriculture and forestry that nurtures soil health and even increases carbon sequestration in soils.[7] With a concerted and coordinated effort involving the federal government, academia, and the private sector, the transition to a bioeconomy has the potential to produce myriad benefits to the nation (see Box 2). Action today at the federal level would also signal to a broad swath of the scientific community and entrepreneurs that the bioeconomy, along with disciplines such as green chemistry, offers an important path to address climate change while also strengthening and growing the U.S. economy and addressing national security, including supply chain concerns.

In addition, a biobased and bio-enabled economy, relying on the ability of nature to perform chemistry that humans have yet to master at scale, is likely to produce entirely new materials and production processes, just as the chemical industry has done (see Box 3). In fact, synthetic organic chemistry performed by humans may be reaching the limits of the possible, while nature is capable of extending the range of available chemicals and materials. As Nobel Laureate Frances Arnold put it, "By far, nature is the best chemist of all time."[8]

BOX 3.

Bioeconomy Products, Available Today or On the Near Horizon, That are Less Damaging to the Environment[9]

- Plant-based meat substitutes with a much smaller environmental footprint
- Muscle cell-derived meat products that reduce animal husbandry reliance and present new prospects for improved health benefits
- Textiles, dyes, carpeting, and furniture whose production slashes carbon dioxide emissions and energy use
- Synthetic leather and new packaging materials made of fungus
- Soil microbes that reduce the use of fertilizer, improve the health of soils, and remove carbon dioxide from the atmosphere
- Cosmetics and personal care items made from sustainable bioproduced components with smaller greenhouse gas footprints and that do not use ingredients sourced from threatened and endangered species
- A new generation of plastics that degrade to harmless compounds in seawater and soil or that can be more easily recycled or reused
- Enzymes that improve efficiency and reduce energy use in traditional industries such as pulp and paper bleaching, textile processing, and food processing
- Biologically produced, carbon-neutral cement and carbon-negative chemicals
- Transparent film made from food waste that captures the sun's ultraviolet rays and converts them into renewable energy
- Sustainable fish meal made from methane that is currently vented into the atmosphere[10]
- Biodegradable and compostable plastic containers whose production is associated with a 200 percent reduction in greenhouse gases
- High-performance biodegradable lubricants and greases
- Polyurethane foam from algae oils left over from omega-3 fatty acid production
- Tailored enzymes that enable washing clothes in cold water
- Environmentally benign and recyclable packing materials
- Crops with an increased ability to sequester carbon
- Sustainable aviation fuels made from waste feedstock that significantly reduce carbon emissions

Laying Out a Path Forward

Although some of these approaches have been initiated, a more complete transition will not be easy or inexpensive. The strategy this document presents, based on input from a Task Force[11] comprising experts covering a broad range of interests and expertise, provides a roadmap the United States can follow that will enable it to maintain its dominant global position in harnessing the modern molecular biology revolution. An added benefit of implementing this strategy is that it will help the nation establish an equitable, vibrant, and sustainable bioeconomy that will provide economic, social, environmental, human health, and national security benefits for decades to come. This strategy focuses on steps needed in five areas: addressing foundational science and technology challenges; fostering a national ecosystem of innovation and commercialization; building a national infrastructure with the capacity for scaling bioproduction; developing a well-trained, diverse workforce to power the bioeconomy; and enabling centralized leadership and a policy environment that incentivizes and supports a circular bioeconomy. As this document lays out, it will be important to address each of these areas simultaneously and as quickly as possible in order to also make the transition to a net-zero carbon economy and ensure U.S. competitiveness.

Note that while supporting discovery science in fields such as engineering biology and biomedicine should remain a national priority, the strategy herein is focused on those parts of the bioeconomy that have either been neglected or require additional support to fully realize their potential to address multiple strategic economic and resiliency needs. Thus, this report does not focus directly on addressing the needs of the already substantial biomedical sectors of the bioeconomy, though investments in foundational research for bioproduction outlined later could also benefit the biopharmaceutical and biomedical sector, just as biomedical research produced the very genetic tools and discoveries that are enabling the rest of the bioeconomy. For example, understanding cellular differentiation and regenerative medicine laid the foundations for the burgeoning cultured meat industry. The biopharmaceutical and biomedical sectors are well-funded and have a significant installed infrastructure relative to the non-biomedical applications of biotechnology. In fact, leadership in the bioeconomy is in some ways a byproduct of sustained investment in biomedical sciences, suggesting that broader investment in non-medical bioproduction could drive even faster growth of the entire bioeconomy.

Moving Beyond Fuels Toward Biobased and Bio-enabled Production of Chemicals and Other Products

Most media coverage of efforts to reduce greenhouse gas emissions and get to a net-zero carbon economy centers on renewable energy solutions such as electrification of major sectors of the transportation industry. Certainly, renewable energy complemented by improving energy efficiency and developing biomass-derived sustainable aviation and marine fuels must play a significant role in moving to net-zero, but the fact is, displacing fossil fuels with renewable energy can only address 55 percent of the nation's carbon emissions. Addressing the other 45 percent of the nation's carbon emissions requires changing the way we manufacture consumer and industrial products and the way we grow our food, and this provides an opportunity for the bioeconomy to contribute in significant ways.

At the same time, as the nation reduces its reliance on fossil fuels for powering the transportation industry, it will be necessary to transition away from the fossil fuel-based feedstocks used to produce 96 percent of U.S.-manufactured products. That transition is starting to happen, and some biobased chemicals already outcompete petrochemicals in several categories, generating at least $125 billion annually and accounting today for somewhere between 17 and 25 percent of U.S. fine chemical revenues.[12] The U.S. Department of Agriculture's (USDA) BioPreferred program, for example, has identified tens of thousands of biobased products in commercial production.[13] In addition, some airlines are already testing biobased sustainable aviation fuel as a replacement for traditional jet fuel refined from petroleum. In fact, the White House recently announced new actions to incentivize production of three billion gallons of sustainable aviation fuel, including a Sustainable Aviation Fuel Grand Challenge and funding opportunities totaling up to $4.3 billion.[14]

One advantage that the bioproduction of chemicals has over traditional chemical processes is the cost of building a bioproduction facility, which in many respects today is similar to a brewery. For example, bioproduction facilities using current technologies cost from hundreds of thousands to hundreds of millions of dollars, depending on their size, complexity, and ability to handle multiple production processes. The relatively low cost of a bioproduction facility, compared to the billion or more dollars that it costs to build a chemical facility using current technologies, means that the return on capital should be quite attractive to the capital markets. Experts consulted for this report expect operating expenses for a bioproduction facility to be relatively low as well.

> Co-locating bioprocessing facilities and their biomass feedstocks would create economic growth distributed across the nation and address the policy goal of revitalizing the economies of rural communities.

In addition, because of the varied nature of biomass and its localized production, the most functional and economical way to build a biomass-to-chemicals industry is to co-locate biomass processing facilities close to their feedstock. For example, a bioprocessing facility could be located adjacent to a municipal waste treatment facility to turn that waste into chemicals, or as one U.S. company is doing in China, a bioproduction facility could be located adjacent to a steel mill, using its industrial carbon dioxide emissions as a feedstock for bioproduction.[15] Co-locating bioprocessing facilities and their biomass feedstocks would create economic growth distributed across the nation and address the policy goal of revitalizing the economies of rural communities, as well as those that now—or once did—rely on fossil fuel production and those struggling because traditional manufacturing jobs disappeared. Adapting to the different natures of regionally produced biomass will require significant end-to-end research investments, from unlocking biogenic carbon from various sources to innovations in associated hardware.

While some might argue that investing in new bioproduction facilities to produce chemicals that existing refineries already make would be a misuse of resources, multiple reports have highlighted the vulnerability of the current U.S. chemical production infrastructure to rising sea levels and an increase in the intensity of storm events. In fact, a 2022 analysis by the U.S. Government Accounting Office estimated that nearly one-third of chemical production facilities are at risk from climate-driven floods, extreme weather events, and wildfires. Indeed, the shutdown of major chemical production facilities following the massive flooding that accompanied Hurricane Harvey in 2017 and the record-setting cold temperatures that hit Texas in 2021 are examples of what the future is projected to hold. As a result, it is likely that chemical production facilities will need to be relocated or fortified at considerable cost that would be equal to or greater than the cost of building new bioproduction facilities. Addressing the climate-related challenges facing U.S. chemical production also presents an opportunity to rethink how the nation produces chemicals and builds new integrated production facilities in a way that provides growth opportunities for the economy and facilitates the transition to a more renewable future. In addition, because many critically important chemicals are now made outside of the United States, having the capability to produce them in the United States would be a strategic asset with national security implications. A multipurpose bioproduction facility, one with a freezer stocked with organisms to produce critically important chemicals, could be an insurance policy against future supply chain shocks.

Why Now?

Aside from the critical role that the bioeconomy must play in achieving the goal of reaching net-zero carbon emissions by 2050, there is another compelling argument for the nation to make an investment today in developing the bioeconomy: national competitiveness and the risk of losing the opportunity to revitalize U.S. manufacturing. For the past several decades, the United States has been following an "innovate here, produce there" model—iPhones designed in California, made in China, for example—rather than the "innovate here, produce here" model that would have capitalized on the nation's comparative advantage over other nations in innovation to remain the manufacturing powerhouse that created the world's wealthiest economy following World War II. The "innovate here, produce there" model cost the nation the opportunity to fully realize the benefits of the electronics revolution and the explosive growth in photovoltaic deployment, two sectors that U.S. innovation made possible but have largely benefited manufacturers in China, Japan, and Korea, at least in part because of lower costs of labor. The result has been a loss of manufacturing capacity, jobs, and economic benefits, as well as the supply chain snafu that developed in 2020, causing inflation to spike in 2021 and 2022, and costing the U.S. economy hundreds of millions of dollars.

Today, the United States is in danger of having the same thing happen with bioproduction, though thus far labor costs have not been the primary concern in this case. While the nation spends hundreds of millions of dollars annually on engineering biology discovery science, underinvestment in process development research, process engineering, bioproduction infrastructure, and workforce development have led to a situation in which a number of U.S. bioproduction innovators are having to rely on testbed and bioproduction facilities outside of the United States. In doing so, they are turning to talent located in other countries to develop bioproduction processes at scale, and exporting their intellectual property to manufacture their products, just as their predecessors in the electronics and photovoltaic sectors did. Moreover, the existing bioeconomy that has developed in the U.S. Midwest around corn processing could be in peril if the demand for fuel ethanol and high fructose corn syrup were to decrease. Therefore, using the existing biomass resources to produce innovative products with sustainable markets could help ensure continued growth of the Midwest segment of the bioeconomy.

In addition, international competitors have explicitly described their aim to dominate the bioeconomy in the 21st century, and are investing to implement associated long-term strategic goals. India[16] and China,[17] in particular, have clearly stated their intention—and crafted long-term plans—to use biotechnology to become the dominant global players. The European Union and member countries have also developed bioeconomy strategies[18] that they are regularly updating. These countries realize that the bioeconomy has the potential to grow dramatically in the next few decades, perhaps allowing them to "own" the bioeconomy network. Once an industry with strong network effects is rooted overseas, it can be difficult to bring back. To avoid falling behind and losing our current advantage in biotechnology and molecular biology, the United States must begin to plan and execute on the same multi-decadal timescales as our competitors. Recognizing the national interests at stake, the Office of Science and Technology Policy (OSTP) in 2012 released the National Bioeconomy Blueprint, but there has been no assessment of progress nor an update to this strategy policy document as of April 2022.

Furthermore, there are clear network effects associated with growing a new sector of the economy. In recent decades, the United States has taken advantage of multiple opportunities to take the lead in new sectors, driving multi-decade returns on investment. Silicon Valley, for example, emerged from a unique confluence of public and private factors, such as the Department of Defense investing in ARPANET and successful tech entrepreneurs deciding to reinvest into new startups. Other countries have largely failed to reinvent the Silicon Valley formula, and as a result, the information economy effectively depends on U.S.-based companies.

Today, the nascent U.S. bioeconomy is on a similar precipice as was Silicon Valley before federal investment to bolster the industry. Both government investment as well as private capital is enabling the basic research that has the potential to catalyze the development of an expanded bioeconomy that includes traditional players and a new and growing ecosystem of startups, though there is still limited investment in converting discoveries into commercial products. A recent and notable example of the powerful impact of partnerships between the federal government and industry are the two mRNA vaccines for COVID-19 coming from an American multinational pharmaceutical company (Pfizer) and an American biotechnology startup (Moderna). Each of these vaccines, along with many other emerging biotechnologies, was fostered by sustained public and private investment and the federal government's advanced commitment to purchase those vaccines, as well as the cultivation of a world-leading research workforce.

> The time is right to capitalize on the current momentum in support of revitalizing technology-based manufacturing in the United States as a means of spurring regional and more equitable economic development.

Dozens of recent reports, hearings, and developing legislation suggest the time is right to capitalize on the current momentum in support of revitalizing technology-based manufacturing in the United States as a means of spurring regional and more equitable economic development. Congress over the past few years has introduced, and in some cases passed, several pieces of legislation directly related to the bioeconomy, including the Bioeconomy Research and Development Act of 2020, which was reintroduced in 2021; the Engineering Biology Research and Development Act of 2019; and the Securing American Leadership in Science and Technology Act of 2020, which was also reintroduced in 2021. The Senate has also passed the United States Innovation and Competition Act of 2021, which included the Bioeconomy Research and Development Act of 2021. These legislative efforts, if signed into law, would provide an excellent foundation for supporting the continued growth of the bioeconomy. Research that would benefit the bioeconomy would also fit under the provisions of the recently signed Infrastructure Investment and Jobs Act, otherwise known as the bipartisan infrastructure deal. It would also dovetail with the recently announced, U.S.-led Net-Zero World Initiative and the 2018 National Strategic Plan for Advanced Manufacturing. In October 2021, OSTP released a Request for Information to inform an upcoming update to the National Strategic Plan for Advanced Manufacturing, including biomanufacturing, indicating that this is a priority area. The following month, the President's Council of Advisors on Science and Technology identified biomanufacturing as one of the President's priorities for national competitiveness. Combined, these two actions signal the Administration's interest and intent to address the U.S. bioeconomy in a strategic manner. Legislation analogous to the recent Creating Helpful Incentives to Produce Semiconductors (CHIPS) for America Act and the Facilitating American-Built Semiconductors (FABS) Act could further accelerate the growth of the U.S. bioeconomy.

> Focused government support can quickly produce solutions, whether it be to catalyze vaccine development during the pandemic or the creation of Silicon Valley and the information technology revolution.

The urgency of passing legislation that would accelerate development of the U.S. bioeconomy is highlighted by the role a vibrant and robust bioeconomy could have played in fortifying vulnerabilities in the nation's supply chain that recent extreme weather events and the COVID-19 pandemic have so clearly laid bare. However, focused government support can quickly produce solutions, whether it be to catalyze vaccine development during the pandemic or the creation of Silicon Valley and the information technology revolution. In fact, Congress recognized the strategic importance and national security implications of emerging biotechnologies in the National Defense Authorization Act of 2022. This act established the National Security Commission on Emerging Biotechnology and charged it with conducting a thorough review of how advances in emerging biotechnologies and related technologies will shape current and future activities of the Department of Defense.

The above legislative efforts are a good starting point for supporting the nation's bioeconomy, but capitalizing on the full potential that the bioeconomy represents requires the U.S. government and industry to make a more substantial and sustained commitment with significant funding, as has been done in the past for other sectors of the U.S. economy. In addition, there is a need for enabling a policy environment that incentivizes and supports the bioeconomy and creates a level playing field for biobased products to compete in the marketplace.

What's the Hold Up?

While the benefits of building a bioeconomy for the 21st century and beyond are both obvious and undeniable, the United States has a great deal of work ahead to address scientific, technological, infrastructure, and other commercialization hurdles to turn potential into reality. In addition, there are concerns about workforce development, policy, and public perception about the role biotechnology can play in addressing national priorities, including climate change and sustainability, that the nation needs to address if the bioeconomy is to thrive not just today but for decades to come. In the policy realm, for example, current federal subsidies for the chemical industry make it difficult for biotechnology products to compete on an equal footing, while a regulatory system hampered by insufficient resources acts as a barrier to rapid commercialization of bioeconomy products with acceptable safety profiles.

Some of the work to address the scientific and technological hurdles is ongoing in academic and private sector laboratories. However, fully realizing the potential of that work requires the type of foundational research, development, and infrastructure support at which the federal government excels. For example, the U.S. government has a history of funding industrial advancements by enabling the connection of digital design and simulation with manufacturing. The most notable examples are CAD/CAM for mechanical engineering and airplane manufacturing and the layout and simulation tools for designing semiconductor chips. Indeed, as a report from the National Research Council described, the federal government has done this successfully multiple times. As the report states, "Federal funding not only financed development of most of the nation's early digital computers, but also has continued to enable breakthroughs in areas as wide ranging as computer time-sharing, the internet, artificial intelligence, and virtual reality as the industry has matured. Federal investment also has supported the building of physical infrastructure needed for leading-edge research and the education of undergraduate and graduate students who now work in industry and at academic research centers."[19] In particular, the report highlights the critical role the federal government played in large, system-building efforts that required the talents of diverse communities of scientists and engineers and that displaced existing, entrenched technologies.

The molecular biology revolution, for that matter, owes its existence to federal funding of biomedical research, and federally funded research has already led to great progress in engineering biology—the direct engineering of microbes, plants, and animals. There is still a need, though, to better generate, organize, catalog, and share all the data on the genes, proteins, and biosynthetic pathways that microbes, plants, and animals use. Doing so will enable bioengineers to use a wide array of digital design and production technologies for biotechnology that are the logical equivalent of those used by the industries that produced iPhones, Teslas, and 787s. Such capabilities would enable bioproduction facilities to accommodate the variable response of living systems that make them more difficult to predictably scale than mass-producing cars or mobile phones. There is little doubt, too, that federal research support in this area will create additional platform technologies that lead to serendipitous advances, just as it did for DNA sequencing, DNA synthesis, and genome editing.

Infrastructure hurdles may be the bigger impediment to commercializing research advances. One significant barrier is the limited U.S. capacity of testbed and intermediate-scale facilities that innovators require to demonstrate that they can scale their laboratory successes and produce enough of their bioproduct to conduct the necessary testing and validation steps, as well as to secure regulatory approval if needed (see Case Study 2). Scaling biobased production processes can be more challenging than scaling traditional chemical processes, in part because biological systems, when scaled, do not always behave as laboratory-scale results would predict. Moreover, the lack of a comprehensive knowledge base on scaling biobased processes means that biochemical engineers often have to go through a repetitive process of trial and error to optimize production techniques.

Another barrier in this realm is the situation where innovators seeking to manufacture their biobased products at scale must deal with a patchwork of bespoke facilities and processes that were most likely not built with their products in mind. Investing in a network of new testbed facilities with a wide range of capabilities would provide innovators with flexibility in their approach to commercial-scale process development. Establishing data and technology transfer standards akin to application programming interfaces used in the software industry would allow direct transfer of data among these facilities and from the laboratory to high-performance bioproduction and help new products reach markets faster. So, too, would developing automated operating systems that can drive experiments, optimize production processes, facilitate technology transfer implementation, and serve to integrate basic product development. Biomanufacturers need standardization for tasks ranging from data gathering to problem solving, important for modern process development and management tools in the same way that the chemical industry has implemented standardization to enable success.

Beyond that, there are one-time costs involved in transitioning from a petroleum-based, throw-away economy to a sustainable bioeconomy. These costs, which include building new production facilities or repurposing existing facilities (see Case Study 3), decommissioning existing chemical refineries, retraining the chemical workforce, and developing replacement processes and materials, will be largely borne by the private sector. Estimates place the total cost of this transition at around $145 billion over the next 30 years[20]—or a little over 25 percent of the new federal spending included in the 2021 bipartisan infrastructure bill—but these costs are limited in duration and would be repaid multiple times over once the transition is complete. As the old saying goes, if we stopped doing things the old, unsustainable way—in this case, turning sequestered carbon in the form of oil, natural gas, and coal into carbon dioxide and other products that cause environmental damage and endanger life on Earth—we could more than afford to do things a different way.

A further constraint on developing bioproduction capabilities in the United States is that there is a severe shortage of bioprocess engineering talent in this country, one that raises the need for education in bioprocess engineering at all levels, from community college to graduate school. Other countries, meanwhile, are actively addressing this issue. The European Union, for example, has high-quality chemical engineering and process development research and training programs, and U.S. companies are increasingly forced to rely on foreign-trained talent. It is common today to hear companies say they have to rely on Dutch process engineers, for example, when trying to hire for their facilities.

There is a severe shortage of bioprocess engineering talent in this country, one that raises the need for education in bioprocess engineering at all levels, from community college to graduate school.

In addition to cultivating more bioprocess engineering talent, the nation also needs to develop a technically skilled and diverse workforce by establishing training and retraining programs at the high school, community college, 4-year college and university, and graduate school levels. A 2019 White House[21] summit recognized that U.S. leadership in the bioeconomy will depend on supporting an education and training pipeline for the next generation of bioeconomy scientists, engineers, technical staff, and innovators. In addition, a 2020 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) on the bioeconomy emphasized the importance of developing programs aimed at providing students with technical skills. In particular, that report suggested that "partnerships between community colleges and industry aimed at growing a technically skilled workforce could create employment opportunities in US regions whose traditional employment opportunities may have changed.

The development of biotechnology capabilities in rural areas and other regions with abundant sustainable sources of biomass, as well as investments in training programs and facilities in those areas, could enable new opportunities for those communities while growing the bioeconomy.”[22]

Considerations Going Forward

While there are many benefits to developing a robust and competitive bioeconomy with a distributed, regional bioproduction infrastructure, there are concerns about the potential for unintended consequences. One concern is that enabling a greater repertoire of biomass as an input source of chemicals, polymers, and other materials should be done in a sustainable manner and not in a way that has negative impacts on ecosystems, food security, and equitable economic development. Just as agricultural practices can either support a healthy ecosystem or damage it, production and use of biomass as a renewable source of chemicals and other materials must be done in a way that does not degrade the environment. For example, it will be critical to avoid negative impacts such as the deforestation, human rights abuses, and biodiversity loss that has occurred as a result of an increased demand for palm oil, or negative impacts on biodiversity due to industrial agriculture’s use of crop monocultures. Without forethought and proper guardrails, demand for biomass might stress the sustainability of agricultural systems and the health of the soil that supports plant growth. There are nature-based approaches that will help counteract some of these concerns, and this is an active area of research that fits well within the purview of the bioeconomy. In the same vein, safeguards and regulatory policies will need to be in place to address concerns about introducing engineered organisms into natural ecosystems. Interdisciplinary efforts to merge supply chain analysis, life cycle analysis, and systems modeling can provide crucial foundations to assess and mitigate these concerns. It will also be important to include local community members as full partners in developing guardrails that can guide regional development of the bioeconomy.

> Creating a vibrant U.S. bioeconomy has the potential to advance equitable and sustainable economic development that benefits economically and socially marginalized communities across the nation.

As the nation transitions to producing chemicals and fuels from biomass, it will need to have a plan to address the potentially disruptive effects that this may have on the workers and communities that depend on traditional chemical production so as to not repeat past failures to assist workers and communities affected by declining industries. One only has to look at tragic knock-on effects that the "innovate here, produce there" model has had on workers and communities in the U.S. Rust Belt who were left behind when production of steel and automobiles moved overseas to understand the importance of having a plan to reskill workers and create employment opportunities in affected communities.

Public understanding and acceptance of biobased products such as chemicals, food, and other materials will be paramount to the ultimate success of transitioning to a net-zero carbon economy. The workforce training and education initiatives this report recommends can play a critical role in informing the public and policymakers about the safety and benefits of biobased and bio-enabled products. So, too, will efforts to ensure that good jobs are available in all parts of the country, not just the coasts, and that access to these jobs is equitable and inclusive. Gaining public acceptance will also require bringing new voices to the table beyond those of industry, science, and the policymaking world.

Greater efforts to include civil society, including advocacy and faith-based organizations, community groups, and ethicists, and a wider range of government departments in decision making will also encourage the bioeconomy to work for a larger group of people. Creating a vibrant U.S. bioeconomy has the potential to advance equitable and sustainable economic development that benefits economically and socially marginalized communities across the nation. However, achieving that vision will require more attention to governance, the political dynamics steering promotion of the bioeconomy, and on the often overlooked social dimensions of sustainability.[23] Leadership must develop inclusive bioeconomy development strategies that acknowledge and repair the legacy of environmental harms suffered by communities of color, tribal communities, and low-income communities.

While these are some of the major considerations that policymakers and various stakeholders will address as the bioeconomy develops, there may be ethical and security concerns that arise along the way, as well as other second and third order effects that we have yet to imagine. As with any transition, it will be important for all stakeholders to be aware of these possibilities and be forward thinking as far as how to address them so that all Americans can benefit from a well-developed, vibrant bioeconomy.

What Do We Need to Do to Enable a Competitive and Circular U.S. Bioeconomy?

Key Takeaways

To capitalize on the transformative opportunities of the bioeconomy, the U.S. needs to:

- Address foundational science and technology challenges;
- Build a national infrastructure for bioproduction scale-up capacity
- Develop a well-trained workforce to power the bioeconomy
- Enable centralized leadership and a policy environment that incentivizes and supports a circular bioeconomy

A concerted national effort—a "warp speed"-type—will require a system-of-systems approach to enable a resilient and competitive bioeconomy.

Partnerships with government, academia, and technology companies at the confluence of automation, software, and biology will accelerate the path to commercial production capacity.

More accessible technical training, visa reforms for high-skilled workers, and industry-informed work experience will help prepare workers for the jobs of the future bioeconomy and provide opportunities in a more equitable manner.

What Do We Need to Do to Enable a Competitive and Circular U.S. Bioeconomy?

This section describes four major areas that if addressed can, over time, enable the United States to create a future circular bioeconomy and move the nation toward a net-zero carbon economy. Doing so would enable the country to unlock the wealth of knowledge, entrepreneurial drive, and venture capital resources that, few, if any other nations possess together. In the United States, a circular bioeconomy would be one that forgoes the traditional linear economic model of "take-make-consume-throw away." The new economic model would use the power of biotechnology, design for bioproduction, and advanced analytics and information technology to create processes that result in a sustainable and regenerative economic cycle in which waste products serve as inputs to create highly valued products and materials that are used as long as possible and reused without drawing down limited resources or generating wastes that are disposed into the atmosphere, landfills, or rivers, lakes, and oceans (Figure 1).

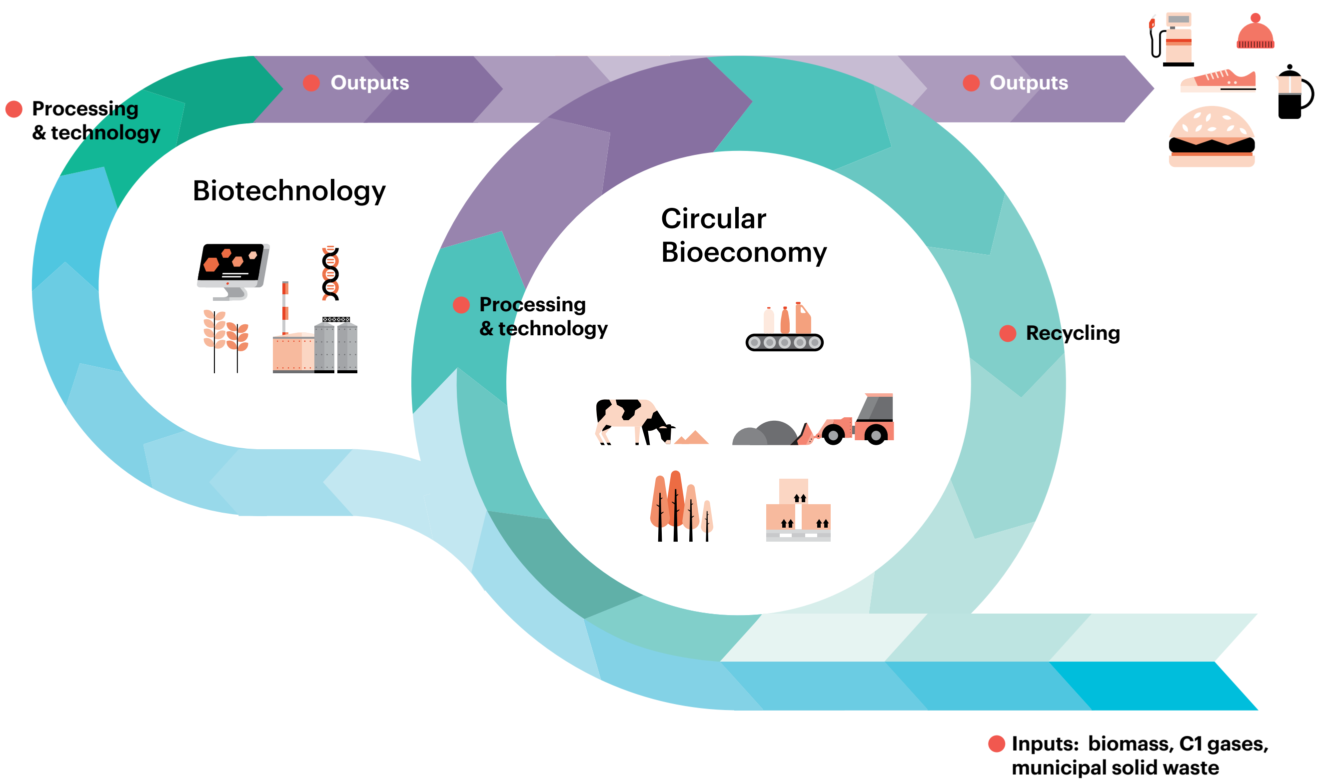

FIGURE 1 Biotechnology will play an enabling role in creating a circular bioeconomy, one that uses sustainable sources of carbon, including recycled products of the bioeconomy, in a manner that maximizes how many times that carbon is continually recycled and reused. At the current time, technology does not yet exist to take all of the outputs identified at the top right of the figure and put them back into the circular process.

U.S. government funding in these four areas would be directed to address challenges and eliminate barriers that would unleash the power and capabilities of the private sector to create markets and drive economic prosperity. Federal investments would also address the national imperative to move to a sustainable net-zero carbon economy that benefits all Americans. In addition, investments in these areas would undoubtedly have unanticipated benefits for other areas of the economy. In fact, federal investments in foundational science and technology, for example, have a long history of leading to unanticipated future applications, including the research that led to the molecular biology revolution that serves as the bedrock of the bioeconomy. The Human Genome Project, for instance, ended up driving more than a trillion dollars in economic returns and was the result of both public and private investment.

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At the same time, there are key roles for industry to play in these efforts, particularly in terms of sharing knowledge and expertise through partnerships with government and academia (See Case Study 5). For example, fostering partnerships between large technology companies with expertise in artificial intelligence and bioproduction companies with knowledge of scale-up challenges and the ability to generate copious data on their processes could dramatically reduce the time that it takes to reach commercial production capacity. In fact, much of the startup and investment activity in the bioeconomy has focused on the confluence of automation, software, and biology. To amplify that investment, the United States should consider developing a program analogous to Europe's Data-Driven Bioeconomy project,[24] which focuses on using big data to enable production of the best possible raw materials for the bioeconomy industry to produce food, energy, and biomaterials while accounting for environmental and social responsibility and sustainability. Another example, one of many ongoing at several of DOE's national laboratories, would be Idaho National Laboratory's program for applying artificial intelligence and machine learning to all aspects of the bioeconomy, including biomass supply, logistics, and processing.[25] Industry also needs to be more involved in developing training programs and providing internships that give students the skills and practical experience they need to enter and be successful in the bioeconomy. Industry will also need to work with federal agencies as partners on horizon scanning to prepare for the economic accounting and regulatory assessments of new products of biotechnology.

The strategy this report lays out emphasizes that while addressing each of these areas is important, tackling them together will be critical for success. Fundamental engineering biology research without a means to scale the resulting advances to commercialization will not achieve the goal. Neither will establishing a testbed infrastructure without the engineering talent and trained workforce to design and operate that infrastructure. Without supportive and modernized policies, the incentives to develop innovative biobased processes and products will be outweighed by market and regulatory risks. In short, a concerted national effort—a "warp speed"-type—will require a system-of-systems approach that tackles each of the four priority areas together.

Addressing the Foundational Science and Technology Challenges

Achieving the biggest return on the nation's investments, both past and future, requires the U.S. government to accelerate research in foundational bioengineering and bioproduction to translate the growing number of engineering biology basic research discoveries to public benefit. Up to this point, federal research support has enabled researchers to develop an ever-growing set of tools, such as CRISPR, to manipulate DNA at will and use those tools to develop animals, plants, microorganisms, and cell-free systems capable of producing a wide range of commercially valuable chemicals and materials. Now, to advance the nation's bioproduction capabilities, research and development efforts need to focus on creating rational design for bioproduction processes that would involve the following:

- Sequencing every organism present in U.S. biomes and depositing the data in an open-source database to accelerate the discovery of useful genetic information and capabilities
- Modeling, designing, and testing novel metabolic pathways to enable bringing useful molecules and products that do not exist in nature to commercial scale
- Developing the rules, data analysis tools, computer modeling capabilities, and data-driven approaches to model building that would enable biotechnologists to rapidly identify and produce the exact genetic modifications in the most suitable organism or cell-free system required to create those pathways and generate the desired biochemical product
- Conducting data-driven discovery using emerging computational approaches, such as machine learning and artificial intelligence, now being employed by chemical engineers, materials scientists, and some early adopters in industrial biotechnology
- Accurately projecting laboratory-scale results to industrial-scale processes
- Creating platforms for the robust biosynthesis of a variety of molecules without having to perform extensive tinkering to obtain commercially useful yields
- Identifying organisms, and even collections of organisms that work together, that could serve as new "chassis" for bioproduction, expanding the breadth of products that can be manufactured routinely
- Doing all of this in a matter of days and weeks instead of months and years

Concurrent with that effort should be research aimed at extending existing DNA production methodology to enable manufacturing whole genomes with high fidelity. Additionally, this effort should also include developing genetic tools for precisely editing animal, plant, and microbial genomes at multiple sites simultaneously to improve existing metabolic pathways and create new ones as part of rational design. Given the importance of biomass to the future bioeconomy, there needs to be a greater research emphasis on plant genomics and higher-throughput genomic manipulations of plant genomes, such as the successful National Science Foundation (NSF)-funded effort to assemble, annotate, and compare 26 diverse maize genomes to increase the productivity of food and feed crops and to develop varieties that can be grown on marginal lands. USDA's Plant

Genetic Resources, Genomics, and Genetic Improvement program, which aims to safeguard and use plant genetic resources, associated genetic and genomic databases, and bioinformatic tools to ensure an abundant, safe, and inexpensive supply of food, feed, fiber, ornamentals, and industrial products, could serve as the home for such an effort.

Scaling biobased production from the benchtop to commercial scale is not straightforward at present owing to a number of factors, including the inherent variability that comes from working with a living organism.

Creating the biobased systems capable of producing valuable chemicals and materials is only a start. What must happen next is for process and chemical engineers to develop the systems and capabilities needed to produce biobased products on a commercial scale. An analogy would be turning a home-based, one-carboy beer fermenter into a full-fledged brewery capable of producing enough beer to stock every liquor store, bar, and restaurant. While there are a number of companies already skilled at doing this for existing products, the vibrant domestic startup ecosystem is struggling to develop and access these capabilities for a number of reasons, detailed below in the section on increasing end-to-end bioproduction capacity.

Scaling biobased production from the benchtop to commercial scale is not straightforward at present owing to a number of factors, including the inherent variability that comes from working with a living organism. Therefore, research is needed to develop methods of dealing with that variability and increasing the efficiency of what can be extracted from the many potential sustainable biological feedstocks (see the case study on future biobased feedstocks), including inputs of waste carbon as an important component of circularity. While DOE, USDA, and NSF have programs in this area, they are relatively small, uncoordinated, and not focused on the complete range of biomass sources or possible products. One exception is USDA's new $10 billion bioproduct pilot program that aims to study the benefits of using materials derived from agricultural commodities in the production of consumer and construction products.

In addition, it will be important to coordinate biomass production-related research and development activities, largely the purview of USDA, and bioprocessing-related research and development activities, which would fall mainly to DOE and NSF, so that feedstocks could be fine-tuned with desirable attributes for specific bioproduction processes. Research funding aimed at fine-tuning biomass attributes should not subtract from USDA's support of sustainable food systems through its Agricultural Research Service and National Institute of Food and Agriculture.

The federal government can also catalyze the transition from a chemical-based economy to a biobased economy by creating a market for the individual carbon fractions that bioproduction would generate, from one carbon to six carbon, as well as lignin for aromatics. Such a step would help establish a sustainably sourced carbon building-block pipeline for the bioeconomy, given that these fractions could then plug into existing value chains and infrastructure (Figure 2). Research into the tolerance for impurities and blends of biomass will also enable this transition.[26]

Plugging into Existing Value Chains

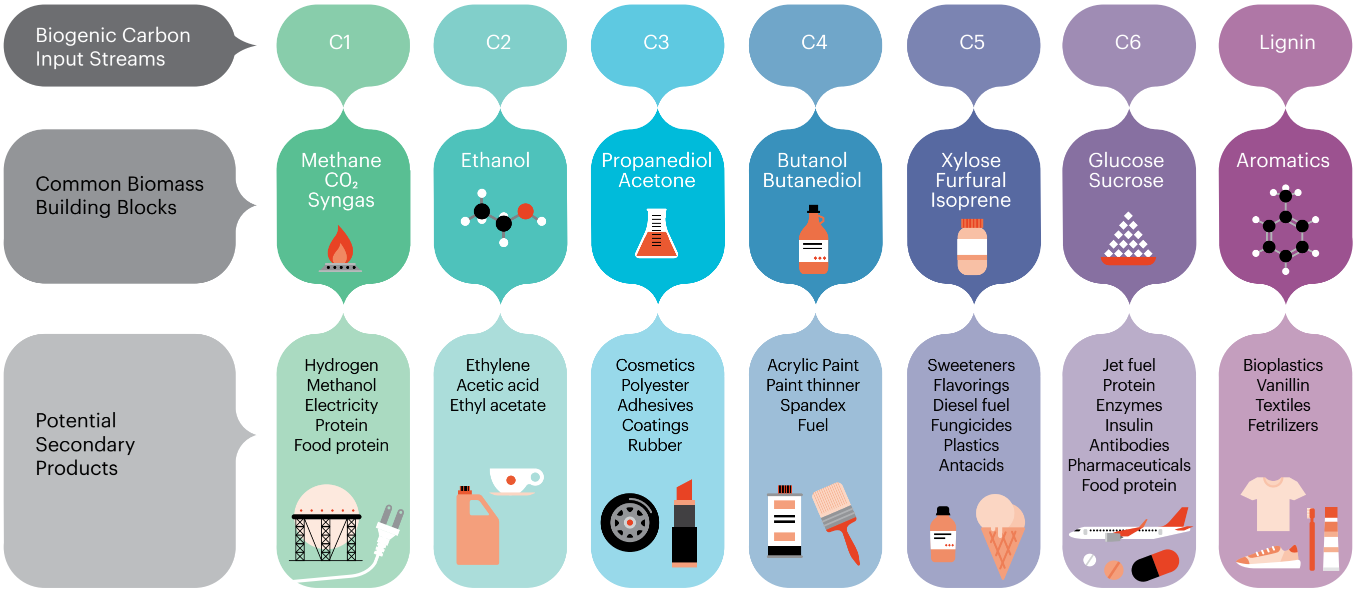

FIGURE 2 A hypothetical biomass-utilizing, carbon building-block pipeline would produce carbon feedstocks that plug into existing value chains and infrastructure for production of a range of consumer and industrial products.

Scaling bioproduction is one place where modeling and simulation capabilities need to play a larger role than it does today. To support the development of those capabilities, funding is needed to establish an easily accessible national computational and database infrastructure that would better support the design-build-test-learn process common in engineering biology by enabling better simulation capabilities and data-driven analyses. This infrastructure would provide process engineers with the ability to perform scale-up experiments and refine operating conditions before moving a laboratory-based process to pilot plant scale and then on to commercial production scale. Currently, scale-up is an expensive and time-consuming process that would benefit from a concerted research effort focused specifically on optimizing and standardizing bioproduction scale-up processes from end to end.

An area that has not gotten much attention, but one that definitely needs it to enable a future circular bioeconomy, centers on how to process the varied biomass sources into feedstocks that will be available to biotechnologists for new bioproduction processes (See Figure 3 and Case Study 4). These include forest-based biomass of many types, grasses and crops, agriculture and aquaculture residues, food production byproducts and waste, municipal waste, waste water, and carbon dioxide produced by other processes, among others, depending on where a bioproduction facility would be located and even what season it is when production occurs. Biomass variability can make any attempts at pre-determining optimal process conditions futile. Bioproduction facilities can learn from the petroleum industry, which uses advanced computer modeling to tune process conditions and fully convert each batch of crude oil into a pre-established suite of chemicals. By applying the same type of analytic tools and modeling capabilities, bioproduction facilities will be able to adapt their processes to accommodate the variability in biomass that result from seasonal and geographic variation to generate useful feedstocks.

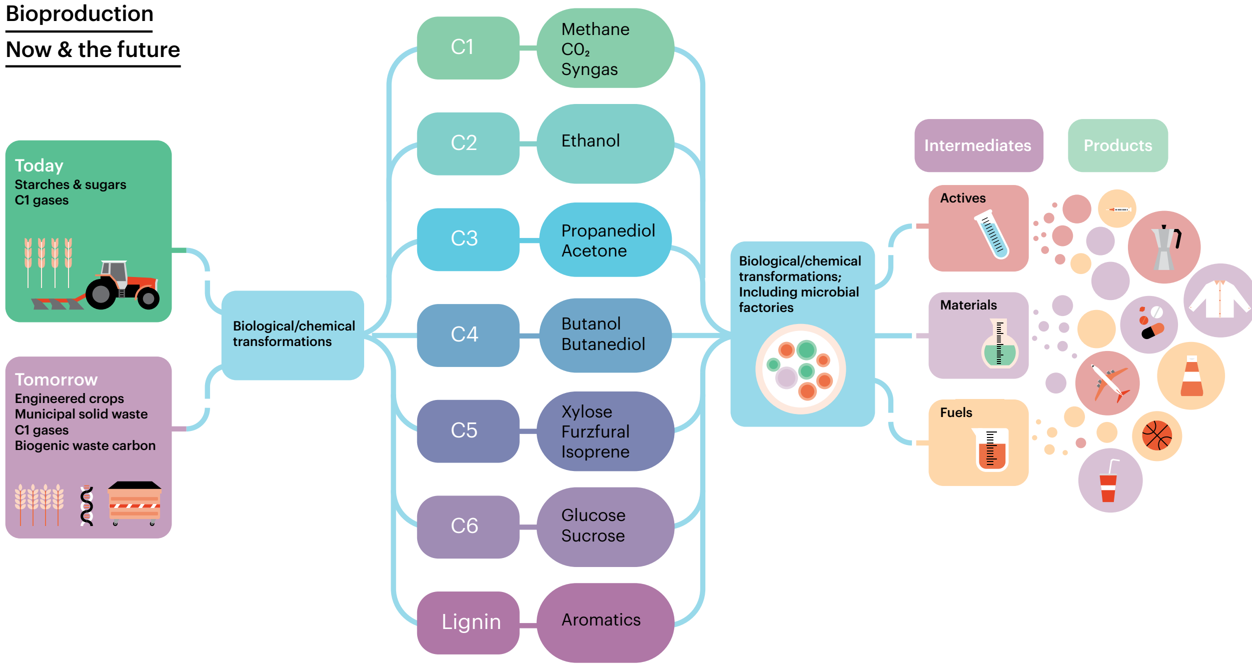

FIGURE 3 With continued development, bioproduction will evolve to use a broader range of feedstocks. As the biogenic carbon sources in the "tomorrow" box become a larger fraction of the manufacturing inputs, a future circular bioeconomy will become closer to reality.

Once the nation has developed the capabilities to use diverse sources of renewable biomass and unlock the carbon in those diverse biomass sources to power the bioeconomy, there may be an opportunity to use one of society's most vexing waste problems, plastics, as a feedstock. Researchers are working on ideas for how to deconstruct existing plastics into smaller molecules that could then serve as feedstocks for bioprocessing into new chemicals and materials. One advantage of this approach is that there is an already existing collection and sorting system for plastics. However, the processes needed to break down plastics into usable feedstocks are a relatively new and developing technology, and research is needed on how to best use that feedstock in combination with biomass feedstocks. That being said, major polymer producers around the globe are investing in chemical recycling infrastructure and anticipate that some of these processes will come to fruition in the next 15 years. It behooves the United States to make larger strategic investments now to capitalize on this alternative feedstock. DOE's Bio-Optimized Technologies to keep Thermoplastics out of Landfills and the Environment (BOTTLE) consortium is contributing to this effort by funding research to develop improved catalytic and biocatalytic recycling strategies to break down today's plastics into chemical building blocks for manufacturing higher-value products, a concept known as upcycling, and the design of tomorrow's plastics to be recyclable-by-design.

The nation's extensive expertise in biotechnology and artificial intelligence puts the United States in an ideal position to address the research needs listed above with appropriate government support. However, an analysis of federal spending to support the research needed to develop a vibrant U.S. circular bioeconomy reveals that such spending has been flat for years.[27] That situation must change, and change now, if the nation is truly serious about rebuilding its manufacturing capabilities, creating millions of good-paying jobs spread equitably across the nation and reaching the goal of building a net-zero carbon economy. The magnitude of the funding needed to accomplish that goal is likely to be a fraction of the $550 billion allocated in the recently passed bipartisan infrastructure deal, and the return on that investment will more than justify it.

Building a National Infrastructure for Bioproduction Scale-Up Capacity

While the scientific, engineering, and technology communities are ready to tackle the foundational science and technology challenges discussed above over the next five years with appropriate support, establishing a nationwide, end-to-end bioproduction capacity to move from the benchtop to commercial production requires a larger-scale effort—and commitment on the part of the U.S. government—that will play out over the next 3 to 15 years.

Development, Testbeds, and Deployment

To incentivize industry and academia to pursue innovation that offers improvements in bioproduction technology at a scale needed to achieve a commercially viable alternative to a petroleum-based economy, funding should be directed to addressing grand challenges in bioproduction, with relevant metrics of success—that the nation's research community could address within a 5-year timeframe, much as the semiconductor and nanotechnology industries addressed their grand challenges with federally funded initiatives. In addition to fermentation, improvements in product purification are needed. This is a place where process engineers could play a vital role by applying the skills they developed for chemical production to a new industry with tremendous growth prospects and societal benefits.

Aside from dedicating funds to addressing grand challenges in bioprocessing and bioproduction, another step would be to follow the models enabled by the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Increasing SBIR/STTR funds dedicated to bioprocessing and bioproduction improvement by 10-fold would spur innovation, as would developing mechanisms to ease the transition out of the SBIR/STTR funding model and changing the statutory requirements regarding commercialization assistance that may hinder small business commercialization prospects and business development in the long run.[28]

Also needed in this realm is support for what are known as testbed facilities or sandboxes: scale-up entities and expertise to help rapidly transfer scale-up knowledge to innovators (Figure 4). The Bioindustrial Manufacturing and Design Ecosystem, or BioMADE, is one example. This entity, with a focus on catalyzing and reducing the risk of investments in relevant infrastructure, is supported by a seven-year award that includes at least $87.5 million in federal funds from the Department of Defense and more than $180 million in cost sharing from non-federal sources. Testbeds and sandboxes would serve the bioproduction industry in the same way that ARPANET paved the way for the internet to develop. Other examples include the National Cancer Institute's Nanotechnology Characterization Laboratory, which provides analytical expertise needed to commercialize nanotechnology-based products but that are too expensive for small companies to afford and require hard-to-find expertise, and the National Renewable Energy Laboratory's National Wind Technology Center, which provides field validation sites and composites manufacturing pilot facilities that have played a critical enabling role in the advancement of wind energy technology that has benefited the entire industry. A network of such industry-enabling facilities will offer the ability to evaluate immature technologies with a fail-fast approach.

FIGURE 4 On the continuum from basic research to commercial production, more investment is needed to support bioproduction research and infrastructure development.

Infrastructure Development

An important sticking point today in translating laboratory research to commercial production is the paucity of testbed facilities where innovators develop their scale-up procedures and innovative manufacturing technologies in partnership with experts in process and chemical engineering that will enable them to bring their products to market faster and at reduced costs. The National Institute of Standards and Technology established the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) as a public-private partnership in 2016 to address just that challenge for the biopharmaceutical industry. Investing in the fundamental science of bioprocessing in the precompetitive space, as NIIMBL is doing for biopharmaceutical production, will benefit the entire industry, both in terms of the knowledge gained and by providing innovators with the opportunity to demonstrate that their processes are reproducible at an intermediate scale before the capital markets will step in to fund building a commercial-scale facility. The federal government can play a catalytic role here by establishing a network of regional testbed facilities—facilities that can process multiple feedstocks using multiple organisms to produce multiple products by multiple mechanisms at multiple scales—that will enable innovators to work out their scale-up processes and generate the performance data that would lay the groundwork for moving to commercial production. Doing so would reduce the risk that currently keeps the capital markets on the sidelines.

> Many companies are now forced to go to contract manufacturers in Belgium, Canada, China, Germany, India, Mexico, the Netherlands, Slovakia, Slovenia, and elsewhere to access needed infrastructure that is not available domestically.

While there are domestic contract bioproduction facilities, many of them serve the biopharmaceutical industry and thus operate under Good Manufacturing Practice standards set by the U.S. Food and Drug Administration. Because of the fees these for-profit contract facilities charge, bioeconomy startups have difficulty competing with biopharmaceutical companies when trying to develop products that have a lower price per pound than a biomedical product or even a cosmetic ingredient. The federal government has made a significant down payment toward addressing some of the needed bioproduction capacity limitations. NIIMBL and BioMADE are examples of sandboxes in the form of public-private partnerships that are dedicated to addressing some of the needs of the bioeconomy. An example of a facility, the Advanced Biofuels and Bioproducts Process Development Unit (ABPDU) was funded in 2009 as part of the American Recovery and Reinvestment Act as an infrastructure investment. This DOE facility, located at Lawrence Berkeley National Laboratory, is so in demand today that it is regularly turning away potential partners who seek to mature their innovative technologies. A third example is the National Renewable Energy Laboratory's pilot-scale Integrated Biorefinery Research Facility. Though originally dedicated to helping innovators achieve commercial-scale production of biomass-derived fuels, this facility has expanded its purview to include the production of any biobased product and now offers innovators access to expertise in integrating multiple technologies for pilot-scale testing and process validation.

Despite these initial federal bioproduction investments, many companies are now forced to go to contract manufacturers in Belgium, Canada, China, Germany, India, Mexico, the Netherlands, Slovakia, Slovenia, and elsewhere to access needed infrastructure that is not available domestically. In addition, there is no comprehensive, publicly available resource that documents the location and functionality of existing domestic bioproduction facilities, as exists in Europe thanks to funding from the Biobased Industries Joint Undertaking as part of the European Union's Horizon 2020 Research and Innovation Programme.[29] As a consequence, in the interim report[30] this Task Force has produced an initial compilation of existing bioproduction facilities and infrastructure that might serve as the basis of a future public database demonstrating the location and whether the asset is publicly or privately affiliated. Subsequently, the facilities' locations were mapped in conjunction with county-level biomass resources[31] and equitable economic development opportunity data[32] to identify sites ripe for potential investment in infrastructure that would enable co-localization of new and/or refurbished facilities with biomass for feedstocks (Figure 5 and Table 1). Analysis of these data demonstrates how it would be possible to select sites that are ready for investment. In an attempt to illustrate how it would be possible to identify opportunities across the country, this report applies a regional geographic constraint by selecting the top counties in each region.

FIGURE 5 Public and private affiliated bioproduction facilities (orange, black, purple, and peach shapes), potential biomass resources (green shading), and example areas ripe for infrastructure development (yellow circles). The areas ripe for infrastructure development were determined using data for counties in each U.S. census region that had the highest scores for 2010 economic prosperity and inclusion indicators (National Equity Atlas, Racial Equity Index), forecasted 2040 potential biomass sources (2016 Billion-Ton Report), and biotechnology college programs in the state. To identify opportunities across the country, what is represented here are the top counties per region (Northeast, Midwest, South, and West) based on these criteria. Without this artificial geographic constraint, the top selections could be different. For the purposes of visual clarity, the specific locations of the icons are approximate.
Credit Albert Hinman, postdoctoral fellow, Engineering Biology Research Consortium

FIGURE 5, CONT.

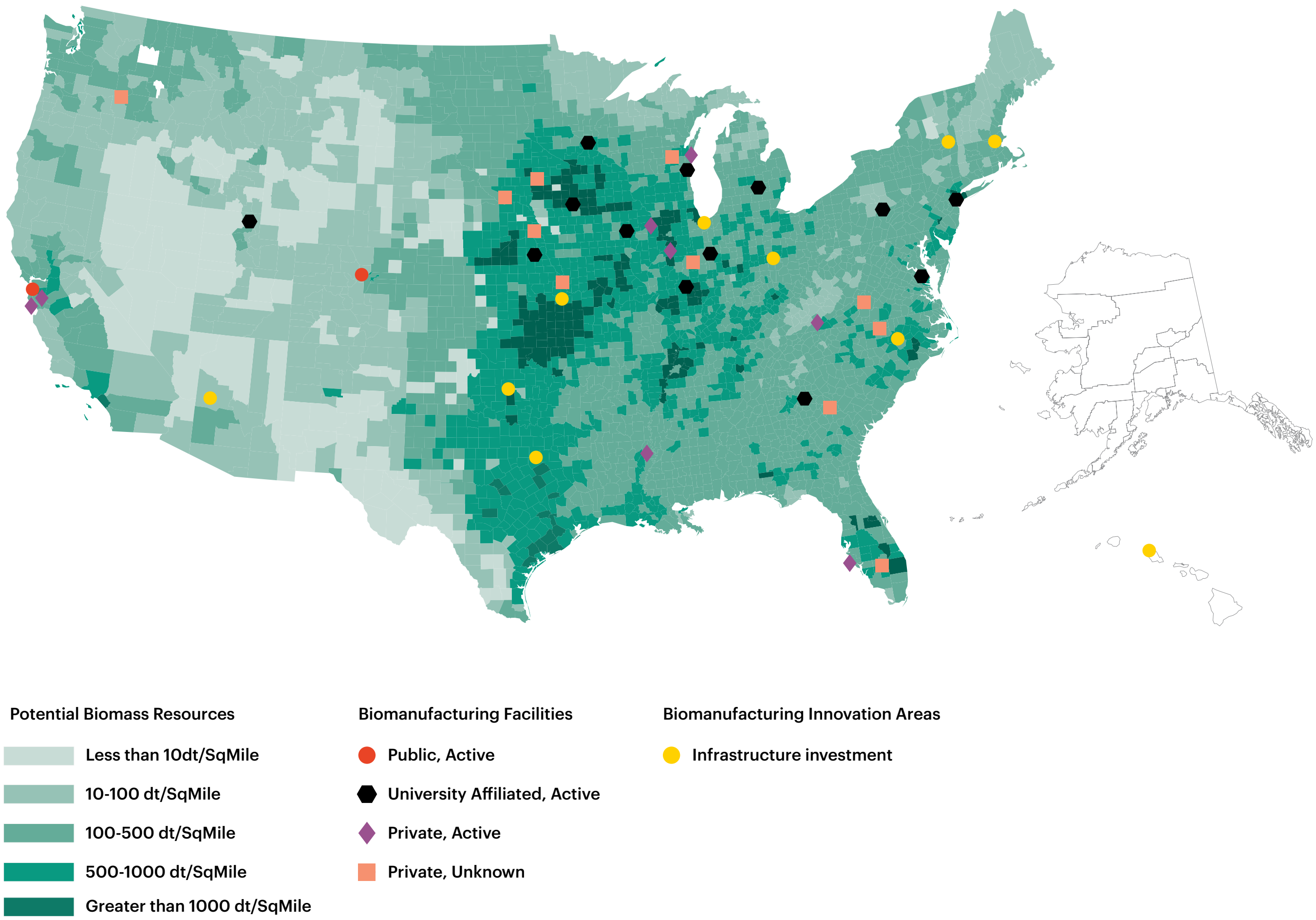

TABLE 1 An illustration of how the information presented in Figure 5 could inform regional investment decisions in bioprocessing capacity. Making actual investment decisions will require more comprehensive data and data-sharing processes, as well input and active participation of communities identified by such an analysis.

Rank	Infrastructure Investment
NORTHEAST	County, State
1	Suffolk, MA
2	Albany, NY
MIDWEST	County, State
1	Warren, OH
2	Johnson, KS
3	Porter, IN

Rank	Infrastructure Investment
SOUTH	County, State
1	Denton, TX
2	Wake, NC
3	Canadian, OK
WEST	County, State
1	Yavapai, AZ
2	Honolulu, HI

For national competitiveness, it is imperative for the United States to act now to establish more of these facilities given that other nations have already taken this step. The United Kingdom, for example, has established the National Biologics Manufacturing Centre, Centre for Process Innovation, and Industrial Biotechnology Innovation Centre to aid its nascent bioproduction industry. In the solar energy field, the failure of the federal government to help fledgling companies get past the intermediate stage of development played a significant role in China's rise as the world's predominant supplier of photovoltaic cells. If the United States does not act now and over the next five years to invest in bioproduction infrastructure strategically and aggressively, the same could happen to the U.S. bioeconomy.

Beyond funding the testbed facilities, the U.S. government could support a nascent bioproduction hardware industry, perhaps by creating plug-and-play centers that provide a continuous stream of bioproduction partners. Such centers could also have a research focus of working toward designing new modular production systems that would enable companies to expand production relatively easily as demand for their products increases. Currently, there are a few innovative companies that have started to design and build new hardware, such as novel bioreactors, to improve process yields, but these efforts alone will not be sufficient to address the entire industry. The Defense Advanced Research Projects Agency (DARPA) has made investments in hardware design to meet the demand for local production of fuel in austere environments that bioproduction could fill, and an opportunity exists to invigorate the bioproduction industry with additional government support. Another area for investing in hardware design could include developing preprocessing equipment that would tolerate heterogeneous inputs, such as rocks and dirt, that often come with biomass.

Developing a Well-Trained Workforce to Power the Bioeconomy

The challenge of mobilizing talent to create a workforce needed to power the bioeconomy comes down to addressing two issues. In the near term, a lack of trained professionals at all levels of educational attainment, from badges, certificates, and associate degrees to master's degrees and Ph.D.s, who can design, build, and run bioproduction processes is hampering the ability of U.S. companies to make the transition from laboratory-scale to pilot- and commercial-scale processes. Beyond the need to develop today's workforce, the longer-term problem to solve is that the nation's school-aged children, as well as the general adult public, are not sufficiently aware about the opportunities that a biobased economy creates for them in terms of generating good-paying jobs and the central role that the bioeconomy and its products will play in moving to a net-zero carbon economy and limiting the potential harms from global climate change. In fact, the bioeconomy presents opportunities for people with interests and skills in a variety of areas and for all education levels, from adults in areas of the country whose jobs have disappeared and who can be reskilled for bioproduction jobs, to engineers and scientists, to economists, communicators, graphic designers, and lawyers.

Training Today's Workforce

As the bioeconomy has grown, so too have its difficulties hiring appropriately trained workers, particularly for bioproduction facilities. A 2019 survey by the National Institute for Bioprocessing Research and Training, for example, found that 78 percent of biopharmaceutical industry leaders had difficult filling positions for bioprocess engineers, automation engineers, manufacturing science and technology staff, downstream processing staff, and commissioning, qualification, and validation engineers. Given that these jobs require different levels of education and training, they provide opportunities for a broad range of the population. As the bioeconomy grows, competition for trained employees will only get worse. Indeed, that same report noted that the biggest challenge for growing the nation's biopharmaceutical industry—just one sector of the bioeconomy—concerns hiring staff with the necessary technical skills.

As is true in the biopharmaceutical industry, there is also a demand for technically trained employees with less than a bachelor's degree to fill good-paying jobs for people in areas such as manufacturing, quality control and quality assurance, and product and process validation. A number of community colleges around the nation offer associate degrees or certificate programs, often in close collaboration with local industry, that prepare students for jobs in the bioeconomy. To increase the number of such programs, the federal government could establish a grant program to create bioeconomy-specific certificates and credentials akin to the Occupational Safety and Health Administration's (OSHA) certification or the Biotechnician Assistant Credentialing Exam certificate. Programs such as these have the potential to reduce the entry costs to the bioeconomy for individuals from underrepresented and marginalized communities, as well as working adults who are looking for a career change, yet may not have the financial resources, time, or desire to pursue a bachelor's degree.

The federal government could establish a grant program to create bioeconomy-specific certificates and credentials … Programs such as these have the potential to reduce the entry costs to the bioeconomy for individuals from underrepresented and marginalized communities, as well as working adults … who may not have the financial resources, time, or desire to pursue a bachelor's degree.

According to the Bureau of Labor Statistics, employment of chemical engineers is projected to grow 9 percent from 2020 to 2030. At the same time, the number of students graduating from college with degrees in chemical engineering has been declining, and one study found that only about 50 percent of chemical engineering graduates get jobs as engineers, with many of them finding employment in more lucrative fields such as finance and software development. A growing and successful bioeconomy means that there are exciting jobs that more closely align with their training, but wages and quality of life will need to be competitive with the other industries that hire these types of engineers. Another issue is that while graduates hold a chemical engineering degree, too many lack the hands-on experience of working in an industrial setting that their European counterparts gain as part of their educational experience. This disconnect is most apparent in the lack of industry-informed work experiences in the bioeconomy as a means of recruiting and retraining regional talent, in contrast to the approach that European countries have taken, which is for programs to require an externship at a company to gain workplace experience as a requirement for graduation.

The federal government has made some effort to incentivize industry to provide such experiences. NSF's Advanced Technology Education program and the Department of Labor's Youth Apprenticeship program both emphasize collaboration among academia, industry, nonprofits, and government to co-develop and co-deliver technical training programs, with industry then committed to hiring program graduates. DOE's Bioenergy Technologies Office (BETO) has several programs that aim to develop a U.S. workforce to strengthen the bioeconomy, including the Algae Technology Educational Consortium's partnerships between academic institutions, national research laboratories, and industry leaders to develop novel educational programs to strengthen industry workforce capabilities by focusing on the skills needed to support the commercialization of algal products. These partnerships help students learn practical applications of farming and biotechnology to develop the skills for the next generation of algal-based jobs. BETO has also created a bioenergy career map, an interactive, educational tool that explores the vast network of bioenergy occupations, illustrates potential career pathways, and identifies the education and training required for each career.[33] The career map profiles over 60 positions and over 100 advancement tracks among careers in the bioenergy industry.[34] Appendix B lists a number of federally supported job and workforce training programs relevant to the bioeconomy.

Process engineering jobs are not the only bioeconomy positions experiencing a worker shortage. Artificial intelligence and data science are areas that experts in the field predict that will need more trained professionals given the role they are already playing in applying the tools of engineering biology. While there are numerous training programs to prepare graduates to work in those fields, the challenge is to make those graduates aware of the job opportunities in the bioeconomy, as opposed to going to work for big digital technology companies. Expanding co-op programs could serve as one avenue for increasing awareness of bioeconomy job opportunities, as well as for increasing the diversity of the bioeconomy workforce.

More generally, visa reforms that would allow American companies to hire high-skilled foreign workers with advanced science, technology, engineering, and mathematics (STEM) degrees would both fill short-term labor shortages as well as facilitate the commercialization of new technologies. For example, the America COMPETES Act proposes to reduce barriers to permanent resident visas for Ph.D.s in STEM fields, which would not only bolster America's research and development capabilities but also allow foreign scientists and engineers to start technology companies in the U.S. bioeconomy.

While the federal government has already taken steps to address some of these workforce challenges, industry has a role to play. By engaging with their local education centers, companies can provide more input into curricula, provide more internship opportunities, and work with local governments to support training and retraining programs. In addition, there is an opportunity for industry to work with education leaders and federal agencies such as the National Institute of Standards and Technology to create national standards and certifications for bioeconomy-related training and retraining programs. While there are already some examples of local certification programs, these are not always recognized by the industry at large. A national standard would assure industry that students completing a certified program anywhere in the United States will have mastered the required level of technical proficiency to become valued and productive employees and assure students that obtaining such a certificate is worth their time and effort.

Preparing for the Bioeconomy Jobs of the Future

As several Task Force members noted from their experiences working with America's youth, students are largely unaware of the exciting and rewarding opportunities waiting for them in biology-based occupations, but when they do learn of them, they become excited and want to learn more. Increasing that awareness starts with revamping the way the nation's schools teach biology, moving away from rote memorization of dry facts to an approach that is more hands-on and experiential.[35] Several organizations are working to enable that transition, but more effort is needed in this area. In particular, there is a need to ensure any programs designed to make biology more interesting and relevant reaches all students given the importance of creating a bioeconomy that is diverse, equitable, and inclusive.

Given the local structure of K-12 education in the United States, it will be imperative to engage local communities in efforts to develop and promulgate such programs in the K-12 ecosystem. Moreover, it will be important for school districts to work with their local community colleges, 4-year colleges, and industry to craft programs that will not only engage students in learning biology, but also do so in a way that prepares them for entry into the workforce or to pursue educational opportunities beyond high school. At the same time, community colleges and universities will need to treat K-12 educators as full partners in these efforts. In particular, 4-year institutions, through which many program development grants are disbursed, will need to adjust their policies to ensure that these funds go to program development and not institutional overhead.

Given that the future workforce will be more brown and more female, it is imperative to make training programs at all educational levels accessible in an equitable and inclusive manner.

Expanding educational opportunities for a broader and more diverse student population in STEM careers is a national imperative, and this is certainly true with regards to the bioeconomy. Improving representation of all segments of the U.S. population is critical to meeting future employment needs of the bioeconomy and ensuring that opportunities for careers in the bioeconomy, which according to the Bureau of Labor Statistics, are expected to pay nearly double the median wage for all workers,[35] are equitable and inclusive. However, far more needs to be done to make students from all backgrounds aware of the career opportunities that the bioeconomy offers. This could be an example of low-hanging fruit given that biology is a field where more women than men earn bachelor's degrees and has a greater share of under-represented groups than other STEM fields.[36] Nonetheless, as a 2021 report from the Pew Research Center illustrates,[37] current trends in degree attainment in the life sciences, physical sciences, and engineering—all relevant to getting a job in the bioeconomy—are unlikely to substantially increase the number of women and individuals from underserved and under-represented populations in the bioeconomy. Given that the future workforce will be more brown and more female, it is imperative to make training programs at all educational levels accessible in an equitable and inclusive manner and, perhaps more importantly, to increase awareness among underserved and underrepresented communities that such programs exist. As Figure 6 and Table 2 illustrate, it is possible to identify priority areas that are ripe for efforts to advance diversity, equity, and inclusion in the bioeconomy using data from the U.S. Census Bureau and tools such as the National Equity Atlas[38] that measure, track, and make the case for inclusive growth.

Increasing the diversity of the bioeconomy workforce in an equitable and inclusive manner will require creating programs that meet potential students where they are, which includes accounting for childcare and transportation needs and providing other forms of assistance. Examples of local and regional workforce development initiatives to meet the needs of local employers can be found in places such as those in Wichita, KS; Birmingham, AL; Riverside, CA; Richmond, VA; and Boston, MA. These exemplars have a particular focus on expanding job opportunities in an equitable and inclusive manner.[39] At the same time, employers will have to ensure that the working environment is inclusive and equitable to retain a diverse and productive workforce.

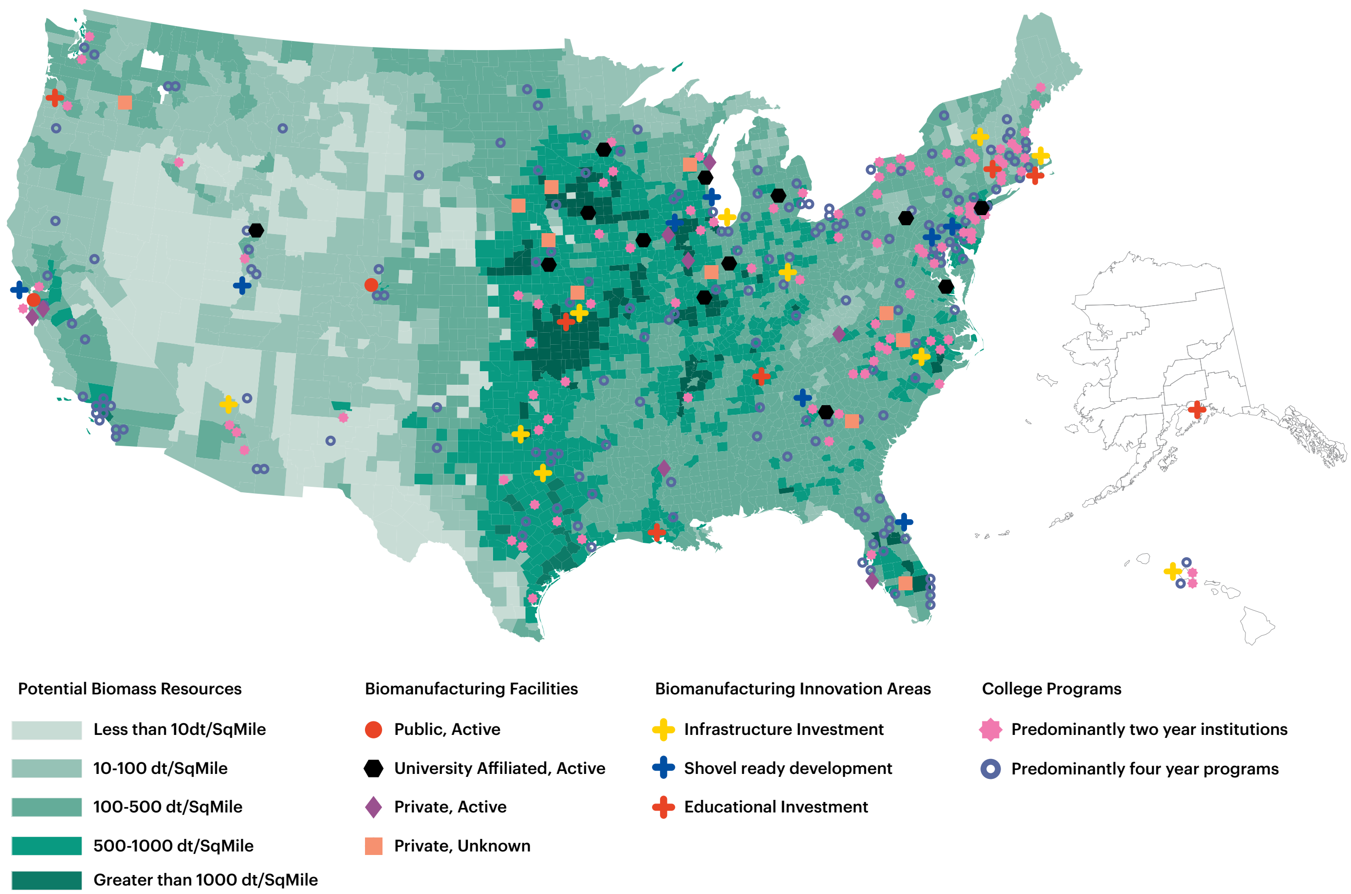

FIGURE 6 College programs (purple stars and pink circles), public and private affiliated bioproduction facilities (orange,black, purple, and peach shapes), potential biomass resources (green shading), and example areas ripe for infrastructure development (yellow plus marks), example areas ripe for educational investment (orange plus marks), and shovel ready candidates (blue plus marks). "Shovel ready candidates" (blue plus marks) refer to counties in each U.S. census region that had the highest scores for 2010 economic prosperity and inclusion indicators (National Equity Atlas, Racial Equity Index), forecasted 2040 potential biomass sources (2016 Billion-Ton Report), college bioeconomy programs in the state (National Center for Education Statistics), and biomanufacturing facilities in the state. The areas ripe for infrastructure and education development were determined using data for counties in each U.S. census region that had the highest scores for 2010 economic prosperity and inclusion indicators (National Equity Atlas, Racial Equity Index) and forecasted 2040 potential biomass sources (2016 Billion-Ton Report), alongside available biotechnology college programs or biomanufacturing facilities in the state respectively. To identify opportunities across the country, what is represented here are the top counties per region (Northeast, Midwest, South, and West) based on these criteria. Without this artificial geographic constraint, the top selections could be different. For the purposes of visual clarity, the specific locations of the icons are approximate. *Credit* Albert Hinman, postdoctoral fellow, Engineering Biology Research Consortium

TABLE 2: An illustration of how the information presented in Figure 6 could inform regional investment decisions in education, as well as "shovel ready" areas ripe for partnership investments. Making actual investment decisions will require more comprehensive data and data-sharing processes, as well input and active participation of communities identified by such an analysis.

Rank	Shovel Ready	Education Investment
NORTHEAST	County, State	
1	New York, NY	Litchfield, CT
2	Baltimore, MD	Providence, RI
MIDWEST	County, State	
1	DuPage, IL	Sarpy, NE
2	Waukesha, WI	Jackson, MO
3	Scott, IA	Kalamazoo, MI
SOUTH	County, State	
1	Arlington, VA	Rutherford, TN
2	Seminole, FL	Lafayette, LA
3	Forsyth, GA	DeSoto, MS
WEST	County, State	
1	San Francisco, CA	Washington, OR
2	Utah, UT	Anchorage, AK

Enabling a Policy Environment that Incentivizes and Supports a Circular Bioeconomy

While technological breakthroughs will be essential to fully realize the potential of the bioeconomy to drive the nation to a net-zero carbon economy, the Organisation for Economic Co-operation and Development (OECD) highlights two additional factors that will define the societal benefits from the bioeconomy: the quality of governance of the bioeconomy and the economic competitiveness of biobased products and processes. Governance in this case refers to the regulatory policies that affect the bioeconomy, and economic competitiveness can be aided by sound financial incentives.

> A critical barrier to creating an enabling policy environment is that there is no central federal home to coordinate activities that would support the bioeconomy.

A critical barrier to creating an enabling policy environment is that there is no central federal home to coordinate activities that would support the bioeconomy. The Department of Commerce should be that central federal "home" and serve as a coordinating node, given that it is responsible for economic development and the bioeconomy represents a massive opportunity for economic development. In fact, serving as the federal home responsible for supporting the bioeconomy fits perfectly with Commerce Department's 2018-2022 Strategic Plan,[40] which calls for it to accelerate American leadership by advancing innovation; enhance job creation by reducing and streamlining regulations and strengthening the U.S. industrial base; and strengthen U.S. economic and national security, including by reducing extreme weather impacts. As the coordinating node for bioeconomic development, the Department of Commerce would be responsible for setting economic priorities and policies, relying on partner agencies for setting engineering or research priorities. In addition, the Department of Commerce could serve as the representative to international bodies relevant to the global bioeconomy policy, including OECD, the International Bioeconomy Forum, and International Advisory Council on Global Bioeconomy.

Innovative Approaches to Regulatory Policies

The regulatory ecosystem for the products of biotechnology is complex and fragmented, yet vitally important for public confidence and safety. Three key agencies—the Environmental Protection Agency (EPA), Food and Drug Administration (FDA) of the Department of Health and Human Services, and U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS)—are largely responsible for regulating the products of biotechnology. In addition to the three key agencies, other federal regulatory agencies or offices are also tasked with the oversight of certain products of biotechnology, including the Department of the Interior's Fish and Wildlife Services, the Commerce Department's National Oceanographic and Atmospheric Administration (NOAA), and the Department of Labor's OSHA.

In 1986, the federal government established the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework).[41] The key point in issuing this framework was to assert that given the technologies available at the time no new laws were required for regulating the products of biotechnology and that that they could be adequately regulated under existing federal laws just as products made by more conventional chemical synthesis or breeding. Furthermore, the Coordinated Framework set out the regulatory paths and identified the relevant statutes and the agencies to which they relate, resulting in a highly decentralized regulatory process.

Federal oversight of genetically modified and, more recently, genome edited crops illustrates the unintended consequence of this decentralized regulatory process and the "regulatory triggers" as defined by each agency's statutory remit. In many cases, this results in each of the three regulatory agencies having oversight, for different reasons, for a single product of biotechnology. For example, APHIS is responsible for determining whether a crop should be regulated or not under the Plant Pest Act—if APHIS determines that the crop does not pose a plant pest risk, USDA requires no further oversight. If that crop contains a biopesticide or "plant protectant," a second regulatory agency, EPA, reviews the pesticidal protein and gene under the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, but not the crop itself. EPA determines whether the available data demonstrate that the biopesticide does not pose unreasonable risks. Specifically, they consider risks to human health, non-target organisms, and the environment. A third regulatory agency, the FDA and its Center for Food Safety and Applied Nutrition, then engages in a voluntary consultation with the manufacturer to determine whether the agency has any further questions regarding the manufacturer's assessment of the crop's food safety. See Table 3 for a snapshot of the laws that govern regulatory decisions and Case Study 6 for more information about the examples in Table 3.

TABLE 3 Regulation of selected bioengineered products under the Coordinated Framework for Regulation of Biotechnology. The table shows the regulatory authority the EPA, the FDA, or the USDA has over each product. The relevant regulatory statutes are printed in italics. Each product listing includes the product name and the element of biotechnology used to create the product (biotech component). The products were selected from a total of 323 products listed on the Future Bioengineered Products database to be representative of a range of biotechnologies, applications, and market readiness. Product selection was limited to those intended for distribution in the United States and thus under the purview of U.S. regulatory agencies. The Future Bioengineered Products database can be found here: https://www.futurebioengineeredproducts.org/.
Credit Sifang Chen, postdoctoral fellow, Engineering Biology Research Consortium

FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act
PPA = Plant Protection Act
FFDCA = Federal Food, Drug, and Cosmetic Act
TSCA = Toxic Substances Control Act

Product	EPA	FDA	USDA
Blight Fungus Resistant American Chestnut Biotech component: Plant	FIFRA authorizes EPA to review and regulate the pesticidal aspect of blight fungus resistance in the chestnut.	FFDCA authorizes FDA to review the modified chestnut for nutritional safety as food.	PPA authorizes USDA to determine the nonregulated status of the modified chestnut based on whether it poses a plant pest risk.
AquAdvantage Salmon Biotech component: Animal		FFDCA authorizes FDA to regulate the fast-growth gene in AA Salmon as a new animal drug, to ensure the rDNA construct is safe for the salmon, that claims about faster growth are accurate, and to ensure the fish is safe for consumption.	
Pivot Bio PROVEN Biotech component: Microbe	TSCA authorizes EPA to regulate the modified diazotroph in Pivot Bio PROVEN as a commercial bioengineered microorganism and ensure it does not pose risks to the environment. *EPA also defines the product as a soil amendment, which is subject to regulations by individual states.		
TransFerm Yield+ Biotech component: Yeast	TSCA authorizes EPA to regulate the modified yeast in TransFerm Yield+ as a commercial bioengineered microorganism and ensure it does not pose risks to the environment.	FFDCA authorizes FDA to review the safety of the engineered yeast in TransFerm Yield+ as a food additive.	

TABLE 3, CONT.
FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act
PPA = Plant Protection Act
FFDCA = Federal Food, Drug, and Cosmetic Act
TSCA = Toxic Substances Control Act

Product	EPA	FDA	USDA
Rainbow Papaya Biotech component: Plant	FIFRA and FFDCA authorize EPA to review and regulate the pesticidal aspect of the viral coat protein produced by the transgenic papaya.	FFDCA authorizes FDA to review Rainbow Papaya for nutritional safety as food.	PPA authorizes USDA to determine the nonregulated status of Rainbow Papaya based on whether it poses a plant pest risk.
SmartStax Pro RNAi Pest Control Biotech component: Plant	FIFRA and FFDCA authorize EPA to review and regulate the pesticidal aspect of RNAi technology in SmartStax used to control corn rootworm.	FFDCA authorizes FDA to ensure the food from crops containing RNAi is as safe as its conventional counterpart.	PPA authorizes USDA to review the risk to agriculture from the use of RNAi and determine the nonregulated status of the modified corn based on whether it poses a plant pest risk.
Upside Foods Chicken Biotech component: Animal		According to an MOU between FDA and USDA on cell-cultured meat, FDA will oversee the collection and growth of cultured cells up until the cell harvesting.	According to an MOU between FDA and USDA on cell-cultured meat, USDA will oversee the processing of harvested cells into meat products and the labeling of those products.
EVERY ClearEgg Biotech component: Recombinant protein		FFDCA authorizes FDA to regulate recombinant proteins used as food, regardless of the source organism, and USDA has no role.	
Oxitec Mosquitoes Biotech component: Animal	FIFRA authorizes EPA to allow the field testing of modified mosquitoes for mosquito population-control as a pesticide under development.	FFDCA authorizes FDA to regulate products intended to suppress disease transmission as drug (FDA transferred jurisdiction of Oxitec's mosquitoes to the EPA in 2017).	

The critical need to streamline this process could be addressed by 1) consistent coordination of the regulatory agencies by OSTP; 2) participation of expert staff from each of the regulatory agencies; and 3) sufficient funding to support streamlining activities. The Coordinated Framework recognizes that although a regulatory agency has the legal responsibility for regulation, the expertise to address the scientific and technical issues might reside in different regulatory agencies. A key and often underutilized part of the framework was the provision that expertise could and should be shared among agencies while maintaining the primary responsibility of the agency for a regulated product. This provision has been invoked infrequently, and increased use of this type of collaboration could contribute to an interagency regulatory streamlining process.

Following the release of the Coordinated Framework in 1986, there have been three efforts to clarify and update the framework, with each update building upon the previous version.[42] The most recent effort was initiated in 2015 when OSTP directed the three agencies to commission the National Academies of Sciences, Engineering, and Medicine to conduct an independent analysis of the future landscape of biotechnology products, with primary focus on determining whether any new risk could result, and if so, how new risk assessment frameworks could be developed to address those new products. In its 2017 report,[43] NASEM concluded that these new products do not pose new risk endpoints, but that the risk assessment pathways to those endpoints may be different. One of the ways in which novel exposure or risk assessment pathways could be anticipated and addressed would be to increase funding to all of the regulatory agencies for purposes of horizon scanning, hiring staff with the appropriate expertise, and developing the appropriate risk assessment frameworks to ensure that public health and the environment are protected. An important aspect of implementing horizon scanning is developing intra-and interagency scientific knowledge to address many of the overarching risk issues associated with the products of biotechnology. Such studies are critically important for the efficient evaluation of regulatory submissions, and should be supported by non-transferable funding to ensure that agencies are adequately prepared to understand the science, safety, and risk that these products may pose.

The 2017 NASEM report also observed that although the Coordinated Framework appeared to have considerable flexibility in applying statutory authorities to biotechnology products, there continued to be gaps and redundancies in those processes. Furthermore, the extent to which regulatory pathways could be coordinated has been complex and poorly understood by many, including regulated entities and the public. The report emphasized the need for a single point of entry through which product developers could enter and be guided through the regulatory system, as well as advocating for formal horizon scanning as part of the individual and coordinated activities of the regulatory agencies.

These efforts at updating the Coordinated Framework and commissioning studies have been well-intentioned, and in many cases, have resulted in thoughtful recommendations that could improve regulatory coordination and processes. However, for complex reasons, the most important being a lack of consistent funding, the recommendations have been poorly implemented. These updates have not led to a significant recalibration of existing regulatory structures, but instead have resulted in the regulatory agencies taking multiple small steps to provide recommendations and guidance to the regulated communities. While these types of non-statutory approaches can be adopted quickly and significantly improve regulatory time frames, cultural approaches to regulation, and communications with regulated communities, they have not altered the perceptions that these processes are, and remain, intractable, incomprehensible, and inefficient. One way to address these shortcomings and the resulting poor perceptions could be for Congress to establish a commission similar to the National Security Commission on Emerging Biotechnology, that would examine options that Congress and/or the regulatory agencies can take to address accessibility, transparency, and efficiency.

Today, the regulatory agencies are understaffed, in part the result of inadequate funding, staff departures, and an aging workforce.[44] Current funding levels are insufficient to maintain day-to-day regulatory functions. Therefore, implementing and maintaining new functions, including a single point of entry into the system and ongoing horizon scanning, would further stress the regulatory system if implemented as unfunded mandates. In the absence of additional financial support, NASEM's observation that "public confidence in government oversight of emerging technologies may be eroded,"[45] could be particularly apt, especially if there are no concurrent efforts to develop mechanisms that provide clarity and transparency for how the regulatory process is conducted.

> An open, transparent, fully staffed and future-prepared regulatory system can only occur with adequate and consistent funding.

There is a necessary tension between the regulated community and regulators, but that does not mean that interactions have to be adversarial. Industry should speak with a unified voice to support calls for Congress to increase funding to fully resource the regulatory agencies so that regulators can make their decisions in a timely manner. Regulators neither endorse nor oppose products, but they do provide a mechanism for the lawful commercialization of those products. An open, transparent, fully staffed and future-prepared regulatory system can only occur with adequate and consistent funding. Such a system would go far in mitigating concerns and perceptions of all stakeholders.

Financial Policies to Propel the U.S. Bioeconomy

According to an analysis by the OECD, bioeconomy-related policies focus primarily on supply-side or technology push measures, such as support for research and development and demonstration projects. In that vein, the federal government could expand bioproduction capacity by incentivizing the use of existing scale-up infrastructure housed within established companies. The U.S. government could also implement tax breaks, subsidies, loan guarantee programs and other financial incentives for further investment in bioprocessing infrastructure and for retrofitting existing facilities, including existing idled cellulosic ethanol and pharmaceutical facilities, as well as other corn-to-ethanol facilities pivoting to additional bioproduction opportunities (see Case Study 7).

However, OECD also noted that a shift to "a biobased economy will likely require a balance of more demand-side [or market pull] measures in order to help ensure a market for innovative products."[46] In particular, OECD emphasized the importance of public procurement in helping to create a market for biobased products. Examples of demand-side incentives include setting targets and quotas, public procurement, tax incentives for biobased products, incentives related to greenhouse gas emissions, and removing fossil fuel subsidies.

In terms of demand-side incentives, OECD recognized the USDA's BioPreferred program as the most advanced effort in this regard. The BioPreferred program—initially established in the 2002 Farm Bill and reauthorized and amended by Congress in the 2018 Farm Bill—requires federal agencies and contractors to give purchasing preferences to biobased products. Specifically, USDA is required to identify eligible product categories and to specify the minimum biobased content required for each category. Currently, there are 139 product categories and tens of thousands of biobased products under the program. In addition to the federal purchasing requirements, the BioPreferred program also includes a voluntary labeling initiative in which a business can display a "USDA Certified Biobased Product label" on a product that meets USDA criteria.

Although the Farm Bill mandates that federal agencies and contractors purchase biobased products as long as there are no cost or performance penalties associated with those products, it does not require regular reporting that would provide insights on the progress or scale of biobased procurement. Updating the reporting mechanisms involved in the federal procurement of biobased products, setting procurement targets, and increasing funding for the program to enable increased awareness and standardized reporting—such as a real-time public-facing dashboard to report federal progress in biobased procurement—would go a long way toward stimulating the bioeconomy and supporting jobs in rural areas where many source materials are concentrated.

Another approach to create market pull would be to establish a strategic chemical reserve, modeled after the strategic petroleum reserve, and to require that a certain percentage of the chemicals in that reserve be made using biological production processes from renewable biomass. A strategic chemical reserve could make supply chains more resilient so as to avoid the type and scope of supply chain issues such as those that developed when refining operations shut down following Hurricane Harvey and again during the 2021 Texas cold snap. A related approach would be for the federal government to contract with and provide a stipend to commercial bioproduction facilities that in exchange would give the federal government the right to pivot production to critical chemicals in times of need. DARPA's Living Foundries program[47] could serve as the means of enacting such arrangements.

Given the expected size of the bioeconomy, with estimates between $4 and $30 trillion, it is also important that the federal government improve its ability to measure the bioeconomy, something NASEM has recommended.[48] Relevant metrics are generally seen as critical to understanding the value of the U.S. bioeconomy, in addition to tracking progress and assessing the impact of policies. Metrics could also be useful in comparing the U.S. bioeconomy with other nations, although the United States is currently one of only a few major countries that have attempted to measure the bioeconomy. Standardizing such metrics would be challenging given differences among national definitions, but they could still serve as useful benchmarks. One place to start would be for the Department of Commerce to revise the NAICS codes[49] to track both biobased and bio-enabled products, and to compile those products by relying on the USDA BioPreferred program. Both actions would provide more robust data on the size of the bioeconomy. In the absence of a concrete measurement plan, economic advances run the risk of being captured under traditional petroleum-based industries and not "credited" to the bioeconomy.

Data-Sharing Policies

Complexities inherent to developing and refining biomanufacturing processes at scale are barriers to the development of commercial-scale bioproduction processes. Given that few stakeholders possess all of the knowledge and capabilities to take bioproduction processes to scale, the opportunity exists for the entire field to share precompetitive knowledge about the engineering and biochemical aspects to process development through partnerships and collaborations. Precompetitive data sharing through public-private partnerships would reduce duplicative efforts to generate basic knowledge, thus accelerating the development of commercial-scale bioproduction processes. Such collaborative activities require intensive technology transfer, including associated data streams, that currently rely on email and generic file-sharing services, which are inadequate. In parallel, there is growing demand for a means to share high-value datasets and software solutions across the community for collective benefit, particularly from work performed at publicly supported pilot-stage facilities. In the same spirit, there is demand for a means for controlled sharing of data analysis capabilities.

On the implementation side, particular challenges arise from the heterogeneity of the data itself. Bioindustrial manufacturing datasets span genetics, 'omics, chemistry, bioprocessing, scale-up and downstream processing, as well as associated performance metrics and economic analyses. Moreover, even datasets that are nominally considered to be the same kind may be formatted differently as a result of differences among instrument vendors, further complicating the establishment of schema and automated data ingestion. To address these issues, innovative data architectures designed to manage and track diverse data types will be needed. To ensure utility, these architectures should be paired with metadata governance principles suggested by findable, accessible, interoperable and reusable (FAIR) data storage practices,[50] which help ensure that analysts can find and interpret the data they need. Both world wide web and application programming interfaces are needed to enable access by users at different skill levels. Innovation in implementation, governance, and data exchange standards will all be required. Considering how challenging the integration and management of such data can be within a single organization, new approaches will be needed to support it across the entire biomanufacturing community. Efforts such as these were important enablers of the microfabrication and integrated circuit industries in the 1980s.

> Achieving the biggest return on the nation's investments, both past and future, requires the U.S. government to accelerate research in foundational bioengineering and bioproduction to translate the growing number of engineering biology basic research discoveries to public benefit.

Security is a high priority as well, posing additional technological and governance challenges. Security requirements are driven by needs to protect intellectual property, to support compliance to contractual obligations (such as regarding disclosure), and to ensure operational continuity. Furthermore, companies anticipate they will occasionally need the ability to exchange sensitive information with government stakeholders. Allaying security concerns within this collaborative ecosystem will require both technological and non-technological measures, including means for precision access control of individual datasets at the individual and organizational levels, and policies for vetting individuals' access at different levels. In addition, there is a need for education and training within companies to identify vulnerabilities and become full partners in efforts to prevent misuse of their powerful technologies. The federal government can help here by providing access to experts in the biosecurity community to help companies make important decisions related to biosecurity. The goal is not for companies to develop their own expertise in biosecurity, but rather to become partners in biosecurity.

Despite the clear need, there is a dearth of available commercial solutions to support such use cases in a domain-specific manner. As a further barrier, even when new vendors try to fill these gaps, companies are hesitant to commit data and resources out of concern for the vendors' susceptibility to market forces, which puts their data at risk. Given this context, these gaps may be best addressed through non-commercial means, such as through public funding or via public-private partnership.

There are many examples of precompetitive data sharing in biomedicine, most concentrating on developing standards and processes rather than on projects that could involve conflicts of interest or intellectual property issues. For example, the National Cancer Institute's Nanotechnology Characterization Laboratory[51] serves as a national resource and precompetitive knowledge base of analytical methods to facilitate the regulatory review of nanotechnologies intended for cancer therapies and diagnostics and accelerate the transition of basic nanoscale particles and devices into clinical applications. GenBank, the NIH genetic sequence database, is an annotated collection of all publicly available DNA sequences and an important venue for sharing genetic sequence information. The Pistoia Alliance,[52] a global, not-for-profit members' organization conceived in 2007, lowers barriers to innovation by providing a legal framework to enable straightforward and secure precompetitive collaboration between more than 100 global members. Ten pharmaceutical companies formed a precompetitive collaboration, the Machine Learning Ledger Orchestration for Drug Discovery (MELLODDY) project, to build more powerful predictive models for drug discovery without compromising data and model privacy.

Nonetheless, intellectual property and antitrust issues can be a particular concern with precompetitive collaborations and are something that data-sharing initiatives must take into account. To minimize potential arguments over intellectual property, one approach is to list the collaborative entity as the patent holder and have members in the collaboration license any patents from that entity. Having such a formal structure for sharing intellectual property is important when there are many collaborators in order to minimize any confusion regarding intellectual property ownership.

Effective data-sharing collaborations will require identifying and prioritizing "bottleneck" knowledge gaps that precompetitive collaboration, the development of information "utilities" such as data standards and infrastructures, less regulatory uncertainty, and more head-to-head evaluations of collaborative models to identify key features and best practices. Such collaborations can address bottlenecks more effectively than having every company do this work on their own. This is an approach the federal government has taken successfully in other contexts. For example, something similar to the National Center for Advancing Translational Sciences' Clinical and Translational Science Awards program could provide a mechanism for greater collaboration, as the institutions that have received these awards have developed ways to share data that could provide a template for many other kinds of partnerships. Other examples include the National Microbiome Data Collaborative, which is mostly focused on sharing data among academic laboratories. While there are many databases for sharing genomics, proteomics, and other 'omics data, these largely house already published data as mandated by journals.

In summary, there is a communal need for shared digital infrastructure to enable the secure exchange, distribution, and analysis of data and software for bioindustrial manufacturing. Such infrastructure will reduce barriers to collaborative research and development efforts across the community, thereby helping to accelerate the bioeconomy. Moreover, it could also provide new opportunities for discovery of manufacturing insights, such as through retrospective mining of the aggregate data generated by the community as a whole.

Concluding Remarks

Key Takeaways

The United States should leverage its unmatched biotechnology expertise to capture a leadership position in a global circular bioeconomy grounded in biotechnology, one that would put the nation in a position to set norms and ground rules for a sector destined to become a major driver of the global economy. To do that, however, the U.S. government needs to make additional investments to facilitate the transition from laboratory scale to commercial scale.

The U.S. bioeconomy is poised to deliver substantial economic and public benefits, but U.S. government investments in bioeconomy-related research have remained stagnant for several years.

A strategic new investment on the order of $2 billion for bioproduction research and development and infrastructure support is required to realize this potential over the next five years. This is a fraction of the $550 billion allocated in the recently passed bipartisan infrastructure deal, and the return on that investment will more than justify it.

Concluding Remarks

A convergence in platform technologies such as artificial intelligence and engineering biology has the potential to accelerate biotechnology solutions in a wide range of economic sectors and advance the United States toward a resilient, sustainable net-zero carbon economy. As a result of the U.S. government's incredible foundational investments in this space, investments that already revolutionized the pharmaceutical industry and are now enabling today's burgeoning biotechnology ecosystem, the nation is in an ideal position to capitalize on that investment by building an economy rooted in biotechnology. Indeed, as the world embraces a circular bio-economy and moves away from products and processes that release copious amounts of greenhouse gases, the United States should leverage its unmatched biotechnology expertise to capture a leadership position in a global circular bioeconomy grounded in biotechnology, one that would put the nation in a position to set norms and ground rules for a sector destined to become a major driver of the global economy. To do that, however, the U.S. government needs to make additional investments to facilitate the transition from laboratory scale to commercial scale.

> The U.S. bioeconomy is poised to deliver substantial economic and public benefit...However, a strategic new investment on the order of $2 billion for bioproduction research and development and infrastructure support is required to realize this potential over the next five years.

As this report spells out, the U.S. bioeconomy is poised to deliver substantial economic and public benefit, but U.S. government investments in bioeconomy-related research have remained stagnant for the last several years despite the rapid rise of new enabling capabilities such as artificial intelligence and genome editing tools that could greatly accelerate achievement of a future multi-trillion dollar global bioeconomy. However, a strategic new investment on the order of $2 billion for bioproduction research and development and infrastructure support is required to realize this potential over the next five years.

The lack of domestic bioproduction facilities and a public database such as the European Pilots4U hinders U.S. industry access to assets that can help mature its technologies. In fact, several U.S. companies with novel technologies have moved their efforts overseas because of the lack of domestic capacity, thus allowing other countries to capture technology rights that would otherwise stay in the United States. It is imperative that the United States address this capacity gap now, and the recommendations below provide a roadmap for doing just that. In addition, the opportunity exists for creating a novel "business-to-business" information technology infrastructure that the proposed bioproduction scaling facilities could implement, enabling innovators to design their innovative technologies with compatibility for scaling in mind.

In summary, biotechnology, through innovation in bioproduction capabilities, should be another tool in the toolbox for a net-zero future by providing better bioproduction processes, innovative technologies that are cleaner and safer for workers and their communities, and applications for fighting and adapting to climate change. This is the time for the United States to make the needed investments and seize the once in a lifetime opportunity to create a future circular bioeconomy based on this "next big thing."

Recommendations

1. A Coordinated U.S. Bioeconomy and an Informed Strategy are Needed
2. More Fundamental R&D is Needed to Translate Discoveries to Market
3. New Distributed Bioproduction Testbed Infrastructure is Needed
4. A Well-Trained, Diverse Workforce is Needed
5. Regulatory Agencies Need More Resources
6. Financial Incentives & Measurement Tools are Needed
7. Data Sharing Mechanisms are Needed

A Coordinated U.S. Bioeconomy and an Informed Strategy are Needed

1. To remain globally competitive, the U.S. government through a National Science and Technology Council interagency effort should develop and periodically update a national bioeconomy strategy focused on providing scalable solutions to advance the bioeconomy in a coordinated way, identifying the Department of Commerce as the "home."

At its core, the bioeconomy will drive economic activity in the 21st century, so a strategy to enable this sector to reach its potential should be viewed as an economic strategy for the United States. The complexity of the U.S. bioeconomy requires taking a systems approach in which actions to address needs regarding research and development, infrastructure, workforce, regulations, security, financial policy, and data sharing are mutually enabling and thus approached in a coordinated manner. A coordinated interagency effort can bring together science and technology experts with economic, security, and regulatory experts to create a robust strategy that addresses the system of systems. This strategy should, over time, provide a pathway/onramp for creating a circular bioeconomy.

A. Given that an economic strategy is needed and the Department of Commerce is the home of economic policy for the U.S. government, the strategy should designate Commerce as the coordinating node of U.S. bioeconomy policy. This designation should come with a mandate to partner with relevant federal agencies, create a National Coordination Office within the Office of the Secretary, and a budget and the necessary authorizations to enable implementation of the national bioeconomy strategy.

Having the Department of Commerce serve as the "home" or coordinating node for the bioeconomy is a nod to its central mission to driving economic development. To be successful, this new role for Commerce should come with sufficient funding and with the power to implement the strategy by creating the partnerships across federal and state entities required for success and by bringing in technical experts.

B. The strategy should be informed by input from industry, academia, state and local governments, local communities, other stakeholders, and the other federal agencies covering domain-area expertise in biotechnology, economics, security, and regulatory policy, and identify and foster critical emerging and foundational technologies for global competitiveness.

A growing bioeconomy will affect many sectors of the economy, raising key issues regarding security and regulatory policy, for example. As such, a mandate for a whole-of-government approach is needed to inform and enact a robust strategy. Representatives from industry, academia, state and local governments, local communities, and other stakeholders will have valuable perspectives that their federal colleagues will need to consider in crafting that strategy. Thus, it will be necessary to create a mechanism for actively soliciting input from outside of the federal government.

C. The strategy should enable the agencies that fund science and technology research to set coordinated research priorities and create synergistic interagency partnerships on key areas that cross mission mandates (for example, federally funded research on feedstocks should include partnerships across USDA, DOE, and NSF).

Having Commerce serve as the coordinating node should not be interpreted as tasking it with setting the scientific priorities; these should be left to the agencies that fund science and technology research. However, the agencies that fund science and technology research should seek to expand their partnerships and engagement with other federal entities to enable coordination and synergies in their work to drive the bioeconomy.

D. Federal government agencies should communicate regularly with relevant state and regional governments to facilitate implementation of the U.S. bioeconomy strategy.

Many aspects of implementing the strategy will require regional, state, and local action, context, and partnerships. State commerce departments and local economic development offices can serve as key players to implement the strategy in ways that best serve their communities. State and local participation will be particularly important for developing education and workforce training programs that respect the local culture and context.

More Fundamental R&D is Needed to Translate Discoveries to Market

2. To secure global leadership in biobased science and scale-up manufacturing, the U.S. government should establish and fund a 5-year, at least $1.1 billion[53] Bioproduction Science and Engineering Initiative (BSEI) that expands budgets and remits of relevant science and technology funding agencies focused on advancing foundational science and technology development for current and future bioproduction, and is focused on addressing unmet research needs that hinder the translation of innovative technologies.

Broadly speaking, innovation in bioproduction capability can be achieved by improving the predictability of living systems at pilot and commercial production scales and enabling modularity in bioproduction. Federal science agencies have made initial efforts toward these priorities, but bolder, larger, and better coordinated efforts are needed to catalyze necessary innovation. The BSEI should enable research focused on the priorities articulated in detail in the strategy.

A. As a "mission-agnostic" science and technology funding agency, NSF should serve as the lead agency for BSEI and should implement it through federal agency partnerships, such as with DOD, DOE, NIST, USDA, and the Department of Health and Human Services, and fund at least two new regional innovation engines (RIEs) a year focused on bioproduction science and engineering.

NSF supports fundamental research and education in all non-medical fields of science and engineering, and its stated mission is "to promote the progress of science, to advance the national health, prosperity, and welfare, and to secure the national defense." NSF's new Technology, Innovation, and Partnerships Directorate, which will fund the RIEs, is the ideal home for this multi-disciplinary bioproduction science and engineering initiative. Through the RIEs and other relevant research, NSF can implement the research priorities described in the strategy section, expand existing relevant commitments, forge new innovative industry partnerships, and advance their preliminary explorations of circular bioeconomy research.

B. The RIEs should forge new partnerships with relevant federal science and technology funding agencies (such as DOD, DOE, NIST, and USDA) to build on existing expertise, leverage earlier investments, and enable coordination for research acceleration.

The FY2022 NSF Budget describes the RIEs to be a vehicle for partnerships (industry, academies, state and local governments), but partnership between federal agencies is not included in that description. Enabling partnerships between agencies with existing expertise could further accelerate the bioeconomy and serve to begin breaking down the silos across application areas. For example, the RIEs could work with DOE programs such as the ABPDU, the Agile BioFoundry, and the Feedstock-Conversion Interface Consortium, as well as USDA's Feedstock Flexibility program to advance foundational research expanding the array of future bioeconomy feedstock options.

New Distributed Bioproduction Testbed Infrastructure is Needed

3. Given the value of maintaining resilient domestic supply chains and creating manufacturing jobs, the U.S. government should invest $1.2 billion in an extensive and flexible bioproduction infrastructure—one that can process multiple feedstocks using multiple organisms to produce multiple products by multiple mechanisms at multiple scales—over two years to expand domestic bioproduction capacity in an equitable and strategic manner. Additional funding for maintaining and sustaining these investments will be needed over time.

To maximize the potential of the U.S. bioeconomy and regain competitiveness, additional pilot and intermediate-scale facilities with inherent flexibility and modularity are needed and must be prioritized.

A. The Department of Commerce should undertake a comprehensive assessment of existing facilities and functionality, building from the work of this Task Force, to identify and realize opportunities for appropriate and equitable placement of future facilities.

Considerations for implementing this expansion include access to feedstock, a trained workforce (or where a potential workforce could be developed with training/reskilling programs), academic and industrial partners to operate these facilities, and regions for where this new industrial activity could most benefit communities.

B. Congress should authorize the Department of Commerce to create a network of 12-15 new and refurbished bioproduction facilities and appropriate the $1.2B needed to build these facilities. Incentives for early-stage technology development will be needed and will accelerate the transition from laboratory technologies to commercial deployment.

Previous federal bioproduction infrastructure investments, such as the DOE's ABPDU, established with the American Recovery and Reinvestment Act, NIST's NIIMBL, and DOD's Advanced Regenerative Manufacturing Institute, have proven valuable in generating important returns on federal investment since they were brought online. DoD's recently-funded BioMADE institute is expected to deliver significant returns as well. However, these assets are insufficient to meet the growing demand by U.S. innovators who are increasingly forced to develop their technologies in foreign countries.

C. Additionally, the Department of Commerce should explore financial incentives, such as those articulated in the CHIPS Act, to provide capital for companies to meet national infrastructure needs creating public-private partnerships that can provide developers access to scaling facilities, and create partnerships with other federal agencies in order to implement objectives underlying the incentives.

Such incentives could be in the form of tax incentives and loan guarantees to enable companies to fund their own new facilities and/or acquire and refurbish existing infrastructure as their technology reaches maturation. This approach has the potential to revitalize communities whose existing bioproduction facilities or chemical refineries are no longer used.

A Well-Trained, Diverse Workforce is Needed

4. Federal and state governments should provide incentives that bring industry and learning institutions of all relevant types (e.g., community colleges, Historically Black Colleges and Universities (HBCUs), Tribal Colleges and Universities (TCUs), Hispanic Serving Institutions (HSIs), 4-year institutions, and others) together to build bioproduction science curricula/certification programs that will provide opportunities for a diverse workforce that is trained with high-demand skills and competencies for immediate industry employment.

A vibrant and successful bioeconomy is going to require a diverse workforce that is ready to provide the talent needed by industry. As the bioeconomy grows and domestic facilities are built, for example, there will be a great demand for technical talent that does not require advanced degrees, which presents an opportunity for individuals with all levels of education to acquire the training or retraining needed without committing to a 4-year degree or more. The availability of such jobs will be particularly important in areas whose manufacturing jobs have disappeared and where reskilling through additional training would provide new employment opportunities.

While the application areas of the bioeconomy are diverse, there are a core set of necessary skills that could be delivered through standardized training programs and codified in a certificate program that is recognized by industry nationally. This approach would give industry confidence that the workers have the right competencies and give trainees confidence that their investment of both time and money will have a fruitful outcome.

A. State Departments of Commerce should prioritize funding educational programs in emerging technologies such as biotechnology and engineering as part of their local business and workforce development efforts and needs. Consistent support, such as through formal inclusion in the state's budget, will enable programs to grow and better serve the needs of local communities.

Local partnerships will be key to fostering the development of a vibrant workforce to power a distributed, robust bioeconomy. Therefore, companies should engage with state and local governments to align on incentives and initiatives that will ultimately benefit those seeking jobs in the bioeconomy. These partnerships can be mutually beneficial as they can provide industry incentives to invest in their local communities and thus help state and local authorities achieve their economic and civic goals. At the same time, state and local governments should use workforce development boards[54] and similar resources to facilitate these partnerships.

B. Modeled after federal training grant programs, the federal government should establish a Bioeconomy Career Pathways Training Program for HBCUs, TCUs, and HSIs to grow an inclusive generation of diverse bioeconomy specialists.

As the mapping exercise in Figure 5 demonstrated, the bioeconomy has the potential to enable revitalization of local communities through the use of regionally available biomass and distributed manufacturing. In particular, as the nation continues to diversify, specific engagement of communities of color will be required to fill workforce needs. While this will certainly benefit individuals in those communities and the communities themselves, such engagement will also benefit the larger bio-economy by bringing different perspectives and experiences to the table and raising different problems that the bioeconomy can address. Research has shown that a more diverse workforce increases the generation of novel ideas and productivity.[55]

C. Additional incentives should promote the hiring and training of individuals from diverse backgrounds, education levels, and abilities. Support structures for nontraditional students will be needed to encourage retention, ranging from physical assistance to childcare solutions.

As workforce demographics shift to include more communities of color and more women, greater support structures will be needed to encourage inclusivity and retention. As the pandemic showed, caretaking responsibilities often fall on women, who saw the greatest changes in employment; providing support structures could be pivotal in keeping all caregivers in the bioeconomy and opening up these careers for those needing accommodations.

D. State and local governments should provide incentives for innovation in the delivery of training materials through a broad range of media such as online video series, virtual reality sessions, and create more opportunities for hands-on training through internships.

The COVID-19 pandemic forced institutions focused on education and training to innovate in the ways they delivered materials. Widespread adoption of novel training delivery methods could provide unique opportunities to workers who need a refresher and to students who may be interested in learning more about careers in the bioeconomy but do not have ready local access to training programs. These methods could be particularly valuable for reaching individuals from disadvantaged and underserved communities.

Regulatory Agencies Need More Resources

5. Congress should provide EPA, FDA, USDA and the other agencies (e.g., Fish and Wildlife Service, NOAA, and OSHA) involved in oversight of the ever-evolving biotechnology products being developed with sufficient funding to enable agility and efficiency while protecting human health and the environment, and to develop the requirements needed for assessments of unfamiliar, novel, and/or complex biotechnology products.

Regulatory agencies, despite being understaffed, play a key role in the future of the bioeconomy by ensuring that products reaching the market do not pose risks to the environment and the public. In that regard, the actions that regulatory agencies take, as well as the transparency with which they make their regulatory decisions, will influence public attitudes about the safety of the products that the bioeconomy produces and the processes it uses to create those products. However, being under resourced is restricting the agencies' capacity for strategic horizon scanning to prepare for future products of biotechnology. In that vein, the 2017 NASEM report, Preparing for Future Products of Biotechnology, called for steps to increase funding for and staffing at the agencies that regulate biotechnology products so that these agencies can be prepared for what the future may bring.

A. Congress should create and secure sustainable funding for a single point of entry through which product developers seeking regulatory authorizations could be assured of a regulatory path that is correct under the law, and is directed to the appropriate regulatory agencies.

Given OSTP's role in interagency coordination, OSTP should become the administrative home of the single point of entry, though OSTP will not participate in any regulatory decision making. Responsibilities would include:

1. Maintaining the single point of entry as a national-level asset for biotechnology product developers to facilitate identification of the lead agency and the regulatory path[56]
2. Engaging in outreach to stakeholders to increase awareness, including drafting and sharing language to be included within future funding opportunities that could give rise to future products of biotechnology
3. Facilitating sharing of staff expertise across the three regulatory agencies
4. Coordinating the three regulatory agencies' efforts to continually streamline regulatory processes

A 2019 Executive Order,[57] directed USDA, EPA, and FDA to work together to create a "Unified Biotechnology Web-Based Platform" as a single site to enable innovators to easily navigate the regulatory system for products of agricultural biotechnology. This web-based platform allows innovators to submit inquiries about a particular product and promptly receive from the agencies a single, coordinated response that provides, to the extent practicable, information and, when appropriate, informal guidance regarding the process that the developers must follow for federal regulatory review.[58] While this is a helpful first step, and can serve as a model for further actions, it only pertains to the products of agricultural biotechnology and does not fully address the needs and functions identified above.

B. Regulatory agencies with the authority to regulate biotechnology products should explore risk-based mechanisms to bring products to market that may not require formal approvals or authorizations, and continue to protect human, animal, and environmental health.

A recent example is the use of "low risk" determinations involving "enforcement discretion" by FDA's Center for Veterinary Medicine (FDA) for genome edited beef cattle.[59] This discretion should be risk proportionate, transparent, predictable, and appropriate to the technology.

C. The federal government should convene a National Commission on Biotechnology Regulatory Processes (similar to the National Security Commission on Emerging Biotechnology) to explore options to make the regulatory system more immediately accessible, transparent, risk-based and efficient, including non-statutory options. In addition, the Commission must consider ways in which public trust in the regulatory process can be improved, including balancing transparency of process and decision-making while maintaining confidential business information in the pre-commercialization space.

This commission should have representatives who are experts in regulatory engagement, including former regulators, regulatory attorneys, industry leaders, academics. If possible the commission should also involve appropriate staff from the regulatory agencies, including the appropriate individual(s) from the U.S. Trade Representative's office. As part of its remit, this commission should evaluate emerging regulatory issues pertaining to biotechnology products, such as federal strategies for investigational environmental releases (e.g., field trials) on privately owned lands or waters, examining opportunities for harmonizing policies that individual states have for environmental releases and labeling, and addressing any issues related to evolving nomenclature. It should also undertake multiple opportunities for public engagement throughout its data gathering and deliberative processes, as well as formal opportunities for public comment.

Financial Incentives & Measurement Tools are Needed

6. The federal government should explore and use all appropriate financial incentives to drive growth of the bioeconomy and enable better measurement capacity to track its growth and the success of policy interventions.

Providing the appropriate financial incentives and supports for the bioeconomy will enable bioeconomy companies and their products to compete with existing products that benefit from subsidies and long-standing infrastructure, which together lowers their net cost of production and gives existing products a price advantage. Capacity to measure the economic impact of the bioeconomy is needed to assess how successful any incentives are at driving the growth of the bioeconomy and adjusting incentives that are not achieving the desired goal.

A. To address bioeconomy needs for metrics, representatives from industry and academia should engage with the Department of Commerce to provide more detailed information to inform updates to the NAICS, particularly relating to inputs and production processes.

The Department of Commerce's current practices are unable to measure the economic impact of the bioeconomy, in large part because of a lack of appropriate metrics. Industry has the potential to inform the metrics by providing the department with the appropriate technical information that would better enable accurate accounting of the bioeconomy though the use of NAICS codes, North American Product Classification System (NAPCS) codes, and manufacturing surveys. While NAICS and NAPCS codes are only updated every five years, annual manufacturing surveys, as well as direct input from industry to the Department of Commerce, could provide more timely information for assessing the economic impact of the bioeconomy.

B. The Department of Commerce should recognize the USDA's BioPreferred label as an entry point for updating NAICS codes to account for bioeconomy products.

Aside from relying on industry engagement, the Department of Commerce should capitalize on USDA's expertise with its BioPreferred program to provide insights into which products are made using different inputs and processes. Relying on the USDA's BioPreferred label, which requires a verified process, should provide Commerce the confidence that these products should be counted differently.

C. Congress should strengthen the mandate within the Farm Bill that requires procurement of biobased products through the USDA BioPreferred program by creating regular mandatory reports to Congress from all government agencies and contractors.

In addition to congressional action to stimulate government procurement, the BioPreferred program should be further expanded and resourced to enable more federal procurement training and public-facing engagement to raise consumer awareness and confidence in biobased products. The Bio-Preferred program provides ready access to information that procurement officers can use to learn about and identify which biobased products meet their needs. This same information could also serve as a means of educating consumers about the wide range of available biobased products. While the Farm Bill already contains purchasing mandates, it does not include reporting requirements to ensure that federal agencies are following through on these purchasing mandates.

Data Sharing Mechanisms are Needed

7. Recognizing the importance of federally funded data on research investments and industry generated data on process development for advancing the bioeconomy, Congress should provide funding for modernizing relevant existing databases and creating data-sharing mechanisms to spur continued progress, such as creative new public-private partnerships with the goal of reducing the time it takes to successfully scale new products from several years to months.

Given the time, energy, and resources that have gone into producing the vast amounts of data that underpins the bioeconomy, investments in facilitating access, annotation, and combination of datasets would extend the impact of those investments to the broader community of developers. For example, innovators lose considerable time and waste significant resources when they have to solve precompetitive process development challenges that others in the field have already addressed. Creating public-private partnerships to enable developers to share precompetitive information and data enables others to learnlearning from the mistakes of others, reducereducing duplicative efforts to generate basic knowledge, and usinge their time and resources more productively. This would accelerate the development of commercial-scale bioproduction processes.

A. To facilitate data sharing, the NIH, DOE, and other agencies that maintain vital bioinformatic databases should receive funding for modernization of these databases and the storage of physical samples, as relevant. Cloud-based data platforms with analysis capabilities should be included in the considerations for modernizing sharing federally funded data.

Databases containing federally funded data should be upgraded to enable greater, secure access to information stored in a standardized format that would enable innovators to combine data from multiple sources. Currently, challenges for using data arise from the heterogeneity of the data themselves and the formats in which the data are stored. For example, datasets relevant to bioindustrial manufacturing span genetics, 'omics, chemistry, bioprocessing, scale-up, and downstream processing, as well as associated performance metrics and economic analyses. Moreover, even datasets that are nominally considered to be of the same kind may be formatted differently as a result of differences among instrument vendors, further complicating the establishment of schema and automated data input into a database. To address these issues, innovative data architectures designed to manage and track diverse data types will be needed.

B. Through the Manufacturing Institutes Initiative, NIST should provide additional resources for establishing and disseminating bioprocess manufacturing standards.

Precompetitive data and information sharing can be used to drive standard setting. Examples of programs to enable data and information sharing include the NCI Nanotechnology Characterization Laboratory, which serves as a national resource and precompetitive knowledge base of analytical methods to facilitate the regulatory review of nanotechnologies intended for cancer therapies and diagnostics and accelerate the transition of basic nanoscale particles and devices into clinical applications; MELLODDY, a precompetitive collaboration among pharmaceutical companies to build more powerful predictive models for drug discovery without compromising data and model privacy; and the recently announced partnership between TeselaGen Biotechnology and BioMADE that will work to improve the informatics infrastructure around fermentation-based biomanufacturing by developing novel technologies that standardize data exchange, connect disparate software systems, and establish secure protocols to facilitate collaboration on artificial intelligence-enabled projects.[60]

C. The Department of Commerce should support open data infrastructure, including those involving collaborations across artificial intelligence and bioproduction, to catalyze rapid innovation around process developments that can enable more rapid growth of the bioeconomy.

An open data infrastructure would enable researchers and innovators to contribute data that would help the field of bioprocess development build the type of knowledge base that any new endeavor needs to accelerate progress. Collaborations among experts in artificial intelligence and those working on bioprocess development, enabled by an open data architecture that would facilitate data exchange, have the potential to dramatically reduce the time it takes for a product to move from the laboratory to the pilot scale and on to commercial production. An open data infrastructure would also allow training programs to access data that their students could use to perform in silico experiments and gain insights into the technical problems they will face in their jobs and possible solutions.

A Strategy for a Resilient and Competitive Bioeconomy

1. Expand Research to Accelerate the Translation of Discoveries into Public and Economic Benefit

2. Foster a National Ecosysytem of Innovation and Commercialization

3. Build a National Infrastructure for Bioproduction Scale-up Capacity

4. Develop a Diverse Workforce to Power the Current and Future Bioeconomy

5. Enable Policy that Incentivizes and Supports a Circular Bioeconomy

A Strategy for a Resilient and Competitive Bioeconomy

The discussion above describes the key assets the United States possesses and the critical areas of research, development, infrastructure, workforce, policy/regulatory challenges that the nation must solve to fully capitalize on those assets. As alluded to earlier in this document, there are multiple considerations that are essential elements of a holistic strategy for advancing the U.S. bioeconomy.

1. EXPAND RESEARCH TO ACCELERATE THE TRANSLATION OF DISCOVERIES INTO PUBLIC AND ECONOMIC BENEFIT

1.1. Foundational Science and Technology Challenges—Science of Scale Initiative: Establish and support strategic bioproduction research initiatives and public-private partnerships to enable rapid transitions from laboratory-scale to industrial-scale processes through predictive modeling and simulations, testing, data collection, and rapid iteration:

1.1.1. Conduct a comprehensive science and technology research needs analysis with academic, government, and industry researchers to identify priorities to address bioproduction translation and scale-up hurdles

1.1.2. Initiate research to address the following areas for both traditional host organisms as well as new organisms (including multicellular organisms and microbial communities) that provide distinct process advantages:

1.1.2.1. Genetic/enzymatic pathway modeling and design software that creates a blueprint for how to produce a valuable molecule(s) (or macromolecule(s)) biologically, including expanding to molecules and products that do not exist in nature and engineering post-translational modifications

1.1.2.2. Whole-cell modeling and design software that supports aforementioned bioproduction pathway modeling in the context of the entire host organism, allowing bioprocess engineers to anticipate how the produced molecule(s) affects the host organism and vise-versa

1.1.2.3. Cellular community modeling and design software that allows bioprocess engineers to anticipate how the modified organisms will interact with each other, with the bioreactor, and with downstream separation and processing steps

1.1.2.4. Foundational open-source tooling and algorithms based on mechanistic, rule-based, data-driven, and artificial intelligence approaches in order to support modeling approaches at all levels

1.1.2.5. Foundational assays and diagnostics that measure the molecular content of cells and generate valuable data that support these modeling approaches

1.1.2.6. Microfluidic tools for rapid strain construction, prototyping, and analyte detection

1.1.2.7. Genetic and characterization tools for microbes, plants, and animal cells with proven or high potential for bioproduction (fermentation and non-fermentation-based scale), including those for reading, multiplexed editing, and writing whole microbial genomes

1.1.2.8. Scalable, flexible and low-cost cell-free systems for manufacturing desired biochemical products, including post-translational modifications

1.1.2.9. Novel living materials with promise for enabling new methods of processing and characterization

1.1.2.10. Surveying and harnessing the microbial diversity of the United States

1.1.2.11. Study of microbial consortia, community metabolism, and functional biodiversity to expand the repertoire of available biochemistries

1.2. Foundational Science and Technology Challenges—Circular Bioeconomy Research:

1.2.1. Establish and support research to foster the use of biotechnology toward a zero-waste, circular bioeconomy

1.2.2. Conduct a comprehensive science and technology research needs analysis with academic, government, and industry stakeholders to identify priorities to enable a circular bioeconomy

1.2.3. Initiate research to address the following areas:

1.2.3.1. Catalog and maintain inventories of sources of biomass and wastes to inform economically viable feedstocks that are regionally available

1.2.3.2. Initiate research efforts to deconstruct, upcycle and/or convert expanded feedstocks repertoires identified above

1.2.3.3. Technologies for expanding and maturing biology-based sequestration and recycling of environmental pollutants, such as heavy metals, and plastics, in addition to key elements such as nitrogen and phosphorus

1.2.3.4. Enhance life cycle analysis to understand inputs and outputs of materials and wastes through bioproduction processes

1.2.3.5. Develop modular unit operations equipment to integrate bioprocessing and chemical processes for designing both existing and novel products

1.2.3.6. Develop economic and processing platforms for non-carbon products of biotechnology (e.g., metals, living cells)

1.2.3.7. Ecosystem surveillance at the molecular level to monitor impact of circular efforts on flows of key elements, such as carbon, nitrogen, and phosphorous

1.3. Foundational Science and Technology Challenges—Regulatory Science: Establish and support research to inform regulatory decision-making (e.g., risk or safety assessments)

1.3.1. Conduct a comprehensive regulatory science and technology research needs assessment with academic, government, and industry stakeholders to identify priorities to address hazards that may be associated with environmental release and distribution of biotechnology reagents and products (to include non-commercial engineered organisms)

1.3.2. Fund pilot projects for iterative risk assessment processes that span the life cycles of products (including engineered organisms), from development through deployment, including contained, instrumented ecosystems to mimic real world conditions

1.3.3. Initiate research to address the following areas:

1.3.3.1. Genotypic and phenotypic characterizations including potential off-target effects

1.3.3.2. Selection and characterization of appropriate comparators

1.3.3.3. Durability of introduced genetic materials and resulting cells

1.3.3.4. Monitoring and surveillance of the dynamics of environmental biomes, including potential gene transfer and its effects

1.3.3.5. Modeling and life cycle analysis

1.3.3.6. Developing vehicles and venues for expression of non-science values-based concerns

2. FOSTER A NATIONAL ECOSYSTEM OF INNOVATION AND COMMERCIALIZATION

2.1. Expand/enhance the NSF I-Corps program to support further translation from academia to industry

2.2. Create a data and computational infrastructure to support emerging and small businesses in product development, including regulatory education from ideation to deployment

2.2.1. Establish a precompetitive knowledge base of bioproduction information and data for technology developers

2.2.2. Create regulatory education modules accessible to technology developers to learn from first principles key steps and processes of regulatory approval

2.3. Explore pilot programs for government-venture capital collaborations to launch and grow companies with promising emerging biotechnologies, such as non-dilutive partial matching investments

2.4. Establish a mechanism for connecting technology developers including small businesses with scale-up facilities

3. BUILD A NATIONAL INFRASTRUCTURE FOR BIOPRODUCTION SCALE-UP CAPACITY

3.1. Network of pilot biomanufacturing facilities/testbeds—Fund and build a network of 12-15 bioproduction facilities distributed across the United States

3.1.1. Conduct a comprehensive study to inform priority sites for new investment (the narrative of this document provides a starting point which includes considerations for equity)

3.1.2. Develop and execute a plan for standardization, integration, connectivity, and dedicated usage of a percentage of capacity by government entities

3.1.3. Design facilities with the intent of providing (re)training opportunities to create a skilled workforce

3.2. **Bioproduction Public-Private Partnerships**—Provide infrastructure funding and financial incentives to enable expansion of industry bioproduction capital assets for use as shared capacity for new industry partners with unmet bioproduction needs

3.2.1. Create opportunities (such as loan guarantees) for existing bioproducers to expand capacity on the condition that a proportion of new assets and expertise will be shared

3.2.2. Establish bioproduction partnership criteria around preferred organisms, fermentation conditions, and culture media for enabling partnerships between companies

3.2.3. Incentivize partnerships between companies with deep computational expertise, such as in modeling, simulation, and artificial intelligence, with those with bioproduction facilities and extensive data on successfully scaling up processes to commercial quantities (>100 m^3 fermentations)

3.3. **Foster hardware and bioprocess innovation for bioproduction**

3.3.1. Next generation manufacturing hardware to modernize/replace traditional bioreactors that fit biomanufacturing needs, using accurate simulations of turbulence models to inform design

3.3.2. Novel sensors for real-time, non-destructive interrogation of key cellular and molecular indicators, including integrated sensors

3.3.3. Novel and more cost-effective downstream processing unit operations, such as next generation membrane processes, liquid extractions, and two-phase systems

3.3.4. Novel and secure software control systems that allow seamless bioproduction facility resource planning, unit level bioprocessor control and real-time data acquisition, and easy connection to advanced off-line analysis and analytic methods

3.3.5. Support for foundational open-source object models and tools needed for predictive modeling of late-stage biomanufacturing performance based on early-stage design choices and laboratory-scale data

3.4. **Digital infrastructure**—Create a digital infrastructure to enable information sharing between developers and facilities

3.4.1. Select and fund a not-for-profit technology transfer and data exchange standard setting organization

3.4.2. Select and fund a not-for-profit venture that captures, curates, and provides detailed precompetitive process data

3.4.3. Establish standards for data-sharing and ontology

3.4.4. Create incentives for sharing between government, industry, and academia

4. DEVELOP A DIVERSE WORKFORCE TO POWER THE CURRENT AND FUTURE BIOECONOMY

4.1. **Industry engagement for bioproduction workforce development**—Leverage what currently exists, recognize what works, identify pathways forward that are aligned with needs of industry and engage underrepresented groups

4.1.1. Conduct a nationwide assessment of unmet bioeconomy industry workforce needs

4.1.2. Create a standard, national, industry-recognized certified training program for bioproduction technicians, including resources for educators to execute the curricula

4.1.3. Create financial incentives for public-private partnerships to enable local industry to inform local curricula development for vocational training, 2-year, 4-year, and master's degrees to fill unmet workforce needs, with particular emphasis on expanding participation among underrepresented groups

4.1.4. Expand and coordinate training programs that are based on industry partnership by addressing the greatest needs whether that be more programs, educators, equipment, or awareness

4.1.5. Establish a bioproduction training program for transitioning and retired military service members

4.2. Develop programs that restructure engineering biology and bioproduction education

4.2.1. Design undergraduate programs that shorten the time to produce well-trained engineering biologists, thus decreasing the time for graduates to enter the workforce

4.2.2. Seed new departments in engineering biology at academic institutions that focus on the process of engineering cells, spanning the non-medical products of bioproduction

4.2.3. Create new initiatives within existing departments to train engineers focused on process development and facility design for bioproduction

4.2.4. Aggressive funding for research in process science and engineering, spanning fermentation, downstream processing, and formulation

4.2.5. Increase accessibility by leveraging community and technical college biotechnology programs, particularly in rural and underserved communities

4.3. Create new, cross-disciplinary training programs from federal funding agencies

4.3.1. Integrate fields outside of bioproduction, including computer science, civil engineering (infrastructure), natural resources, social sciences, and communications

4.3.2. Integrate traditionally siloed programs within biotechnology, such as agriculture with bioproduction

4.3.3. Integrate economics, life cycle analysis, political science, environmental sciences, and regulation with genetic engineering and bioproduction

4.4. Enable international education-to-workforce pathway

4.4.1. Streamline the visa approval process for immigrants with bioeconomy expertise, with an increased emphasis on retaining immigrants who did their training in the U.S.

4.5. National awareness campaigns—Conduct awareness raising campaigns about career opportunities for all education levels available through the bioeconomy

4.5.1. Engage underrepresented and underserved communities, particularly in communities where new facilities will be built

4.5.2. Create modules for graduate students on training grants that demonstrate different career pathways, such as regulatory, science policy, biosecurity

4.5.3. Use multiple media approaches, such as documentaries, social media, and print, to raise awareness of the bioeconomy, biotechnology products, and the potential for public benefit

4.5.4. Create pathways for K-12 engagement with biotechnologies and engineering biology design principles

5. ENABLE POLICY THAT INCENTIVIZES AND SUPPORTS A CIRCULAR BIOECONOMY

5.1. Coordinate the U.S. Bioeconomy—Create a coordinating function for promoting and protecting the U.S. bioeconomy and facilitating international engagement

5.1.1. Designate an entity that is responsible for strategic economic development and international bioeconomy coordination, such as the Department of Commerce

5.1.2. Develop and implement an interagency strategy for informed, responsible growth and resilience of the U.S. bioeconomy

5.1.3. Create a public-private partnership advisory council to facilitate interaction between governmental entities and representatives from the U.S. bioeconomy community

5.2. Enable enhanced measurement of the U.S. bioeconomy

5.2.1. Create new economic codes to better measure the bioeconomy and track trends

5.2.1.1. Undertake an assessment of the permeation of biobased products, processes, and services in the U.S. economy to inform revisions of the NAICS and NAPCS codes to enable trends tracking

5.2.1.2. Develop and execute a plan to refine and regularly collect comprehensive statistics and trends on bioeconomic activities, including convening synthetic biology/stakeholder companies to inform code change needs

5.2.2. Create bioeconomy satellite accounts linked to central national accounts that include databases of biological information as assets and over time expand to include environmental and health benefits attributable to the bioeconomy

5.2.3. Conduct an assessment of the bioeconomic opportunity loss to overseas development, including assessing number of companies that expand overseas

5.2.4. Assess whether there are critical technologies that require additional consideration before offshoring

5.3. Enable and enforce federal procurement of biobased products set forth by statute

5.3.1. Adequately resource the BioPreferred program to effectively train federal procurement offices, expand the BioPreferred catalog, and increase outreach

5.3.2. Mandate regular reports to Congress that detail federal agency and contractor procurements of biobased products as mandated by the Farm Bill for public transparency

5.3.3. Establish federal biogenic renewable carbon procurement targets for strategic chemical reserve

5.4. Enable a well-resourced regulatory ecosystem for products of biotechnology

5.4.1. Establish a single point of entry for developers to understand the appropriate regulatory path to commercialization

5.4.2. Engage all relevant USG departments/agencies (e.g., EPA, USDA, FDA, OSHA, Fish & Wildlife Service, NOAA) to ensure that developers have a comprehensive understanding of their requirements

5.4.3. Create a standardized submission format for regulatory dossiers to facilitate multi-agency coordination and prevent developers from having to create redundant but different dossiers

5.4.4. Establish horizon scanning capabilities for the broad range of agencies with oversight responsibilities for regulation of products of biotechnology to anticipate developments and inform appropriate government oversight

5.4.5. Mandate that federally funded research include express consideration and funding of regulatory considerations

5.4.6. Increase consideration of existing tools to enable speedy decisions for familiar products, such as use of enforcement discretion

5.4.7. Establish an interdisciplinary bioeconomy regulatory career-long training program for staff involved in oversight and commercialization of biotechnology products

5.4.8. Establish a joint bioeconomy regulatory fellowship program involving the EPA, FDA, and USDA offices for practitioners along the entirety of the career spectrum and a capstone project focused on identifying interagency coordination mechanisms

5.4.9. Convene a National Commission on Biotechnology Regulatory Processes to inform updating the statutes that govern the regulatory system to be more reflective of modern biotechnologies

Illustrative Case Studies

1. Protecting Vulnerable Species with Sugar, Yeast, and an Engineering Biology Platform Technology
2. Building a Network of Pilot Biomanufacturing Facilities
3. Repurposing to Power the Bioeconomy
4. Future Biobased Feedstocks
5. Advancing the Bioeconomy by Sharing Resources and Knowledge
6. Illustrating the Complex Regulatory Ecosystem
7. Local, State, and Federal Financing Models That Can Incentivize Biomanufacturing

CASE STUDY 1

Protecting Vulnerable Species with Sugar, Yeast, and an Engineering Biology Platform Technology

Key Takeaways

- Platform technologies provide flexibility and versatility
- Federal funding for process development and scaling played a critical role
- Biobased production from renewable resources can protect threatened and endangered species

In 2004, armed with a grant from the Bill and Melinda Gates Foundation, researchers at Amyris, then a year-old, fledgling biotech company with a novel engineering biology technology, set out to develop an efficient process for producing artemisinin. At the time, obtaining this key ingredient in the first-line therapy for malaria depended on the unpredictable harvest of sweet wormwood and the expensive process for extracting small amounts of artemisinin present in the plant's leaves. By 2006, company scientists had engineered brewer's yeast to produce a chemical called artemisinic acid that could be easily converted into artemisinin, and in 2008 Amyris handed the technology free of charge to the French pharmaceutical company Sanofi, which began commercial production of artemisinin in 2013.

Though the demand for artemisinin produced in this manner never met expectations, in part because of a dramatic fall in the price of artemisinin, the work put into enabling its production by yeast has not gone for naught. Artemisinin and artemisinic acid belong to a family of naturally occurring chemicals called terpenoids or isoprenoids that have many uses in pharmaceuticals, personal care products, and liquid fuels. Through the long and involved process of inserting 13 genes into yeast to produce commercial-scale quantities of artemisinic acid—those involved estimated it took approximately 150 person-years[61]—Amyris scientists learned how to add the necessary genes to yeast and produce another terpenoid known as farnesene that opened the door to producing a wide range of terpenoids. The result was a versatile, engineering biology platform technology for converting sugar from sugarcane into high-value personal care and pharmaceutical products.

Farnesene, it turns out, is a precursor molecule that with a bit of clean chemistry can be converted to other natural ingredients that Amyris produces, as well as to farnesane, which can be used as diesel and jet fuel. Though the company explored becoming a producer of biofuels, going so far as to build a production facility in Brazil to capitalize on its extensive sugarcane to ethanol infrastructure, it realized that instead of becoming a minor player in the small margin liquid fuels industry, it could use its engineering biology platform to produce high-value, high-margin fine chemicals.

One of the first such products was squalane, a common ingredient in skin care products thanks to its moisturizing and anti-aging properties. The problem with squalane, and its naturally occurring precursor squalene, is that its major source was the liver of deep sea sharks. By one estimate, 2.7 million deep sea sharks were harvested in 2012 alone to meet the cosmetics industry's need for squalane.[62] Today, Amyris's biobased squalane produced from sugarcane accounts for 70 percent of the world's market, with the company estimating that sugarcane grown on approximately 170 acres, or one-fifth the size of Central Park, is saving two to three million sharks a year.[63] Squalene, the precursor to squalane, also has important uses, particularly as an immune-boosting component of the mRNA vaccines developed to fight COVID-19, as well as other vaccines.

Today, in addition to squalane and squalene, Amyris has taken 11 different terpenoids to scale—another two dozen are in active development—and even has its own line of what it calls its clean beauty and health brands based on the products of its engineering biology platform. One of its products, manool, was traditionally obtained from fallen Manoao pine trees, an endangered species native to New Zealand. Manool is a key ingredient used to make woody, amber notes in the fragrance industry. Another, a sandalwood-like oil called santalol, replaces the need to cut down sandalwood trees, a threatened species. The company has even developed an unrelated process to convert discarded sugarcane ashes into cosmetic-grade silica, which is usually obtained from non-renewable sand dredging, which requires significant energy consumption and emits large amounts of carbon dioxide.

In addition to illustrating the value of developing a versatile platform technology, Amyris's story is notable for a few other reasons relevant to the strategic plan outlined in this report. The first is the important role that federal funding played in enabling the company to take its technology to commercial scale. Two grants from DARPA helped the company accelerate the time to market for any new molecule it produced via fermentation, while multiple grants from DOE helped the company optimize the conversion of cellulosic feedstocks to molecules such as farnesene via fermentation.

This story also illustrates the importance of selecting appropriate markets to serve with biobased products created from renewal biomass feedstocks: in this case, the company's decision to use its renewable, biobased processes to become a leading producer of high-value products for the growing consumer market for "clean" personal care products, rather than a niche producer of liquid fuels. Finally, the company's continued success depends, at least in part, on its ability to hire well-trained process engineers and computer scientists.

CASE STUDY 2

Building a Network of Pilot Biomanufaturing Facilities[64]

Key Takeaways

- A network of pilot-scale biomanufacturing facilities, located strategically to take advantage of regional sources of biomass, local post-secondary training programs, and opportunities for equitable economic development, would give the nascent U.S. bioeconomy a competitive edge and drive product commercialization
- A shortage of pilot-scale facilities is inhibiting transition of bio-based products from the laboratory scale to commercial markets

Modern biotechnology tools, including those from engineering biology, struggle to break into commercial manufacturing. To realize the promise of industrial biomanufacturing for economic impact and sustainability, the United States needs a concerted, strategic push to catalyze the creation of a pilot-scale infrastructure to transition biomanufacturing processes from laboratory research to economic opportunity and manufacturing jobs. Indeed, realizing the promise of industrial-scale biomanufacturing would open the door to a distributed, resilient network for biobased chemical manufacturing, bringing jobs and opportunities to local communities and securing a domestic supply chain.

At a high level, biological synthesis and manufacturing of industrial chemicals occurs in three developmental phases:

1. Proof of concept, in which companies develop a biobased system to synthesize a chemical of interest at a scale of milligrams to grams in bioreactors that typically are 100 liters or smaller. As a result of increasing public and private investments in engineering biology, companies can make almost any chemical in a predictable and reliable manner at this scale.
2. Pilot-scale development and product testing, during which companies work out the biomanufacturing and downstream processes capable of producing kilogram quantities of a chemical that potential end users can assess in terms of performance characteristics or comparability to existing industrial chemicals.
3. Commercialization, which is when companies take a pilot-scale process and transition it to a relevant commercial production scale of often 100,000 liters or more. Several U.S. biomanufacturing companies have significant infrastructure at this scale, but this infrastructure is largely inaccessible to small- and medium-sized enterprises to access a consequence of the relatively small number of publicly available pilot-scale production facilities in the United States that would enable these companies to complete phase 2.

Developing a substantial pilot-scale infrastructure aims to solve a major roadblock at the second of these steps. Typically, a company is not able to validate a potential product, whether produced via biomanufacturing or traditional chemical manufacturing, until it can produce on the order of a kilogram for testing. Today, however, a company with a biobased product finds itself in a Catch-22 situation: To get to that kilogram, it may need to use larger-scale equipment in the 1,000-to 5,000-litter range because the yield of its product is low given that it has not yet optimized the bioproduction process, which also requires working with larger-scale equipment. However, existing facilities operating at that scale are hesitant to take on an unproven or inefficient process because it fails to meet their benchmarks for cost recovery.

That first kilogram is also the most expensive to make—in large part because scaling a biobased production process is less predictable and thus more challenging and time-consuming than scaling a traditional chemistry-based process. As a result, it can be too expensive for a fledgling industrial biotechnology company and its investors to take a risk on a product that may not make it to market. This holds back innovation and possible market entry and is driven in part by the lack of access to infrastructure to do that work in a speedy and cost-efficient way.

The challenge today, then, is to de-risk the economic model of offering pilot-scale manufacturing as a service so that companies will no longer be forced to use the small number of those facilities available on a for-service basis in Europe and Mexico to get through the pilot phase of development. While the cost of a single pilot production facility may only be $75-100 million, the return on investment for private capital has not been proven, so companies that wanted to build pilot-scale manufacturing facilities, either for their own process development activities or to make them available as a fee-for-service business for others, may not be able to recover their investment. The solution to this problem—one that would accelerate the transition from promising laboratory technologies to commercial output—is for the United States to invest in a networked, pilot-scale infrastructure in a manner that enables early-stage technology development efforts to conduct the scale-up work needed to justify subsequent investments in a robust infrastructure for high-volume domestic production of bioproducts.

Fully realizing the potential of the nascent U.S. biomanufacturing industry, one that would support regional and equitable economic development, requires the nation to invest on the order of $750 million to $1.2 billion to build an integrated network of 10 to 12 pilot-scale biomanufacturing facilities. These facilities should be located strategically to take advantage of regional sources of biomass, foster the growth of a biomanufacturing workforce, and promote equitable economic development. A substantial federal investment to support the bulk of the capital expenditures and 24-month runways for operational expenses should catalyze state and possibly private sector partnerships to share the cost of establishing the facilities as a non-profit network.

These facilities, once established, can be self sustaining via facility user fees, with any excess revenue funneled back into research and development to continually strengthen the network's capabilities. The federal government took one step in this direction when it created BioMADE, the new Bioindustrial Manufacturing Innovation Institute,[65] but this is a modest investment that excluded infrastructure and will not come close to meeting the demand for a U.S.-based pilot-scale infrastructure. In that regard, one only needs to look at BioBase Europe, which is currently the gold standard for biomanufacturing pilot facilities and is catalyzing the growth of a European biomanufacturing industry. A series of infrastructure grants from the European Commission helped establish this pioneering network.

Facilities in the proposed U.S. network could specialize based on several factors as a means of covering the different aspects of producing the wide range of chemicals that biomanufacturing has the potential to produce.

- Proximity to regional feedstocks, such as corn stover in Iowa, sugar beets in Montana, switchgrass in Virginia, pine forest residue in Georgia, almond hulls in California's Central Valley, and others
- Product class, given that biomanufacturing can create a wide array of products that often have different scaling and post-production needs
- Biomanufacturing methods, in which facilities could specialize on a particular production technique, such as aerobic versus anaerobic versus solid-state fermentation, non-fermentation or cell-free systems, or different types of purification or downstream processing
- Specific workforce development components

An optimal model for these facilities would be for them to operate as a single non-profit network that a single entity, such as BioMADE, owns and operates for the good of the industry. Such a model would allow for robust coordination across the network and provide broad benefits to industry members if facilities are differentiated. It would also allow for income pooling to reduce individual facility risk, greater opportunities to reinvest excess income back into biomanufacturing innovation, and consistency across the ecosystem of diversified facilities. As the map below illustrates, the overlap of regional sources of biomass, post-secondary training programs, and opportunities for equitable economic development provides ample opportunities for locating the individual facilities in the network across the nation.

Once established, this infrastructure would rapidly increase the number, value, quality, and diversity of biobased products reaching the market. Facilities can, and should, also focus on being a locus of bio-innovation in their communities—spurring investment and innovation. There are several benefits of having this capability in the United States:

1. The global supply of such facilities is far too low to meet the demand and international competition for using the limited number of these facilities could freeze out U.S.-based companies.
2. These facilities would be part of the nation's innovation pipeline and proximity often matters to build an innovation ecosystem. If one of the objectives is to catalyze a robust biomanufacturing pipeline, co-locating facilities with U.S. innovators, a trained workforce, and a ready source of biomass as feedstock will accelerate the maturation of that ecosystem.
3. While these facilities are primarily about scale-up to get to a larger commercial scale, they are still *manufacturing* facilities. As the COVID-19 pandemic has shown, fragile global supply chains can be disrupted and the ability to pivot domestic manufacturing capabilities is crucial. These facilities, which would be funded through public and private investment, can be thought of as a national network on "warm standby" that would be able to respond to national or regional emergencies or disruptions to the supply chain, as occurred when massive flooding accompanying Hurricane Harvey in 2017 and record-setting cold in 2021 shut down refining operations.
4. Biomanufacturing has the opportunity to provide value-added materials with unique properties. Some of these properties may be used to strengthen national security, and domestic development and production is important for those specific objectives.

CASE STUDY 3

Repurposing to Power the Bioeconomy

Key Takeaways

- Abandoned petrochemical and corn-to-ethanol plants can be repurposed for bioproduction of chemicals and food protein made from sustainable biomass
- Repurposing existing facilities can power equitable regional economic development and job growth and enable reskilling of people to fill good-paying bioeconomy jobs

One of the promising aspects of continuing to develop the U.S. bioeconomy is the opportunity to convert existing corn-to-ethanol and surplus petrochemical facilities into bioproduction facilities. In fact, several companies are already doing just that, and the result is not only turning an unproductive asset into a productive one, but creating economic growth and jobs in parts of the country that could use a boost.

For example, Solugen has converted an abandoned petrochemical plant in Stafford, TX, into a facility that uses “cell-free” bioproduction processes with enzymes to produce 10,000 metric tons of specialty chemicals a year. Solugen’s first product was hydrogen peroxide, an industrial chemical that is usually made with natural gas as a feedstock in a process that requires high heat, generates hazardous waste products, and is energy intensive. In contrast, the feedstock for Solugen’s enzyme-based process is corn syrup produced by wet mills in Iowa, a commodity that has seen a falloff in demand in recent years. The process, which does not involve fermentation, operates at low heat, uses much less energy, and produces no waste. The company has since developed other enzyme-based processes to produce chemicals used in water treatment applications and to harden concrete, with others in development.

In addition, Solugen not only repurposed an abandoned facility, as well as equipment once used to make candy, but it also retrained former petrochemical refinery workers to operate the reengineered facility. Rather than expand this existing facility as it grows its product offerings, the company plans to repurpose unused facilities around the country to create a distributed network of plants that will help grow regional economies and reduce transportation-associated emissions.

Overseas in Italy, Novamont, a producer of bioplastics, is using a process developed by Genomatica, a San Diego-based biological engineering company, to produce 30,000 tons a year of 1,4-butanediol, a key chemical used to make biodegradable and compostable products such as fruit and vegetables bags, mulch film and coffee capsules, as well as biodegradable lubricants and greases, biobased ingredients for the cosmetics industry, and most recently, sustainable biocide preservatives. The company’s processes all use sustainable biomass processed in industrial sites that were decommissioned or no longer competitive. One of Novamont’s corporate goals is to reinvigorate regional economies in Italy and to do so using regional biomass produced in a manner that protects soil health and helps soil regenerate.

Back in the United States, Superbrewed Food has turned an abandoned corn-to-ethanol plant in rural Minnesota into a facility that produces food-quality protein using micro-organisms found in the human gut. The company's first product was a sustainable fish feed, and subsequent products include cream cheese, cheddar cheese, and mozzarella cheese made from its cultured plant-based protein. The Minnesota facility will eventually be able to deliver 40 million gallons worth of plant protein-based milk from the microbial cultured protein.

In the same vein, Nature's Fynd is using fungi that grow naturally in Yellowstone National Park, and originally discovered as part of a NASA-sponsored project, to produce food-grade protein from renewable and sustainable biomass. This process, which relies on a proprietary liquid-air interface fermentation technology that is easily scalable, takes place in a facility built in the historic but abandoned Union Stockyards on Chicago's South Side. The company has made a practice of hiring and training residents from the local community, yet another example of providing new purposes for facilities and new careers for people as part of the growing bioeconomy.

CASE STUDY 4

Future Biobased Feedstocks

Key Takeaways

- A future circular U.S. bioeconomy depends on an ability to efficiently use waste biogenic carbon
- Sustainable biomass has the potential to serve as the feedstock for U.S. chemical production
- More research is needed to address the technical challenges of converting most biomass into desired bioproducts

Imagine a future where a plane carrying flame retardant to drop on a forest fire is powered by fuel derived from forest slash generated by forest fire prevention programs. That future is not out of reach should the nation's efforts to convert sustainable biomass into feedstocks for aviation fuel and chemical production come to fruition.

The 2016 Billion-Ton Report states that the United States has the capacity to produce a billion tons of sustainable biomass annually without affecting food production for domestic consumption or export or leading to deforestation or land degradation.[66] If fully utilized, those billion tons could be used by a thriving bioeconomy to generate 25 percent of the nation's liquid transportation fuels and 50 billion pounds of biobased chemicals, as well as cut carbon dioxide emissions by 450 million tons and support 1.1 million U.S. jobs.

All biomass contains sugars, and sugars can be converted to a variety of chemicals, including ethanol, a "first generation" renewable fuel produced from the fermentation of corn that is included in 98 percent of U.S. gasoline. Indeed, the successful conversion of plant-based sugars into a variety of chemicals, not just ethanol, from corn and sugarcane has been advancing steadily. In fact, an estimated 20 percent of chemical production now comes from biomass rather than petroleum.

Unfortunately, releasing the sugars tied up in cellulose, a major structural component of all plants, is not as easy as liberating it from corn kernels, sugar cane, or sugar beets. Nor is it easy to release the useful chemicals known as aromatic compounds, from lignin, a complex polymer that serves as the other major structural component of plants. To accomplish that task, researchers are working—with some success—to harness the natural ability of many microorganisms to break down cellulose and lignin into their constituent sugars and aromatic compounds. Making this challenge more difficult, particularly if the goal is to use the wide variety of plant-based waste materials and post-consumer wastes, is the heterogeneity of the residues left after harvesting crops, processing food, or turning trees into lumber and paper, which will require more than one approach to liberating those sugars for further processing and biomass refineries that can handle heterogeneous materials.

Once research solves that challenge—and that should be possible using the tools of molecular and engineering biology—biomass can be converted into what are called platform chemicals that are then used to produce a variety of industrially important chemicals. Platform chemicals produced today via conversion of petroleum feedstocks include levulinic acid, furfurals, sugar alcohols, lactic acid, succinic acid, phenols, olefins, and terpenoids (see the Amyris case study for all the uses of terpenoids). The vision for a circular bioeconomy rests on the idea of converting biomass into chemicals that are then used to make materials that would eventually, when their useful lifetime has ended, serve as another source of biomass for conversion into fuels and chemicals. U.S. biotechnology leadership provides a promising foundation for a future strategic renewable feedstocks research effort with significant potential to open the door to converting the carbon that exists in plants to the carbon we can use sustainably.

CASE STUDY 5

Advancing the Bioeconomy by Sharing Resources and Knowledge

Key Takeaways

- Sharing resources can maximize the use of existing infrastructure and be a force multiplier for expertise and knowledge
- Resource and knowledge sharing can reduce the time to move novel products from the lab to the marketplace

The world-leading U.S. biobased research infrastructure continues to produce the discoveries needed to power the nation's resilient, competitive bioeconomy, but translation of those discoveries into the commercial processes that lead to economic activity and bioeconomy jobs is lagging. Having a network of pilot plant facilities, as discussed elsewhere in this report, is a necessary step for catalyzing the translation of those processes that require fermentation, but it is not sufficient to unleash the bioeconomy's full potential unless successes at the pilot stage can then transition to commercial-scale production. This is where government-incentivized public-private partnerships can play an important role.

Economically viable commercial-scale production requires several inter-connected and mutually reinforcing capabilities:

- Available fermentation capacity of at least 100,000 liters to achieve economy of scale
- An experienced process engineering team to take it from pilot scale to commercial scale
- A robust industrial production organism
- Fermentation capacity suitable for making a variety of products. Anaerobic tanks used to make ethanol and beer, for example, are abundant but limited in the types of products they can produce. Tanks with oxygenation are required to make proteins and many other products
- Downstream processing capability is required to purify the fermentation products
- Formulation and blending capabilities to make liquid and solid products
- Cost-effective sanitation protocols to avoid contamination
- Special precautions for making food-grade products
- Regulatory expertise to bring products to market
- A supply chain to deliver the finished product
- Commercial route to market

Developing these capabilities takes time and financial resources that very few startup companies possess. While venture capital, the traditional source of funding, sees the enormous potential payoff from a vibrant U.S. bioeconomy, investors are reluctant to put up funds at the necessary scale, having been burned during the advanced biofuels wave of capital-intensive investments that failed to generate expected returns. One avenue that a startup can take is to find a contract manufacturer to produce their product, but contract manufacturers are in high-demand and access to their capacity is limited. In addition, contract manufacturers only manufacture—they do not provide regulatory expertise, a supply chain, or a commercial route to market, nor will they work to optimize the production process.

Government-incentivized public-private partnerships with established players can address this problem without requiring every company to invest in physical infrastructure. Currently, there are two fermentation-based industries with production know-how and excess capacity—breweries nationwide and wet-mill ethanol plants in the Midwest—that are looking to use their excess capacity to produce new, high value-added products but may need additional investments in equipment to produce and purify other products. Now imagine if the federal government were to provide funds for these facilities to upgrade their infrastructure so that they could serve as commercial-scale manufacturers in exchange for providing those services at a cost that a startup could bear and which venture capital would find attractive. Such a partnership could also include a provision that these facilities would serve as part of a national network on "warm standby" that would be able to respond to national or regional emergencies or disruptions to supply chains of various types.

There are also established firms, particularly those that use biobased and bio-enabled processes to produce fine chemicals such as flavors and fragrances and food products, who may also have available capacity. In that case, a public-private partnership could provide funds to reserve a certain percentage of the firm's capacity for use by a company looking to scale their production process. The startup might also contract with the established firm to provide other services, such as process refinement, downstream processing, and even supply chain and marketing services, though there are intellectual property issues, such as who owns the rights to any improvements the established firm might develop.

Information Sharing

In addition to sharing of physical assets, knowledge sharing would also fuel the bio-economy, especially in the case of precompetitive knowledge that could inform bioprocess development and reduce the need for every research group, whether in academia or industry, to reinvent the wheel every time it attempted to transition a process to the pilot scale. Academic investigators, for example, neither study bioprocesses at scale, nor publish extensively in this field. In addition, there is currently no incentive to publish failed studies or lessons thereby learned. These unfortunate realities have led to decades of substantial repetition of failed experiments in the community as a whole, resulting in significant knowledge gaps and a waste of resources that could be better applied toward further derisking scale-up.

One solution, proposed by staff at the Advanced Biofuels and Bioproducts Process Development Unit (ABPDU) at Lawrence Berkeley National Laboratory, a non-profit process development unit funded by DOE, would be to develop a responsive learning/artificial intelligence platform technology that researchers could use to predict the outcomes of fermentation and downstream recovery and purification experiments based on the collective experience and learnings of the research community and input from experts in the field (Figure CS5-1). Non-proprietary data to power the system would come initially from ABPDU's process development experience, and the database—and the accuracy of its predicted outcomes—would grow as researchers who use the system volunteer to contribute precompetitive experimental details and outcome data. The system would include a web-based tool for users to input their experimental plans and receive experimental guidance to avoid common pitfalls and maximize resources (Figure CS5-2).

Aside from sharing knowledge to benefit process development, this system would also enable early career scientists and engineers to learn about process development without having to perform actual experiments. In essence, this system would be creating an ever-evolving reference source that would benefit the entire bioeconomy.

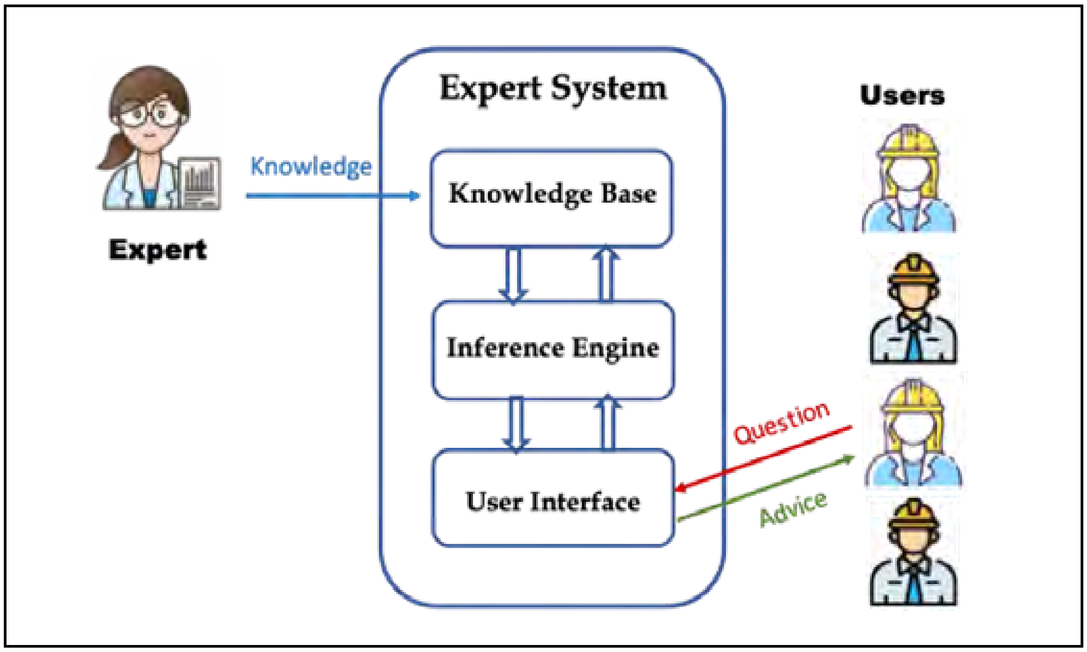

FIGURE CS5-1
A data-sharing, inference-based system allows expert knowledge to scale to many users. *Credit* Deepti Tanjore, ABPDU

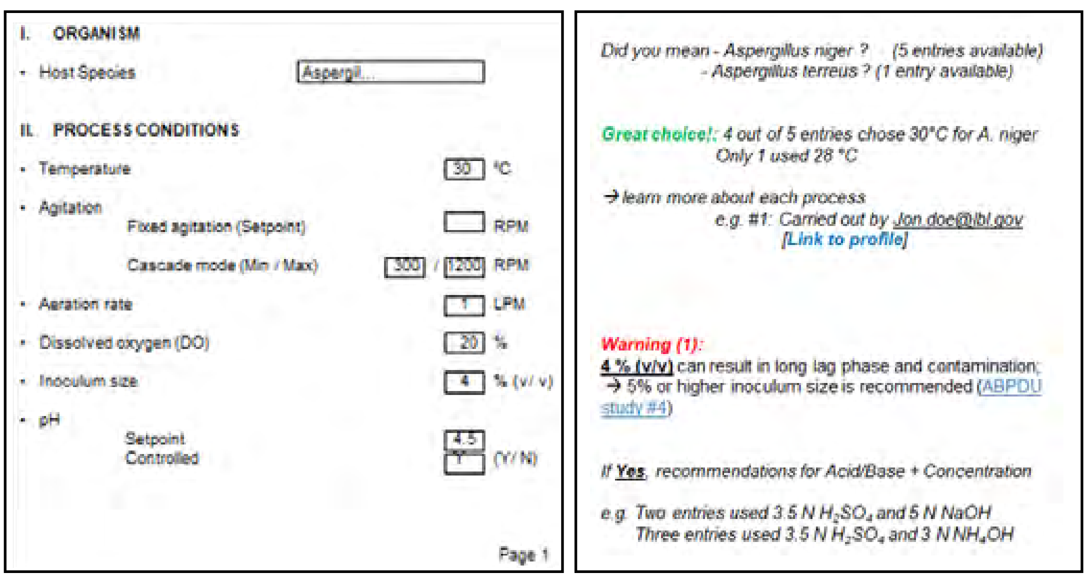

FIGURE CS5-2
An example of the form users would fill in and advice the system would generate. *Credit* J.P. Prahl, ABPDU; Deepti Tanjore, ABPDU

CASE STUDY 6

Illustrating the Complex Regulatory Ecosystem

Key Takeaways

- Many bioeconomy products must receive approval from multiple regulatory agencies before they can reach the market
- In complex, multi-agency regulatory assessments, companies have to submit different sets of data to each agency
- Time to market for a novel product of biotechnology can be long

The regulatory ecosystem for products of biotechnology is complex, fragmented, and time-consuming, with EPA, FDA, and USDA each being responsible for certain aspects of regulating the products of biotechnology. There are many challenges that the developers of bioeconomy products face in getting their products approved for commercial use. As shown previously in Table 3 the three regulatory agencies play a role in bringing a bioeconomy product to market. Table CS6-1 contains information on the products selected for this case study, including the name of the product developer/manufacturer, the product's current market status, and a brief description of the product and its significance as a regulated bioengineered product. The table also delineates a timeline of major regulatory decisions related to each product, though it is not a complete timeline of every regulatory decision that was made on the product. The timelines were compiled using publicly available literature and information collected from databases maintained by EPA, FDA, and USDA. Forthcoming regulatory decisions are labeled as TBD. Regulatory decisions that have been made but whose dates could not be found are labeled with N/A. It is clear from the available data that "first-in-kind" products of biotechnology can have a complex path and long time to market.

TABLE CS6-1 — EXAMPLE PRODUCTS AND THE TIMELINE OF MAJOR REGULATORY DECISIONS This table contains information on the products selected for the case study, including name of the product developer/manufacturer, the product's current market status, and a brief description of the product and its significance as a regulated bioengineered product. The table also delineates a timeline of major regulatory decisions related to each product (note that it is not a complete timeline of every regulatory decision that has been made on the product). The timelines were compiled using publicly available literature and information collected from databases maintained by the EPA, the FDA, and the USDA. Regulatory decisions that are forthcoming are labeled as TBD. Regulatory decisions that have been made but whose dates could not be found are labeled with N/A.
Credit Sifang Chen, postdoctoral fellow, Engineering Biology Research Consortium

Table CS6-1 Example products and the timeline of major regulatory decisions.

Product	TIMELINE OF MAJOR REGULATORY DECISIONS
Blight Fungus Resistant American Chestnut *SUNY ESF* *Market status: under development* Genetically engineered (GE) blight-resistant chestnut trees developed using an oxidate oxidase-encoding gene from wheat; the first transgenic trees being considered for restoration use.	**2020:** SUNY ESF submits Petition for Nonregulated Status. **2023:** USDA anticipates publishing a final decision on the petition. **TBD:** EPA will review environmental safety and interactions with the blight fungus. **TBD:** FDA will review blight-resistant chestnut for nutritional safety since both people and animals use chestnuts as food.
AquAdvantage Salmon *Aquatic Bounty Technologies* *Market status: on the market* GE Atlantic salmon developed for faster growth; the first GE animal intended for human consumption.	**1995:** ABT requests an Investigational New Animal Drug exemption from FDA to pursue the development of AquAdvantage Salmon. **2015:** FDA releases Environmental Assessment and Finding of No Significant Impact approving AquAdvantage Salmon application.
Pivot Bio PROVEN *Pivot Bio* *Market status: on the market* GE diazotrophic microbes that enable biological nitrogen fixation for corn; the first commercial biofertilizer for cereal crops.	**2019:** Pivot Bio inquires the USDA on the regulatory status of the product. **2020:** USDA confirms that it does not consider the diazotrophic bacteria, as described by Pivot Bio, to be regulated as a plant pest. **N/A:** EPA determines the product falls under the soil amendment category and are therefore regulated by individual states.
TransFerm Yield+ *Mascoma* *Market status: on the market* GE strain of yeast that expresses glucoamylase enzyme, developed to improve the efficiency of ethanol fuel production from liquefied grains.	**2019:** FDA receives GRAS notice from Mascoma **2020:** FDA completes evaluation of Mascoma's GRAS notice **N/A:** TransFerm Yield+ meets the review requirements via completion of a Microbial Commercial Activity Notice.
Rainbow Papaya *Cornell University, University of Hawaii* *Market status: on the market* GE papaya cultivar with resistance to papaya ringspot virus; the first commercialized transgenic fruit crop.	**Feb, 1996:** University of Hawaii and Cornell University submit to USDA a Petition for Determination of Nonregulated Status. **May, 1996:** USDA approves Petition for Determination of Nonregulated Status. **Jan, 1997:** University of Hawaii and Cornell University submit to the FDA a safety and nutritional assessment. **Sep, 1997:** FDA concludes consultation on transgenic virus resistant papaya.

Table CS6-1 Example products and the timeline of major regulatory decisions (cont).

Product	TIMELINE OF MAJOR REGULATORY DECISIONS
SmartStax Pro RNAi Pest Control *Monsanto* *Market status: under development* GE corn seeds developed using Ribonucleic acid interference (RNAi) technology to control corn rootworm; the first time RNAi technology has been used against this insect.	**Oct, 2013:** Monsanto submits Petition for Determination of Nonregulated Status to USDA. **Nov, 2013:** Monsanto submits to FDA a safety and nutritional assessment. **Oct, 2014:** FDA completes evaluation of Monsanto's submission to determine any safety or regulatory issues with respect to its use in food or feed. **Oct, 2015:** USDA approves Petition for Determination of Nonregulated Status. **Jun, 2017:** EPA issues notices of pesticide registration for SmartStax products.
UPSIDE Chicken *UPSDIE Foods (f/k/a Memphis Meat)* *Market status: under development* Chicken meat developed from cultured animal cells; the first cultured meat product intended for sale in the US.	**Mar, 2019:** FDA and USDA publish MOU stating FDA will oversee collection and growth of cultured cells, and USDA will oversee processing of those cells into meat products and product labeling. **N/A:** Pre-market consultation process with FDA to evaluate the production process and produced biological material. **N/A:** After pre-market consultation, FDA to conduct routine inspections of cell banks and facilities. **N/A:** USDA to carry out inspections at establishments where cells derived from livestock and poultry are harvested.
EVERY ClearEgg *The EVERY Company (f/k/a Clara Foods)* *Market status: on the market* Egg white proteins cultivated from GE yeast; the first bio-identical egg product intended for sale in the US.	**Mar, 2019:** FDA and Clara Foods hold pre-submission (GRAS notice) meeting. **Sep, 2020:** FDA receives Clara Foods' GRAS notice submission. **Sep, 2021:** FDA completes evaluation of Clara Foods' GRAS notice submission.

CASE STUDY 7

Local, State, and Federal Financing Models that Can Incentivize Manufacturing

Key Takeaway

- All levels of government can craft financial incentives to enable the growth of a national bioeconomy with an emphasis on regional economic development

With leadership of the $4-plus trillion global bioeconomy at stake, it behooves local, state, and federal governments to provide the necessary financial incentives to help address the barriers to creating a vibrant, resilient U.S. bioeconomy and rise to challenge of global competition in this advanced technology space. Providing such incentives for nascent technology-based industries is not unprecedented. Thanks in large part to early federal investment in computer research and development, the United States is home to globally dominant information technology companies. Local, state, and federal investments and incentives have also enabled the United States to become the world leader in the biomedical sector.

Local and state governments are not new to the incentive game, as they routinely offer companies billions of dollars in fiscal incentives, including cash grants, rebates, and tax credits, to entice them to relocate, expand, or stay in a specific locality. According to a Brookings Institute report, local and state economic development incentives range between $45 and $90 billion annually.[67] The city of Vacaville, CA, for example, provided seed funding in 2020 that helped establish the California Biomanufacturing Center, a 501(c)(3) non-profit organization supporting industry development and workforce training in partnership with Solano Community College and the University of California at Davis. This initiative is part of the city's plan to establish a series of manufacturing centers of excellence in highly specialized segments of innovative industries, including bioproduction of chemical products, materials, and fuels, for the purposes of economic development. As part of this program, the city has created a new zoning paradigm to simplify and facilitate desirable biotechnology investments with the biomanufacturing center, and it provides a central point of contact for reviewing all new biotechnology-related projects that process land-use applications within 100 days of submission. Previously, Vacaville provided a 10-year property tax rebate to entice Genentech to build a manufacturing facility in the city.

In 2019, the citizens of Oklahoma City approved a $71 million investment in the city's innovation district, which includes bioscience companies. The investment includes funds to encourage further development for minority-owned small businesses, better connectivity in and around the district, and the construction of an "Innovation Hall" to serve as a central place to facilitate activities that will grow the city's innovation economy. The city was also awarded a American Rescue Plan grant that will go toward investing in biotechnology-focused infrastructure and workforce training.

Another city with big plans to be a biomanufacturing center, albeit in the biomedical space, is New York. In 2021, the city announced plans to invest $38 million in biotechnology centers at four institutions in the city. Montefiore Medical Center, for example, will use $13 million to create a biomanufacturing operation focused on cell, gene, and antibody therapy production for both early-stage and established companies.

At the state level, the Federal Reserve Bank of San Francisco estimated in 2014 that financial incentives from state governments have boosted biotechnology jobs overall in states that offered incentives and generated sizable effects in local service sectors. In general, states have used research and development tax credits, which provide a credit against a business's income taxes that is proportional to its expenditures on qualified research and development and biotechnology-specific subsidies. Biotech-specific tax credits have included tax credits on investment or job creation by biotech companies, sales and use tax exemptions for purchasing equipment used in biotech activity, low-interest loans to biotech startups, and lump sum grants to biotech companies.

California, for example, provides a special incentive for biobased production facilities through a 6 percent income tax credit for "special purpose buildings" and a property tax provision that allows companies to depreciate biotechnology equipment more rapidly. Kansas has used grants from NSF and strategic investments to establish the Center for Environmentally Beneficial Catalysis at the University of Kansas as a center focused on converting biomass—Kansas has the fourth largest amount of biomass—into chemicals. The state believes that its investment will create thousands of jobs in rural communities and generate billions of dollars in economic activity. Outside of biomanufacturing, Michigan used tax incentives totaling $780 million for advanced battery manufacturing and research to land four advanced battery production facilities worth a total of $1.7 billion that will employ several thousand workers. GM and Ultium Cells, for example, received a $600 million grant, Ultium was granted a $158 million tax break, and the local utility and surrounding township received $66.1 million to upgrade infrastructure at the site of the planned production facility.

At the federal level, the federal R&D credit rewards companies that create and improve products involving technical uncertainty and a process of experimentation, and biomanufacturing companies are prime candidates for claiming this benefit. The Commerce Department's Build to Scale program manages a portfolio of grant competitions that further technology-based economic development initiatives that accelerate high-quality job growth, create more economic opportunities, and support the future of the next generation of industry leading companies.

In terms of national financial support for biomanufacturing, Europe provides several examples from which the United States can learn. The Pilots4U program, funded by the Biobased Industries Joint Undertaking under the European Union's Horizon 2020 Research and Innovation Programme, is a platform that mapped all open-access pilot- and multipurpose demo-infrastructures across Europe that are open to all companies and research institutes. Its purpose is to create a visible and easily accessible network that will support the development of a thriving bioeconomy. While the initial public funding for the project itself ended, the database of facilities is still operating and searchable.[68] Pilots4U also conducted a gap analysis and European industry survey to identify the infrastructure and expertise required from open-access centers and built a business case to address the identified gaps. Europe has also established the European Network for Pilot Production Facilities and Innovation Hubs (EPPN), akin to the network of pilot facilities this document has proposed creating in the United States. The European Commission provided €195 million in funding to establish this network of 24 facilities and develop a digital ecosystem to serve as an interactive marketplace for its members. EPPN also serves as a single entry point for any user to access pilot facilities and services across Europe and early-stage access to intelligence on more efficient development processes.

Appendices

Appendix A

Experts Who Provided Input for this Effort

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George Frisvold
Gopal Sarma
Gregory Stephanopoulos
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James Gardner
Jason Webber
Jeff Lievense
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Federal Input for this Effort *Over 130 people from the following contributed to this effort:*

Department of Commerce
Department of Defense
Department to Energy
Department of Health and Human Services
Department of State
Environmental Protection Agency
Executive Office of the President
National Science Foundation
U.S. Department of Agriculture
Staff from the U.S. House of Representatives
Staff from the U.S. Senate

Appendix B

Federal Job and Workforce Training Programs

A survey of the current U.S. government job and workforce training programs, many of which are under resourced, that are relevant to the bioeconomy. This list is to illustrate the types of programs that exist and is not meant to be comprehensive.

Credit Michael A. Fisher, Federation of American Scientists; and Simonai Santiago, Federation of American Scientists

Agency	Program	Purpose
National Science Foundation	Advanced Technological Education (ATE)	Focuses on 2-year Institutions of Higher Education, supporting the education of technicians for the high-technology fields that drive our nation's economy, such as biotechnology. As of September 2021, about 18 percent of funded ATE programs directly support the bioeconomy
Department of Agriculture	Education and Workforce Development Program (EWDP)	EWDP, within the Agriculture and Food Research Initiative, develops the next generation of research, education, and extension professionals in the food and agricultural sciences
Department of Agriculture	Additional programs	https://www.nal.usda.gov/topics/vocational-education-and-job-training https://www.usda.gov/our-agency/careers/usda-pathways-programs https://www.usda.gov/youth/career https://www.fns.usda.gov/snap/et https://www.fs.usda.gov/working-with-us/opportunities-for-young-people https://www.dm.usda.gov/employ/student/index.htm https://nifa.usda.gov/topic/workforce-development

Agency	Program	Purpose
Department of Energy	Bioenergy Technologies Office	Promotes bioenergy workforce development opportunities such as those through the Algae Technology Educational Consortium
Department of Energy	Algae Technology Educational Consortium (ATEC)	Develops educational programs to strengthen industry workforce capabilities, by focusing on the skills required to support early-stage research and development, along with the commercialization of algal products. A collaboration between the Bioenergy Technologies Office, the Algae Foundation, and the National Renewable Energy Laboratory
Department of Energy	OPERATION BioenergizeME	A bioeconomy outreach hub within the Bioenergy Technologies Office that includes educational resources and other information
Department of Commerce	Sea Grant	The National Oceanic and Atmospheric Administration's Sea Grant supports research, extension, and education to enhance the practical use and conservation of coastal, marine and Great Lakes resources in order to create a sustainable economy and environment
Department of Commerce	Manufacturing USA Institutes	While all the Institutes should be solicited for any bio-relevant education or training programs they are involved in, the most directly relevant are the National Institute for Innovation in Manufacturing Biopharmaceuticals (currently funded projects in talent / pipeline development and incumbent worker training), Advanced Regenerative Manufacturing Institute (lists closing the skills gap in tissue and organ manufacturing by providing training opportunities to undergraduates, graduates, veterans and non-college bound youth as a priority), and the Bioindustrial Manufacturing and Design Ecosystem (leveraging its member network to provide world-leading innovation in education and workforce development programming for bioindustrial manufacturing), but all should be regularly solicited for any job / workforce / education training programs they are involved with
Department of Commerce	Manufacturing Extension Partnership (MEP)	The National Institute of Standards and Technology's MEP provides extremely valuable training and educational services, and every state's MEP should have a biotechnology, biofabrication, or biomanufacturing capability
Department of Health and Human Services	Division of Training, Workforce Development and Diversity	This division within the National Institute of General Medical Sciences supports individuals and institutions that foster research training and the development of a strong and diverse biomedical research workforce

Agency	Program	Purpose
Department of Education	Office of Career, Technical, and Adult Education	Administers and coordinates programs that are related to adult education and literacy, career and technical education, and community colleges. The Division of Academic and Technical Education is particularly involved, but the programs sponsored need to be pulled out and highlighted better
Department of Labor		There are various portals affiliated with DOL, including its main page, CareerOneStop (includes American Job Centers and mySkills myFuture), Job Corps, and Apprenticeship.gov
Environmental Protection Agency	Brownfields Job Training Grants	Allows nonprofits, local governments, and other organizations to recruit, train, and place unemployed and underemployed residents of areas affected by the presence of brownfield sites, including training in phytoremediation, bioremediation, or redevelopment of brownfields with bioenergy power production
National Nanotechnology Initiative	Associate Degrees, Certificates, & Job Opportunities hub	Collection of resources pointing toward workforce and job training
FedCenter (Second tier resource with limited bioeconomy-relevant material)	FedCenter.gov	A few random bio offerings (joint initiative of EPA's Office of Enforcement and Compliance Assurance, the Army Corps of Engineers' Construction Engineering Research Laboratory and the Office of the Federal Environmental Executive)
Global Change Research Program (Second tier)	GlobalChange.gov	Supports three international science organizations in organizing conferences, workshops, and trainings for scientists and policy makers from around the world, including those in their early career stages, to assist in building global change research capacity in the developing world, including sustainability science, of which the bioeconomy has a major role (13 participating federal agencies)

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