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NATIONAL BIOECONOMY BLUEPRINT

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THE WHITE HOUSE
WASHINGTON

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Executive Summary

"The world is shifting to an innovation economy and nobody does innovation better than America."

—President Obama, December 6, 2011

Economic activity that is fueled by research and innovation in the biological sciences, the "bioeconomy," is a large and rapidly growing segment of the world economy that provides substantial public benefit.[1] The bioeconomy has emerged as an Obama Administration priority because of its tremendous potential for growth as well as the many other societal benefits it offers. It can allow Americans to live longer, healthier lives, reduce our dependence on oil, address key environmental challenges, transform manufacturing processes, and increase the productivity and scope of the agricultural sector while growing new jobs and industries.

Decades of life-sciences research and the development of increasingly powerful tools for obtaining and using biological data have brought us closer to the threshold of a previously unimaginable future: "ready to burn" liquid fuels produced directly from CO_2, biodegradable plastics made not from oil but from renewable biomass, tailored food products to meet specialized dietary requirements, personalized medical treatments based on a patient's own genomic information, and novel biosensors for real-time monitoring of the environment. Increasingly, scientists and engineers are looking to augment biological research with approaches from other scientific disciplines for solutions to our most demanding scientific and societal challenges and seeing exciting options that will profoundly affect our future.

Technological innovation is a significant driver of economic growth, and the U.S. bioeconomy represents a growing sector of this technology-fueled economy. Agriculture, one of the country's largest industries, is heavily based on advances in biological research and development (R&D). According to the USDA, U.S. revenues in 2010 from genetically modified crops were approximately $76 billion.[2] Beyond agriculture, based on the best available estimate, 2010 U.S. revenues from industrial biotechnology—fuels, materials, chemicals, and industrial enzymes derived from genetically modified systems—were approximately $100 billion.[3]

The growth of today's U.S. bioeconomy is due in large part to the development of three foundational technologies: genetic engineering, DNA sequencing, and automated high-throughput manipulations of biomolecules. While the potential of these technologies is far from exhausted, a number of important new technologies and innovative combinations of new and existing technologies are emerging. Tomorrow's bioeconomy relies on the expansion of emerging technologies such as synthetic biology (the direct engineering of microbes and plants), proteomics (the large-scale study and manipulation of

1. http://www.oecd.org/document/48/0,3746,en_2649_36831301_42864368_1_1_1_1,00.html
2. The $76 billion estimate was derived by prorating the published ERS estimates of revenue (cash receipts) from the relevant crops published here: http://www.ers.usda.gov/data/FarmIncome/finfidmu.htm#cashrec by the estimated share of GM crops for each crop.
3. Biodesic 2011 Bioeconomy Update (Biodesic is a private consulting firm and sole source of data of this type.) http://www.biodesic.com/library/Biodesic_2011_Bioeconomy_Update.pdf

proteins in an organism), and bioinformatics (computational tools for expanding the use of biological and related data), as well as new technologies as yet unimagined. There is also a set of emerging trends in recent research that foreshadow major advances in the areas of health, biological-based energy production, agriculture, biomanufacturing, and environmental clean-up.

In recognition of the potential of the U.S. bioeconomy, in 2010 the Administration included, in its science and technology priorities to inform Federal agency budget submissions,[4] a priority for Federal agencies to "support research to establish the foundations for a 21st century bioeconomy." Agencies began focusing their efforts accordingly, and have made significant early progress in building a foundation for the future bioeconomy. In addition, strategic objectives that would help to enable a future vibrant U.S. bioeconomy with potential to deliver major economic and social benefits began to emerge.

The modification of biological organisms and construction and use of organisms not found in nature carry potential safety and security risks if misapplied, raising issues of responsible conduct including ethics, responsible use, and environmental awareness, among others. These advances raise important ethical and security issues that are also top priorities for the Administration, but go beyond the scope of this document.[5] [6] [7] [8]

On September 16, 2011, President Obama announced that his Administration would release a National Bioeconomy Blueprint as part of his commitment to supporting scientific discovery and technological breakthroughs to ensure sustainable economic growth, improve the health of the population, and move toward a clean energy future. Modeled after the Administration's 2011 Blueprint for a Secure Energy Future,[9] this **2012 National Bioeconomy Blueprint has two purposes: to lay out strategic objectives that will help realize the full potential of the U.S. bioeconomy and to highlight early achievements toward those objectives.**

The National Bioeconomy Blueprint describes **five strategic objectives** for a bioeconomy with the potential to generate economic growth and address societal needs. Although progress is being made in all of these areas, much work remains if the United States is to remain competitive in a changing world. Summarized below (and described in more detail in Section 2 of this report) are the strategic objectives and the next steps that will help realize the full potential of the U.S. bioeconomy.

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

Although many studies show that research provides a healthy return on investment, a major justification for government investments in science and technology is to overcome market failures; these occur when private investors invest less in technology than the socially optimal level because they cannot reap the full benefits of their investment. In this context, scientific discovery is a public good that benefits all.

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4. Executive Memorandum (M-10-30) http://www.whitehouse.gov/sites/default/files/microsites/ostp/fy12-budget-guidance-memo.pdf
5. http://oba.od.nih.gov/biosecurity/about_nsabb.html
6. http://bioethics.gov/cms/synthetic-biology-report
7. http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf
8. http://www.whitehouse.gov/the-press-office/2011/12/05/fact-sheet-seventh-review-conference-biological-and-toxin-weapons-conven
9. http://www.whitehouse.gov/sites/default/files/blueprint_secure_energy_future.pdf

The pursuit of a greater understanding of natural systems yields knowledge, ideas, and technologies that the private sector can build on, sparking economic growth by giving rise to new products, services, and jobs. Coordination of Federal bioeconomy-related research activities can improve the efficiency and effectiveness of those investments and is especially important when budget growth is constrained. Coordinated strategic programs and targeted investments will accelerate progress in biological research and technology areas, and this in turn will drive discovery for an American bioeconomy.

Moving Forward: Coordinated, integrated R&D efforts will help strategically shape the national bioeconomy R&D agenda.

Expand and Develop Essential Bioeconomy Technologies – Foundational technologies have made possible unprecedented discoveries in biological research. Multiagency collaborations for emerging foundational technologies such as synthetic biology, biology-related information technologies, proteomics, and others are being fostered in order to grow the bioeconomy.

Integrate Approaches across Fields – The complexity of modern research questions requires that traditional boundaries between fields of study become permeable and programs concentrate expertise from diverse disciplines around societal challenges where it is needed most. The Administration will prioritize additional multidisciplinary efforts to enable biological research at the boundaries of fields, such as physics, chemistry, engineering, computer sciences, and mathematics, that support the bioeconomy.

Implement Improved Funding Mechanisms – Creating or modifying funding mechanisms to support creative, high-risk/high-reward research can enable researchers to pursue daring—and potentially groundbreaking—research that may be constrained by typical funding mechanisms or approaches. Agencies should further explore the use of new or modified funding mechanisms in and across agencies to stimulate the discovery of new bioinventions with potential to grow the bioeconomy.

2. Facilitate the transition of bioinventions from research lab to market, including an increased focus on translational and regulatory sciences.

If it is to be successful and thrive, the bioeconomy will be based on a steady flow of new products and services that address American needs. To ensure this flow, policies must be developed and taxpayer dollars must be used responsibly to foster an ecosystem that supports discovery, innovation, and commercialization.

Moving Forward: A dedicated commitment to translational efforts will accelerate movement of bioinventions out of laboratories and into markets.

Accelerate Progress to Market – An increased focus on entrepreneurship, translational sciences, regulatory science, and technology transfer can help ensure that ideas with potential for application move beyond the laboratory. Strategic, coordinated investments in translational and regulatory sciences will accelerate progress in many sectors of the bioeconomy. To capitalize on the promise of the newly reauthorized Small Business Innovation Research (SBIR) program, agencies should evaluate and update SBIR programs. Some relevant objectives include reducing application response times, hiring/training program staff to enhance relevant in-house experience, and increasing the use of industry experts as peer reviewers to evaluate industry proposals.

Enhance Entrepreneurship at Universities – Academic research is traditionally disconnected from its economic implications, making it difficult for innovative ideas to progress beyond the lab. Integrating entrepreneurship and industry involvement into the university research experience will facilitate the path from research to commercialization and help innovative ideas reach the marketplace. As an additional benefit, students can be exposed to the broader benefits of academic pursuits, as well as introduced to potential future careers in areas outside of academia. Innovative programs that enhance entrepreneurial activities at universities are needed to help academic discoveries become commercial realities.

Utilize Federal Procurement Authority – The purchasing authority of the Federal government offers opportunities to help drive some aspects of the bioeconomy. By procuring biobased and sustainable versions of products used in agency missions, the Federal government supports markets and promotes innovation, while creating jobs in rural America where many of these businesses are located and bio-products are manufactured. To drive the creation and growth of new bioeconomy markets, Federal agencies should prioritize procurement of biobased and sustainable products where appropriate and cost-effective.

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

Regulations are essential for protecting human health and the environment and reducing safety and security risks associated with potential misapplications of technology. When they are not carefully crafted or become outdated, however, they can become barriers to innovation and market expansion and discourage investment.

Moving forward: Improved regulatory processes will help rapidly and safely achieve the promise of the future bioeconomy.

Improve Regulatory Processes and Regulations – Agencies should improve predictability and reduce uncertainty in their regulatory processes and requirements. To reduce costs and impediments to investments but without compromising safety and efficiency, attention should be given to application review times, sequential reviews by multiple agencies should be coordinated to allow parallel reviews, and specific guidance should be issued in response to stakeholder needs. When an emerging technology enters the regulatory process, Federal agencies must have a robust framework that identifies lead agency responsibilities, clarifies supporting agency roles, and delivers timely, specific guidance for applicants.

Collaborate with Stakeholders – Improved agency regulatory processes rely on productive stakeholder collaborations to identify needs and impediments to progress and investment. Federal agencies should focus on building new, and augmenting existing, stakeholder collaborations to inform efforts, streamline processes, and reduce costs and response times, while preserving safety and ensuring substantive benefit to public health.

4. Update training programs and align academic institution incentives with student training for national workforce needs.

Many jobs in science and technology-related businesses remain unfilled despite high rates of local unemployment.[10] Opportunities exist to enhance training efforts at all levels to keep pace with changing career pathways. At the K-12 and undergraduate levels, the Administration has made significant progress in developing approaches to improve science, technology, engineering, and mathematics (STEM) education, and to increase the number and diversity of STEM students. For example, in 2009, the President launched the Educate to Innovate campaign to move American students from the middle to the top of international rankings in STEM achievements over the next decade. Building upon and expanding these efforts, particularly with regard to graduate-level training enhancements, would help to align academic institution incentives with training for future workforce needs. Also needed is the development of metrics to measure progress over time.

Moving forward: Federal agencies should take steps to ensure that the future bioeconomy has a sustainable and appropriately-trained workforce.

Employer-Educator Partnerships – Foster increased industry participation in the development of programs and in training students at all levels for the future bioeconomy workforce.

Reengineer Training Programs – Incentives for academic institutions to enhance entrepreneurship and restructure training programs would better prepare the future bioeconomy workforce, whether individuals are bound for careers in industry or academia. Federal agencies should develop incentives for institutions to adapt training to meet the needs of the 21st century bioeconomy workforce. Following reengineering of training programs, agencies should consider convening industry stakeholders from various sectors to assess the success of training programs to meet the needs of employers.

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

Partnerships enable private industry, government agencies, and academic institutions to pool resources and expertise around an idea, dramatically improving chances for success. Many companies do not invest in early ideas because they are unlikely to pay off immediately. This is one place where the government can play a crucial role. The President has emphasized that the Federal government, universities and companies should work together to invent, deploy, and scale the cutting-edge technologies that will create new jobs, spark new breakthroughs, and reinvigorate America today and in the future.

Moving forward: Federal agencies should provide incentives for public-private partnerships and precompetitive collaborations to benefit the bioeconomy broadly.

Catalyze Public-Private Partnerships – Great potential exists for partnerships and collaborations where sharing information about successes and failures is anticipated to generate transformative outcomes. Federal agencies are encouraged to broadly pursue opportunities for effective public-private partnerships in health, energy, agriculture, and manufacturing to leverage Federal investments and industry investments and expertise.

10. http://www.conference-board.org/data/helpwantedonline.cfm

I. Background and Impacts of the U.S. Bioeconomy

"Innovation also demands basic research."

—President Obama, January 24, 2012

A bioeconomy is one based on the use of research and innovation in the biological sciences to create economic activity and public benefit. The U.S. bioeconomy is all around us: new drugs and diagnostics for improved human health, higher-yielding food crops, emerging biofuels to reduce dependency on oil, and biobased chemical intermediates, to name just a few. The public benefit gained through biological research can be seen through the eyes of a patient who receives a critical medication that did not exist a decade ago, a farmer whose higher-yield crops are turned into fuels, food, and intermediate chemicals, and a small-business owner whose innovative biobased products are breaking new ground in manufacturing. Increased societal needs for food and energy, combined with new knowledge/discoveries in biology and new methods for harnessing biological processes, have dramatically increased the economic potential of the bioeconomy.[11]

Today's bioeconomy grew from several scientific and technological developments that transformed the practice and potential of biological research, including three of particular importance: genetic engineering, DNA sequencing, and robotic technologies that perform high throughput molecular operations rapidly and accurately. These technological advances have led to the development of many of the important drugs, products, and processes in widespread use today.

However, a growing U.S. population requires increased health services and more resources such as food, animal feed, fiber for clothing and housing, and sources of energy and chemicals for manufacturing. In short, it needs a new and more potent bioeconomy fueled by innovative ideas and practices that can help address these needs in new, more powerful ways.

The 2009 National Research Council report *A New Biology for the 21st Century*[12] stressed the potential of biological research—the potential to improve health outcomes for all Americans, feed growing populations with higher-yield crops of improved nutritional value, and decrease American dependence on petroleum-based products while increasing domestic biomanufacturing of fuels and chemicals. The report examined the state of biological research in the United States and recommended that the Nation "capitalize on recent technological and scientific advances that have allowed biologists to integrate biological research findings, collect and interpret vastly increased amounts of data, and predict the behavior of complex biological systems." The report also emphasized the benefit of coordinated Federal efforts to integrate biology with other sciences—namely physics, chemistry, and computer sciences—and with mathematics and engineering to address societal challenges in health, energy, environment, and agriculture that provides food, feed, fiber, and fuel.

11. http://www.oecd.org/document/48/0,3746,en_2649_36831301_42864368_1_1_1_1,00.html
12. http://www.nap.edu/catalog.php?record_id=12764

The National Bioeconomy Blueprint describes a number of key elements that will contribute to achieving the potential of the U.S. bioeconomy. Input from government, industry, and the public has helped to define them.[13] They are:

- a full spectrum of basic and applied R&D activities performed by academic, government, and private sectors
- public-private partnerships
- a supportive commercialization system for bioinventions
- innovative regulatory policies that reflect government awareness of needs for and impediments to progress
- a skilled and creative workforce
- public support for technological advances
- flexibility to accommodate the evolving needs, discoveries, and challenges

The Blueprint has two purposes: to lay out strategic objectives that address the key elements to help realize the full potential of the U.S. bioeconomy, and to highlight early achievements toward those objectives.

This document describes a vision for the future bioeconomy and recent trends that inform that future; it provides economic information about today's bioeconomy and highlights examples of Federal agency efforts to accelerate the Federal bioeconomy agenda. The examples described in the second chapter were selected from hundreds of examples that Federal agencies submitted for this Blueprint. Efforts to promote the U.S. bioeconomy are well underway. Real themes that drive innovation are emerging from Federal agencies through exciting new activities designed to enable new discoveries through basic research, foster economic growth, and create new jobs.

The Emerging U.S. Bioeconomy

Life science research and the development of increasingly powerful tools for obtaining and using biological data and biobased materials have brought the Nation to the threshold of only previously imagined opportunities for discoveries with transformative potential. Momentum is building. Scientists and engineers are increasingly looking to augment biological research with approaches from other scientific disciplines for solutions to our most demanding scientific and societal challenges, and seeing exciting options that will profoundly affect our future. Increasing this momentum, capitalizing on a wide array of multi-disciplinary knowledge and tools, and recognizing important trends promises a vibrant bioeconomy with vast societal benefit.

Imagine a world in which there are "ready to burn" liquid fuels produced directly from CO_2, biodegradable plastics made not from oil but from renewable biomass, tailored food products to meet specialized

13. To help develop the National Bioeconomy Blueprint, OSTP issued a National Bioeconomy Blueprint Request for Information (RFI) with 17 questions for public input. http://www.whitehouse.gov/blog/2011/10/12/building-bioeconomy. OSTP also provided a briefing for the National Science and Technology Council's Subcommittee on Life Sciences, and a number of professional societies after the RFI was released to gather input.

dietary needs, a drug that can cure any viral infection, and novel biosensors for real-time monitoring of the environment.

While achieving these visionary examples might seem daunting, current progress shows they may soon become reality (see examples in insets).

Bioeconomy Trends: Health

Treatment of disease is changing dramatically. Over the last 60 years, the treatment of disease has relied primarily on drugs derived from traditional chemical synthesis and the application of a variety of devices and procedures largely designed to treat disease symptoms rather than the underlying cause.

Broad Spectrum Anti-Viral: Researchers at the Massachusetts Institute of Technology's Lincoln Laboratory reported in 2011 creation of a broad-spectrum antiviral technology that selectively kills any virus-infected cell but does not harm uninfected cells.[16]

Many of our most promising therapies today are biologically derived molecules—proteins, antibodies, vaccines, and cells—specifically directed at the cause agents of disease. Examples of biology-based therapies include: protein therapies for the treatment of anemia, heart attacks, and stroke; antibody therapies that inhibit growth of cancers; and a new cell-based vaccine for prostate cancer. A fundamental change from treating the symptoms to treating the causes of disease was the direct result of an increased understanding both of biology and disease. Today there are expanding opportunities to design and deploy new therapies based on an ever-increasing understanding of biology and disease.

Our approaches to treatment are becoming more specialized. The Human Genome Project[14] has helped enable an emerging new era of personalized medicine. The ability to sequence and compare genomes of patients cheaply and quickly has the potential to transform medicine. Instead of today's typical treatments, which are based on how a group of individuals is predicted to respond, treatments are beginning to be geared to each individual's specific conditions. The Personalized Medicine Coalition reports that advances in recent technologies have increased the momentum of personalized medicine—customized healthcare based on specific genetic or other information of an individual patient.[15]

14. http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml
15. http://www.personalizedmedicinebulletin.com/files/2011/11/Case_for_PM_3rd_edition1.pdf
16. http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0022572

Bioeconomy Trends: Energy

The current backbone of our energy and chemical industries is carbon-based fossil fuels. Today we rely primarily on oil, coal, and natural gas to run our cars, heat our homes, and provide the raw material for a wide range of products from drugs to plastics to fertilizers. But we need to make ourselves more secure and control our energy future by harnessing all of the resources that we have available and embracing a diverse energy portfolio. Furthermore, leading the world in clean energy is critical to strengthening the American economy and addressing global climate change. Agricultural innovation has already used breeding practices and biotechnology to develop new crop varieties tailored as raw materials for energy production and new processes that improve the conversion of biomass to fuel and chemical products. Now, technologies are advancing to better harness the potential of microorganisms and plants to produce fuels, intermediate chemicals (e.g., the precursors for plastics), and other biomaterials. However, these are just initial entrées. The application of synthetic biology and other genetic-manipulation techniques will enable the rational design of organisms to produce conventional products more efficiently as well as novel products, including: modified seed stocks that yield plants with improved oil and starch content for biofuel production; enzymes from engineered microorganisms that are optimized for the production processes and environmental conditions required for industrial-scale chemical and fuel production; and microorganisms designed for the production of novel chemicals and biomolecules difficult or impossible to produce using current technologies.

Diesel from CO_2: Through photosynthesis, plants, algae, and some bacteria use the energy of sunlight to convert CO_2 into a variety of organic compounds needed for growth and survival. A Massachusetts-based company re-engineered photosynthetic organisms to synthesize, from sunlight and CO_2, molecules that form the chemical basis of diesel fuel.

Designing Biological Systems for Next-Generation Biomanufacturing: Synthetic biology is enabling scientists to rapidly design organisms that can be used in the production of renewable chemicals, biofuels, renewable specialty and fine chemicals, food ingredients, and health-care products. Bioacrylic acid heralds the advent of synthetic-biology-enabled manufacturing: acrylic acid ingredients are used to make adhesives stronger, paints more durable, and diapers more absorbent, and today petroleum-based acrylic is an $8 billion global market.[17]

Even solar energy conversion has the potential to be transformed through increased understanding of biological approaches to solar-energy capture.

Bioeconomy Trends: Agriculture

By 2030, the world population is predicted to reach 8.3 billion,[18] compounding the need for food. A growing population and limited arable land require new approaches to meeting the world's nutritional needs. A recent report by the National Research Council demonstrates that substantial progress is being made. In one example, the report estimated that through the use of biotechnology-enabled control of corn rootworm, 10 million acres of farmland produced $231 million in additional annual revenue from

17. http://www.bio.org/articles/current-uses-synthetic-biology

18. Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2010 Revision, retrieved 11/1/2011, from http://esa.un.org/unpd/wpp/index.htm

crop yield gains, reduced insecticide use by 5.5 million pounds annually, and eliminated 5.5 million gallons of water annually from the farming process.[19] Most recently, in December 2011, drought tolerant corn was approved by the USDA, and strategies to improve other crops for drought-tolerance are underway. Biotechnology advancements combined with breeding techniques are expected in the near future to lead to crops with other desirable traits such as improved nutritional value, enhanced disease resistance, and higher crop yields. As research moves beyond the biotechnology and breeding techniques of today, an increased understanding of biodiversity and food crops as ecosystems has the potential to transform the management and practice of agriculture and move this mainstay of the bioeconomy to a new level.

Bio- and chemical-based catalytic processes will play a greater role in the future of agriculture. The USDA predicts that two types of biorefineries will emerge: those that use microbial catalysts to directly convert feedstock (sugar or lipid) into a vast array of commercially valuable products, and those that are feedstock-agnostic and produce a single chemical intermediate, such as lactic acid or glycerol, for later conversion into final products.

Allergen-Free Peanuts: Researchers at a number of institutions in the United States have made inroads towards eliminating or inactivating allergenic proteins in peanuts. If successful, these approaches could lead to significant health benefits for Americans and economic opportunities for the peanut industry.

Biodegradable Plastics from Biomass: A major commercial "polylactic acid" bioplastic is already made today from cellulose. However, the ability to replace petroleum-based plastics with this bioproduct is constrained by the limited availability of the specific cellulosic source material. To address this limitation, USDA scientists discovered a bacterium that can ferment a broader range of cellulosic biomass materials into polylactic acid, enabling commercial production on a much larger scale. With an estimated $375 billion market for chemical, plastic, and rubber products based on petroleum, this represents a substantial bioeconomy opportunity.[20]

Bioeconomy Trends: Environment

From clean air and water, to abundant food and raw materials for much of our building construction, to the more intangible benefits of nature and ecosystem services, we depend on the living world to support and enrich our quality of life. The well-being of the living world and its ability to provide sustainable resources depend on responsible human stewardship, which in turn requires fundamental knowledge. Basic and applied biological research has the potential to produce a whole generation of the new knowledge and technologies needed to understand how the living world functions, to monitor and mitigate human impact, and to develop informed approaches to use and restore environments. Already, modern biotechnology is making inroads into environmental management and restoration. Microorganisms and their constituents are being used to detoxify industrial waste and clean up ecosystems contaminated by environmentally hostile practices. The growing field of environmental restoration ultimately holds the key to reclaiming healthy, functioning ecosystems in heavily degraded areas (e.g., recovery of watershed function) and may eventually allow mitigation of some of the effects of climate change by enabling the design of ecosystems with improved capacity for

19. The Impact of Genetically Engineered Crops on Farm Sustainability in the United States, NAS/NRC, 2010, pg. 139

20. http://www.nist.gov/mml/polymers/upload/854_01_02a.pdf

removing carbon from the atmosphere[21] and sequestering it in biomass for other uses. In addition, industries such as textiles and paper have moved toward biobased products and away from use of petrochemical products for both manufacturing and clean-up, and they now use microorganisms or biologically derived industrial enzymes that are more environmentally friendly and cost effective.

From traditional plant breeding to synthetic biology, biofuels to medical treatments to petroleum replacements, future biomanufacturing will be greatly facilitated by the ability to design and use biological systems and organisms quickly. The modification of biological organisms and construction and use of organisms not found in nature carry potential safety and security risks if misapplied, and require a range of considerations for responsible conduct including ethics, responsible use, and environmental awareness, among others. These advances raise important ethical and security issues that are also top priorities for the Administration, but go beyond the scope of this document.[22] [23] [24] [25]

Biosensor Pollution Monitoring: Biosensors are devices composed of a biological sensing component linked to a signaling component, working together to reveal the presence of an element, molecule, or organism of interest. In 2011, a team at the Virginia Institute of Marine Science reported creation of a portable biosensor that could detect marine pollutants, including oil, much faster and more cheaply than current technologies. If deployed near oil facilities, such sensors could provide early warning of spills and leaks and track dispersal patterns in real time.[26]

Bioeconomy Trends: Sharing

Non-traditional research collaborations that feature the sharing of information, resources, and capabilities are transforming the bioeconomy. Precompetitive collaborations—where "competitors" partner and pool resources—are growing as partners seek new ways to leverage constrained resources and surmount shared problems. Partnerships for innovation are increasingly observed as a response to changing economic and technological conditions.

In agriculture, as the public and private sectors seek increased information for the bioeconomy on potential crop characteristics, there is increased sharing, both domestically and internationally, of genetic information. The sharing of genetic information enhances U.S. agricultural competitiveness for food, energy, chemical production in plants, and other biobased-product crop species.

In the health sector, precompetitive collaborations are having significant impacts in clinical-trial design and biomarker discovery, among other areas. Combined industrial R&D has contributed to transformative progress despite major challenges such as increased management costs due to "'outside" collaborations and the need to develop effective communication networks across companies.

21. The July 31, 2009, issue of *Science* was devoted to this topic.
22. http://oba.od.nih.gov/biosecurity/about_nsabb.html
23. http://bioethics.gov/cms/synthetic-biology-report
24. http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf
25. http://www.whitehouse.gov/the-press-office/2011/12/05/fact-sheet-seventh-review-conference-biological-and-toxin-weapons-conven
26. http://onlinelibrary.wiley.com/doi/10.1002/etc.546/full

Impacts of the U.S. Bioeconomy

Technological innovation is a significant driver of economic growth, and the U.S. bioeconomy represents a growing sector of this technology-fueled economy.[27]

Impacts in the Biomedical Sector

Since the beginning of the twentieth century, life expectancy has nearly doubled.[28] Deaths from HIV/AIDS, initially an invariably fatal disease, have decreased by 94% in the United States.[29] Biomedical innovation is a major strength of the U.S. research enterprise. In 2010, approximately 29% of all jobs in the pharmaceutical and medicine manufacturing industry were in computer, engineering, and science occupations, and 28% were in production occupations, both low-skilled and high-skilled.[30]

The National Institutes of Health (NIH) invests over $30 billion annually in biomedical research, 80% of which is awarded through approximately 50,000 competitive grants to more than 300,000 researchers at over 2,500 universities, medical schools, and other research institutions. Approximately 10% of the NIH budget supports research conducted by nearly 6,000 scientists in its own laboratories. These investments are aimed to foster creative discoveries and research strategies and their applications as a basis for protecting and improving human health, and to expand the medical knowledge base to enhance the Nation's economic well-being and continued high return on the public investment in research.

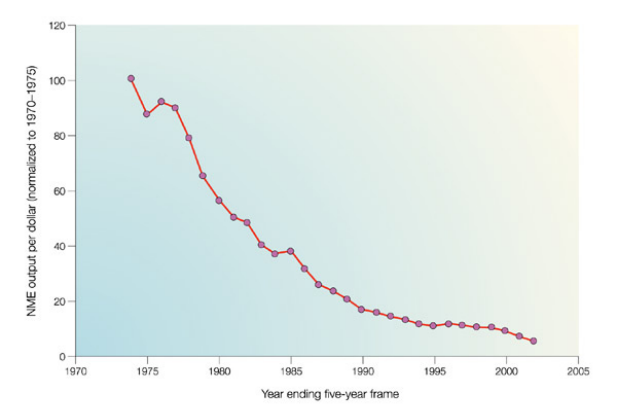


Figure 1. 30-year decline in new molecular entities per dollar spent on R&D. There has been a 30-year decline in pharmaceutical industry productivity, as measured by new molecular entities per dollar spent on R&D, normalized to 5-year rolling average of 1970 to 1975. While R&D costs have increased 50-fold during this time period, the output of investigational new drug candidates and new drug application products has stayed flat.[27]

One issue that government and industry must address is that increased investment in research has not resulted in a concomitant increase in approved drugs. Figure 1 shows that the number of FDA-approved new molecular entities has not kept pace with the pharmaceutical sector's spending over time. Experts have cited internal drug pipeline productivity declines, delays in application review caused by both industry and regulators, and a decreasing number of tractable medical challenges as reasons for this decline in productivity. Advances in translational and regulatory sciences, improvements in the

27. Biodesic 2011 Bioeconomy Update (Biodesic is a private consulting firm and sole source of data of this type.) http://www.biodesic.com/library/Biodesic_2011_Bioeconomy_Update.pdf
28. CRS Report for Congress, Life Expectancy in the United States, Order Code RL32792, updated August 16, 2006
29. Schimerling, R., Harvard Health Publications, Harvard Medical School, 2009.
30. http://www.bls.gov/oco/cg/cgs009.htm
31. Figure Source: IOM (Institute of Medicine). 2010. Extending the spectrum of precompetitive collaboration in oncology research: Workshop summary. Washington, DC: The National Academies Press

transfer of technology from the public to the private sector, regulatory process improvements, Federal workforce enhancements, and innovative public-private partnerships have potential to help overcome these challenges.

Impacts in the Agricultural and Industrial Sectors

In 2010,[32] agriculture, forestry, fishing, and hunting employed a total of 1.3 million wage and salary workers, and another 853,400 self-employed and unpaid family workers. About 85% of employment was in crop production and animal production, and about 80% of the establishments involved employ fewer than 10 workers. Decades of advancement in research areas such as plant breeding, plant genetics and genomics, soil science, microbiology, biological control, invasive species, and organic agriculture, have made modern agriculture a robust enterprise with substantial outputs in 2011 despite sub-optimal weather conditions.[33] Industrial uses for biotechnology extend well beyond health and agriculture. The industrial biotechnology sector uses genetically modified microbes as "cell factories" to produce a diversity of commercial products including vitamins, natural preservatives, biobased polymers, and enzymes for cleaning and textile industries, among many others. Given the vast array of different products, accurate economic numbers that represent industrial biotechnology's impact on these products are difficult to ascertain.

According to the USDA, agriculture is responsible for one out of every 12 jobs in America, and America's farmers and ranchers are the most productive in the world. In 2011, agricultural exports reached record levels of sales—$137.4 billion, resulting in a $42 billion trade surplus[34]. In 2010, revenues from genetically modified plants and microbes, a single economic indicator of the U.S. bioeconomy, were estimated in one assessment to account for approximately $300 billion in U.S. revenues, equivalent to more than 2% of gross domestic product.[35] According to the USDA, U.S. revenues from genetically modified crops were roughly $76 billion.[36]

Based on the best available data, U.S. revenues from industrial biotechnology were estimated to be $115 billion.[37] Compared to numbers for 2009 revenues for these same sectors—revenues from genetically modified plants and microbes for health, agriculture, and industrial biotechnology—these estimates suggest that many sub-sectors of the bioeconomy are growing rapidly.

32. http://www.bls.gov/emp/ep_table_207.htm and http://bls.gov/cew/
33. http://www.nass.usda.gov/Newsroom/2012/01_12_2012.asp
34. http://www.fas.usda.gov/info/IATR/111611_Exports/
35. Biodesic 2011 Bioeconomy Update. (Biodesic is a private consulting firm and sole source of data of this type.) http://www.biodesic.com/library/Biodesic_2011_Bioeconomy_Update.pdf
36. The $76 billion estimate was derived by prorating the published ERS estimates of revenue (cash receipts) from the relevant crops published here: http://www.ers.usda.gov/data/FarmIncome/finfidmu.htm#cashrec by the estimated share of GM crops for each crop.
37. Biodesic 2011 Bioeconomy Update. (Biodesic is a private consulting firm and sole source of data of this type.) http://www.biodesic.com/library/Biodesic_2011_Bioeconomy_Update.pdf

Foundational Technologies: Today and for the Bioeconomy of the Future

Today and for the Bioeconomy of the Future

Decades of biological research have revealed detailed information about the components of complex systems that characterize life—genes, cells, organisms, ecosystems—and how they interact. As mentioned earlier, genetic engineering, DNA sequencing, and high-throughput technologies have transformed the practice and potential of biological research. Yet, there is substantial room for advancement and discovery; additional scientific and technological revolutions are needed to fundamentally improve the approaches needed to confront the complex societal challenges of the future.

Emerging technologies such as synthetic biology, proteomics, and information technologies, including bioinformatics and computational biology, have the potential to create a vibrant bioeconomy.[38]

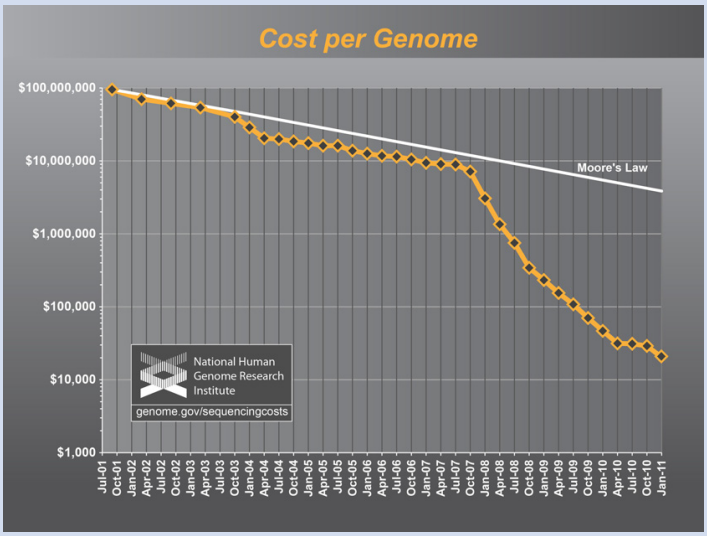


Figure 2. "Cost per Genome" – the cost of sequencing a human-sized genome. Data from 2001 through October 2007 represent the costs of generating DNA sequence using first generation sequencing technology. Beginning in January 2008, the data represent the costs of generating DNA sequence using 'second-generation' (or 'next-generation') sequencing platforms. The change in instruments represents the rapid evolution of DNA sequencing technologies that has occurred in recent years.[38]

Synthetic Biology: The ability to quickly and cheaply read and synthesize DNA sequences has transformed biological research. As shown in Figure 2, the costs of sequencing a genome decreased dramatically from 2004 to 2011.[39] Expansive genetic libraries, with billions of genome variants created daily, are now available due to huge strides in "reading and writing" DNA. While the sequencing of the first human genome took 13 years and cost $2.7 billion, researchers can now sequence a human genome for a fraction of that cost (~$7,700) and within two weeks' time. Synthetic biology, the design and wholesale construction of new biological parts and systems, and the re-design of existing, natural biological systems for tailored purposes, integrates engineering and computer-assisted design approaches with biological research. Since natural biological systems are so complicated, a primary focus of synthetic biologists is developing technologies that make the engineering of biology easier, faster, and more predictable. This ability to quickly engineer organisms in laboratories holds vast potential for the bioeconomy, as engineered organisms could dramatically transform modern practices in high-impact fields such as agriculture, manufacturing, energy generation,

38. www.genome.gov/sequencingcosts
39. Wetterstrand KA. DNA Sequencing Costs: Data from the NHGRI Large-Scale Genome Sequencing Program Available at: www.genome.gov/sequencingcosts.

and medicine. Much work lies ahead, including identifying and standardizing biological and molecular components, but this powerful new area of technology has immense potential. Strategic investments in synthetic biology have the potential to move the bioeconomy forward in all sectors.

Proteomics: Proteomics is the large-scale study of proteins, which, like DNA, are essential components of organisms. Proteomics is more complicated than genomics because unlike a genome that is virtually constant in a given cell, a proteome—the collection of a cell's proteins and their various molecular decorations—can vary dramatically from cell to cell and even within a single cell across time. Although the complexity of proteomic analysis presents a technological challenge, a cell's proteome provides an essential understanding of an organism's state. This has obvious value for basic biological research, and a number of practical applications as well. For example, comparing the proteome from a healthy lung cell with one from a cancerous lung cell may help identify a protein, a missing or abnormal molecular decoration of a protein, or unusual combination of proteins that may be promising drug targets.

Information Technologies: Research areas such as bioinformatics (the use of computational tools for expanding the use of biological data) and computational biology (the use of analytical and theoretical methods, mathematical modeling, and simulation techniques to study biological systems) have emerged as essential to the bioeconomy. As biological research continues to take advantage of increasingly larger and more complex datasets—including whole human genome sequences, proteomic profiles of cells, and high-resolution image files of biological specimens—the ability to store, analyze, visualize, and share data has become increasingly challenging. New information technologies to enable scientists to handle so-called "big data" will help stimulate the next transformative step toward realizing the potential of biological research across sectors.

In addition to advances in basic biological research, these emerging and other as yet unimagined foundational technologies will provide the next quantum jump in the ability to understand biological systems and further realize the potential of the bioeconomy.

II. Federal Bioeconomy Strategic Objectives

Strengthening Research and Development

"And if you have any doubt about the importance of this Federal investment in research and development, I would suggest that you talk to the cutting-edge businesses in your own states. They will tell you that if we want the next big breakthrough, the next big industry to be an American breakthrough, an American industry, then we can't sacrifice these investments in research and technology."

—President Obama, February 2011

Strategic Objective: Support R&D investments that will provide the foundation for the future bioeconomy.

A critical factor in leveraging biological systems to drive an innovation-based bioeconomy is the strength of the scientific enterprise investigating those systems, including basic and applied research. A robust biological/biomedical R&D enterprise, backed by government, foundations, and for profit investments, is necessary to produce the new knowledge, ideas, and foundational technologies required to develop products and services that support businesses and industries and help create jobs.

Nature has evolved countless biologically based systems with potential for new applications to address problems in health, energy, food, and the environment. Expanding basic knowledge of living systems and their molecular machinery will inspire new concepts for the creation of artificial processes and products that will address current and future needs. A sustained effort to understand and take advantage of natural living systems will produce novel solutions and encourage the growth of the bioeconomy.

Many government departments and agencies fund biological research with intramural and/or extramural funding programs (see box next page). Hence, the President has called for agencies to identify strategic R&D investments, as well as increase the use of flexible funding mechanisms to improve program efficiency and provide the best opportunity to enhance economic growth. Federal agencies are answering the call. As shown below, agencies are supporting development of the bioeconomy in a variety of ways: identifying strategic R&D progress to inform future efforts to enhance the bioeconomy; developing foundational transformative technologies; integrating approaches from engineering, physical sciences, and computational sciences; and implementing new flexible funding mechanisms. Shown below is a fraction of the bioeconomy projects and programs already started by Federal agencies.

Strategic Bioeconomy R&D Agency Progress to Date

Federal Departments and Agencies that Support Biological Research

Department of Agriculture
- Agricultural Research Service
- National Institute of Food and Agriculture
- Forest Service

Department of Commerce
- National Oceanic and Atmospheric Administration
- National Institute of Standards and Technology

Department of Defense
- Defense Advanced Research Projects Agency
- Defense Science and Technology Program
- Office of Naval Research
- U.S. Army Medical Research and Materiel Command

Department of Energy
- Office of Science
- Office of Energy Efficiency and Renewable Energy
- Advanced Research Projects Agency-Energy

Department of Homeland Security
- Science and Technology Directorate

Department of the Interior
- Fish and Wildlife Service
- U.S. Geological Survey

Environmental Protection Agency

Department of Health and Human Services
- Centers for Disease Control and Prevention
- Food and Drug Administration
- National Institutes of Health
- Assistant Secretary for Preparedness and Response

National Aeronautics and Space Administration

National Science Foundation

Veteran Affairs Department

United States Agency for International Development

Smithsonian Institution

Exploring New Scientific Discoveries for Potential to Treat Neurological Diseases: After the 2007 discovery of so-called induced pluripotent (adult) stem (iPS) cells, NIH moved quickly to better understand these cells' potential to assist development of cell-based models for drug discovery and new therapies. The generation of iPS cells from human somatic cells (such as fibroblasts, cord blood, and peripheral blood) has enormous potential for revolutionizing our understanding of disease mechanisms and spurring progress in therapeutic discovery. NIH funded three consortia to develop iPS cell lines for Parkinson's disease, Huntington's disease, and amyotrophic lateral sclerosis. NIH has built resources quickly and begun to characterize these cells as models of disease. The data from this work are freely available to scientists in industry as well as academic researchers with the goal of spurring the maximum innovation from a single investment. In addition, NIH also founded a new center in 2011, the Center for Regenerative Medicine, to accelerate the development and testing of new clinical protocols using iPS-cell-based treatments.

Improving Predictions of Vaccine and Drug Toxicity and Efficacy: NIH, the Defense Advanced Research Projects Agency (DARPA), and the Food and Drug Administration (FDA) have launched a collaborative research initiative to develop a "chip" that reproduces human physiological responses to drugs and vaccines. Designed to engage academic, industry, and government scientists, this five-year, $140 million effort aims to develop technologies that quickly provide molecular signals of toxicology and efficacy. The goal is to accelerate drug discovery and development while decreasing the testing of drugs and vaccines in animals.

Improving Homeland Security with Biological Research: The Department of Homeland Security (DHS) Science and Technology (S&T) Directorate is leading the development of a genomics-based approach to microbial forensic analysis. This capability will allow identification and characterization

of any microbial organism, including "unknown" organisms such as emerging, engineered, chimeric, or purely synthetic organisms. Establishment of the genomics approach involves development and refinement of several intersecting technologies including bioinformatic analysis, metagenomic analysis, and comparative genomics. DHS and the National Center for Biotechnology Information will establish a comprehensive catalog of genomes that covers the full diversity (phylogenetic, functional, spatial, and temporal) of pathogens to enable new capabilities with applications to the fields of public health, homeland security, food safety, and medical diagnostics.

Transforming the FDA Archives into a Driver of Discovery and Development: The FDA currently houses one of the largest known repositories of clinical data, including safety, efficacy, and performance information, and an increasing amount of post-market safety surveillance data. Integrating and analyzing these data could revolutionize the development of new patient treatments and allow researchers to address fundamental scientific questions about how different patients respond to a therapy. Harnessing the power of these data will benefit from collaborations to develop new analytical methodologies and better standardization of the data for integration, all while protecting proprietary information. FDA is rebuilding its information technology and data analytic capabilities and establishing "science enclaves" that will allow for the analysis of large, complex datasets while maintaining proprietary information. In addition to potential new therapies for patients, these efforts will result in significant and demonstrable reductions in costs to drug and medical device developers.

Increasing Availability of Renewable Fuels, Intermediate Chemicals, and Biobased Products: President Obama directed the Secretaries of Agriculture and Energy to expedite and increase production of and investment in biofuel development by providing funding to encourage innovative biorefineries that produce the next-generation of biofuels from biomass and replace fossil fuels with biomass energy systems. To support the President's goal of reducing America's oil imports by one-third by 2025, the U.S. Department of Agriculture (USDA) and Department of Energy's (DOE) Biomass Program committed in April 2011 up to $30 million over three to four years to support R&D in advanced biofuels, bioenergy, and high-value biobased products. In addition, in September 2011, USDA's Agricultural and Food Research Initiative committed more than $136 million to develop regional Coordinated Agricultural Projects for bioenergy systems through partnerships between academia, government, and industry. The projects funded through these initiatives will help create a diverse group of sources for alternative renewable fuels and biobased products. Advanced biofuels produced from these projects are targeted to reduce lifecycle greenhouse gas emissions and to play an important role in diversifying America's energy portfolio.

Expanding the Versatility of Biofuel Energy Solutions: In 2010 the Advanced Research Projects Agency-Energy (ARPA-E) developed and deployed "Electrofuels," a first-of-kind biofuels technology program to encourage development of new biological routes to fuels that bypass the limits of both current and

various advanced approaches to biofuels. ARPA-E invested $45 million across 13 innovative projects that target the development of unexplored, unapplied microbiology for biofuel production. The Electrofuels program relies on "chemolithoautotrophic" microbes, which can use inorganic carbon as their sole carbon source and are capable of growth and production in the complete absence of either sunlight or organic food sources. The Electrofuels program represents the first concerted effort to investigate the potential of chemolithoautotrophy as a platform for biofuel production.

Converting Carbon Dioxide to Liquid Fuels: Plants Engineered to Replace Oil (PETRO) is a ~$30M program launched recently by ARPA-E. Current agriculture-based biofuels are limited by the small amount of energy captured by photosynthesis and inefficient conversion of plant mass into fuel. The PETRO program aims to create plants that capture more energy from sunlight and convert that energy directly into fuels by optimizing processes of energy capture and conversion to develop robust, farm-ready crops that deliver more energy per acre with less processing prior to delivery to retailers. If successful, PETRO will create biofuels from domestic sources such as tobacco and pine trees for half their current cost.

Improving of Biofuel and Bioenergy Crops: In August, 2011, under the USDA-DOE Plant Feedstock Genomics for Bioenergy Program, $12.2 million was awarded for research to improve special crops for biofuels by increasing their yield, quality, and ability to adapt to extreme environments. Relying on modern genomics to develop novel breeding strategies, researchers focused on switchgrass, poplar trees, sorghum, miscanthus, and energy cane, among other promising plants with potential for growth on marginal lands that are poorly suited for food crops. Potential benefits of this research range from decreasing oil consumption to increasing options for American farmers, while adding new jobs and driving wealth creation in rural America.

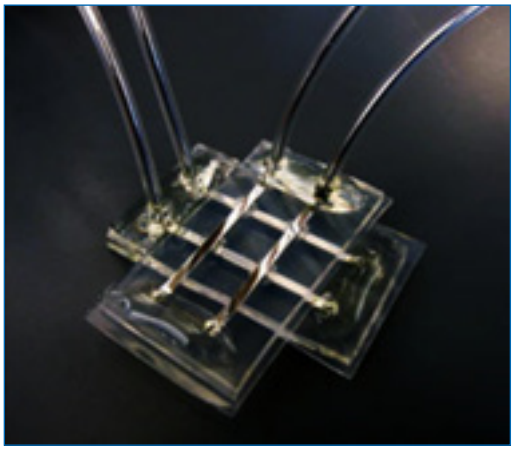
Exploring the Potential of Research for Innovations in Bioenergy and New Building Practices: Since 2009, the National Science Foundation's (NSF) Engineering Directorate has invested over $200 million in bioenergy research. In 2012, the NSF will initiate a Foundation-wide Sustainable Energy Pathways (SEP) effort ($34 million) aimed at harvesting energy from renewable resources and discovering "nature-inspired" processes for sustainable solutions to energy challenges. Under SEP, NSF's Engineering Directorate will focus on integrating new scientific advances in energy research into good building practices.

Developing New Agricultural Research Programs that Drive Job Creation: To further advance energy innovation and meet the 2022 Federal Renewable Fuels standard goal, in September 2011 USDA committed more than $136 million to five major agricultural research projects aimed at developing regional, renewable energy markets, generating rural jobs, and decreasing America's dependence on oil. These efforts focus on a variety of projects that complement existing bioenergy efforts across government, academia, and the private sector, including research on converting closed timber mills into bioenergy development centers, using sustainably grown woody crops to produce biogasoline, and planting legumes with grasses to add value to marginal lands and reduce fertilizer use.

Driving State-of-the-Art Organic Agriculture: U.S. producers are increasingly turning to certified organic farming systems for their potential to lower input costs, decrease reliance on nonrenewable resources, capture high-value markets, and boost farm income. To accelerate progress in these efforts, the USDA committed $19 million in September 2009 to universities across the country to address critical organic agriculture issues through the integration of research, education, and extension projects.

Organic agriculture challenges such as nutrient and weed management, biodiversity conservation, and antioxidant production in organic grains are among the issues this effort has addressed. This work assists organic producers in developing new practices for efficient, responsible farms while meeting rising consumer demand. Technological and management advances, useful for a wide range of agricultural systems, are also made possible as a result of this advanced organic production research.

Transforming Manufacturing through Bioinnovation: A substantial number of recent promising biomanufacturing opportunities led the Administration to recognize the value in investing in emerging technologies that can create high-quality manufacturing jobs and enhance global competitiveness. In support of this, DARPA launched its Living Foundries Program, which is designed to harness biology as a revolutionary manufacturing platform for the flexible and rapid production of new or improved high-value materials, fuels, medicines, devices, and capabilities for the Department of Defense. This effort seeks to develop the tools, capabilities, and methodologies to create a transformative shift in the ability to engineer biology through the integration of ideas, tools, and approaches from the biological, computational, and engineering fields. Living Foundries aims to compress the biological design-build-test cycle and expand by 100-fold the complexity of systems that can be designed and engineered. Key to success will be opening up the biological design and manufacturing process to new researchers and novel approaches, allowing information to be readily shared, and establishing a design ethos founded on predictability and reproducibility.



Employing Biomanufacturing to Enhance Economic Growth: In line with the Administration's interest in investing in emerging technologies that will create high-quality manufacturing jobs and enhance U.S. global competitiveness, the NSF Engineering Directorate is committed to investing in bio- and bio-inspired manufacturing that will catalyze innovations in energy conversion technologies and health care. In the energy sector, novel bio-membranes for advanced fuel cells and optimization of bio-refineries are NSF-supported activities that promise to enhance the development of clean energy technologies critical to U.S. economic growth and energy independence. For health-care applications, NSF-supported biomanufacturing research includes exploration of advanced tissue engineering processes to "print" replacement organs for regenerative medicine and organ transplantation. NSF has also supported research for bio-inspired fabrication methods for production of flexible bioelectronics to enable truly biocompatible retinal or cochlear prosthetic implants. These and other advances not only have the potential to spur significant growth in the "clean-tech" biotechnology and medical device sectors, but could also transform the lives of many individuals suffering from debilitating conditions.

Developing Foundational Technologies

Forging Scientific Advancement with Integrated Cyberinfrastructure: Increasingly, researchers need information technology tools to enable them to interpret large quantities of complex data from multiple disciplines. In February 2011, the NSF announced an agency-wide crosscutting effort, Cyberinfrastructure

Framework for 21st Century Science and Engineering, to provide a comprehensive, integrated, sustainable, and secure infrastructure to accelerate research and education and new functional capacities in computational and data-intensive science and engineering. The future bioeconomy relies on collaborations among biologists, scientists from other disciplines, and engineers, and the ability of these teams to harness so-called "big data"—extremely large, complex datasets that are difficult to store, analyze, and visualize—in fields of direct relevance to the bioeconomy. For example, the size of DNA sequencing databases is reported to be increasing by a factor of 10 every 18 months, and doing comparisons of complex DNA datasets, such as DNA sequences of organisms found in the human gut, can take days of computing time. Realizing the full value of "big data" for the bioeconomy will require new partnerships between public and private sectors, and strategic efforts to shape the national bioeconomy research agenda.

Transforming Environmental Health Protection with High-Throughput Technologies: High-throughput technologies have revolutionized DNA sequencing and drug discovery, among other labor-intensive scientific endeavors. In 2011, the Environmental Protection Agency (EPA) announced plans to test 10,000 chemical compounds for toxicity using high-throughput tests instead of animals. Whereas a person can precisely profile up to 20 compounds a year for various specific toxicities, a new robot capable of screening thousands of compounds a week was put to work in the Tox21 collaboration involving the EPA, NIH, and the FDA. The chemical compound collection contains chemicals found in consumer products, industrial processes, and food additives, as well as human and veterinary drugs. In addition to speed and scale, this high-throughput approach offers additional benefits such a significant cost savings and a reduction in the use of animals for toxicity testing purposes.

Unlocking the Promise of Synthetic Biology: With an increasing number of new biologically derived products approaching proof-of-concept phase, the Administration recognizes the potential of biological systems to influence the future of energy production in the United States. In response, the DOE's Biological and Environmental Research program has committed $30 million to initiate research efforts to identify biological design principles that will provide understandings of plant and microbial systems to enable synthetic redesign. Combined with computer-aided design and testing, these new understandings will provide key insights relevant to the goals of reorganizing and remodeling cellular processes to accelerate exploitation of biological systems for clean energy.

Integrating Approaches from Engineering, Physical Sciences, and Computational Sciences

Forging New Collaborations across Scientific Disciplines to Address National Challenges: BioMaPs and Ideas Labs: Because national challenges in health, energy, food, environment, and manufacturing are increasingly complex, the Administration is seeking groundbreaking ways to develop innovative solutions for these complex problems. Toward this goal, the NSF has developed two new programs and is investing $28.94 million in Fiscal Years 2011 and 2012 in pioneering research to mine potential at the intersections of the life and physical sciences. The first program, started in 2011, is BioMaPS, an interdisciplinary effort of NSF's Directorates for Biological Sciences, Math and Physical Sciences, and Engineering to derive fundamental new knowledge at the intersections of these major disciplines. The second is Ideas Labs, aimed to identify the most innovative multidisciplinary research projects to address key scientific challenges by bringing together a diverse group of researchers from multiple fields. Bringing together the biological sciences, mathematics, physical sciences, and engineering, these new efforts promise to explore the potential of multidisciplinary approaches to solving large-scale national challenges.

Inspiring New Commercial Products and Technologies through Fundamental Biological Research: Fundamental biological research has affected nearly every aspect of our daily lives. The Administration believes that the key to a prosperous U.S. bioeconomy is a constant influx of knowledge about the living systems that make up our world. Numerous examples demonstrate how discovery inspires new ideas and ways of thinking that not only augment future research but also supply entrepreneurs with a vast array of fresh concepts for new commercial products. One important area of discovery is synthetic biology, which combines biology with engineering in cutting-edge, interdisciplinary research aimed at developing innovative approaches to new product development. Early results from synthetic biology, including NSF-supported fundamental research in microbial metabolism that enables reengineered microorganisms to produce the anti-malarial drug artemisinin or create polyester precursors, are already being accelerated by new companies. The development of new rapid diagnostic tools based on synthesized "peptide chips," supported by a National Science Foundation Early concept Grant for Exploratory Research (EAGER), is another example of discovery spurring innovation. This research led to the formation of a start-up company that produces diagnostic chips for detecting evidence of many infectious diseases in miniscule volumes of blood. A second EAGER award resulted in the Genemeter, a portable DNA identification device, which has been licensed and is being marketed by a small company as part of a third-generation, lower cost bench-top sequencer for genomics applications.[40]

Implementing New Funding Mechanisms to Maximize the Potential of Bioeconomy Investments

Using the Power of Prizes to Drive Innovation: In his September 2009 Strategy for American Innovation, President Obama called on all agencies to increase their use of prizes to mobilize America's ingenuity to solve some of our Nation's most pressing challenges while advancing agency missions.[41] Through a prize, an agency can articulate a goal without having to specify the approach or predict the team that is most likely to succeed, and, importantly, pay only for success. In September 2010, the Administration launched Challenge.gov, a one-stop shop where entrepreneurs and citizen solvers can find public-sector prizes. As a result, in its first year alone, Challenge.gov featured more than 125 prizes from nearly 40 agencies, generating novel solutions to problems relating to childhood obesity, advanced vehicle technologies, financing for small businesses, Type 1 Diabetes, and many other national priorities. In December 2010, Congress passed the America COMPETES Reauthorization Act granting all Federal agencies broad authority to conduct prize competitions as called for by the President.[42]

Driving Interdisciplinary Ventures with New Funding Mechanisms: In Fiscal Year 2012, NSF launched CREATIV (Creative Research Awards for Transformative Interdisciplinary Ventures), a pilot grant mechanism to support bold interdisciplinary projects in all NSF-supported areas of science, engineering, and education research. A unique characteristic of this new effort is that only internal merit review is required—addressing recent concerns that under constrained Federal research budgets, external review panels tend to favor conservative research projects. CREATIV is aimed to provide substantial funding to

40. http://www.whitehouse.gov/assets/documents/SEPT_20__Innovation_Whitepaper_FINAL.pdf
41. http://www.whitehouse.gov/assets/documents/SEPT_20__Innovation_Whitepaper_FINAL.pdf
42. http://www.whitehouse.gov/sites/default/files/microsites/ostp/competes_report_on_prizes_final.pdf

unusually creative high-risk/high-reward interdisciplinary proposals, and applies to all NSF-supported areas of research. Since the future bioeconomy relies on an increasing number of creative interdisciplinary efforts, this new funding mechanism promises to provide a new avenue for funding from which bioeconomy efforts may benefit.

Moving Forward: Public input supported the Administration's priorities to develop coordinated, integrated R&D efforts to continue to strategically shape the national bioeconomy R&D agenda. For example, research that maximizes the value of Federal datasets and better predicts safety of bioeconomy-related products will help grow the bioeconomy. Multiagency collaborations for emerging foundational technologies such as synthetic biology, biology-related information technologies, and proteomics will help leverage agency investments to maximum impact. Additional suggestions from public input indicated that more inter- and multidisciplinary efforts should be prioritized, as should efforts to align research efforts in health with medical needs. Flexibility in the use of new and existing funding mechanisms in and across agencies will be vital to stimulating the discovery of new bioinventions with potential to grow the bioeconomy.

Advancing From Lab to the Market

"The first step in winning the future is encouraging American innovation."

—President Obama, January 2011

Strategic Objective: Facilitate the transition of bioinventions from research lab to market, including an increased focus on translational and regulatory sciences.

The Administration's Strategy for American Innovation[43] is designed to promote sustainable growth and the creation of quality jobs by fostering bioeconomy entrepreneurs and businesses. A key part of the strategy is to foster the growth of new companies and support established companies by increasing commercialization of promising new technologies and products emerging from research laboratories.

However, commercialization of these basic research discoveries has proved challenging. Too many fail to make the transition from research to market, a product-development stage that has been called the "valley of death" because of challenges related to the high and increasing cost of bringing a new therapeutic to market, scientific complexity, and the lack of experienced business management. To directly address these challenges, the Administration has launched initiatives that promote translation of ideas to products. The Startup America Initiative calls on the Federal government and the private sector to take action to dramatically increase the success of entrepreneurs in moving their discoveries and ideas to commercialization. Five areas are highlighted for action: unlocking access to capital; connecting mentors with entrepreneurs; reducing regulatory barrier; tax relief; and other economic incentives for small businesses. The National Institute of Standards and Technology (NIST) Hollings Manufacturing Extension Partnership (MEP) provides technical and business assistance to smaller manufacturers through a nationwide network in all 50 states and Puerto Rico through grant-supported partnerships between Federal and state governments and non-profit organizations. In partnership with other organizations,

43. http://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf

MEP is developing the National Innovation Marketplace[44] to facilitate supply chain connections between original equipment manufacturers and potential suppliers, to encourage technology translation and adoption. The America Invents Act provides entrepreneurs the tools they need to obtain patents more quickly and to defend them against litigation challenges, both at lower costs. The BioInnovation Initiative aims to accelerate development of medical advances through historic collaborations between NIH, FDA, and the private sector—notably biotechnology, pharmaceutical, and device companies. In Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance, the President called on Federal agencies to be leaders in environmental, energy, and economic performance.[45] As part of this Executive Order, the Administration committed to leveraging agency acquisitions to foster markets for sustainable technologies and environmentally preferable materials, products, and services. In December 2011, the President signed HR1540, the bill that reauthorized the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs for another 6 years.[46] From 2002-2006, approximately 25% of *R&D Magazine*'s top 100 annual innovations came from companies that had received SBIR grants. The recent reauthorization brought significant changes to the SBIR program, including allocation and award increases, as well as authority to provide SBIR grants to small companies owned in majority by multiple venture capital operating companies, hedge funds, or private equity firms. Specifically, the SBIR allocation is slated to increase 0.1% annually from 2011 to 2017, from 2.5% to 3.2%. The NIH, DOE, and NSF are authorized to grant up to 25% of SBIR funds to small companies owned in majority by multiple venture capital companies, whereas all other agencies are allowed to grant up to 15% of SBIR funds to such companies.

As shown below, many Federal agencies are taking actions that will promote the bioeconomy in key areas, such as increasing support for translational research, driving commercialization with the procurement power of the government, enhancing entrepreneurial activities at universities, and improving technology transfer.

Increasing Support for Translational Research

Transforming Biomedical Translational Sciences: In 2010, the NIH proposed a reorganization to allow the creation of a new center, the National Center for Advancing Translational Sciences (NCATS), and in December 2011, NCATS was formally established. As envisioned, NCATS will identify barriers to the discovery and development of drugs and diagnostics for a wide range of human diseases and conditions, and provide science-based solutions to reduce costs and time required to bring products to market. Translational science solutions developed by NCATS can be further developed by the private sector for applications in industry. Assisted by a working group of external advisors representing venture capital and drug companies, academia, and the philanthropic sector, NIH will develop strategies to collaborate with the private sector, as well as contribute to the translational research enterprise as a whole.

Accelerating Progress to Market through a New Regulatory Science Initiative: The NIH and FDA are collaborating to support regulatory science research, an interdisciplinary area of biomedical research that serves to generate new knowledge and tools for assessing experimental therapies, preventives, and diagnostics. It is critical to ensure that the regulatory and research landscapes are aligned to encourage entrepreneurs to develop novel technologies in some of the most promising cutting-edge research

44. http://innovationsupplychain.com/usa/
45. http://www.gpo.gov/fdsys/pkg/FR-2009-10-08/pdf/E9-24518.pdf
46. http://www.gpo.gov/fdsys/pkg/BILLS-112hr1540enr/pdf/BILLS-112hr1540enr.pdf

fields. Collectively, the NIH and FDA are contributing approximately $9 million over three years to support four research projects in the high-priority areas of nanotechnology, microdevice development for testing safety and efficacy, adaptive clinical trial design, and a novel strategy for testing eye irritation that reduces dependence on animals. Over the course of the upcoming year, the grantees and NIH and FDA project leaders will discuss how to maximize the impact and value of anticipated research findings and how to demonstrate the applicability of each new or improved tool or method to the regulatory decision making process.

Catalyzing Advanced Biofuels Production through Consortia: In 2009, with $85 million in funds made available by the American Recovery and Reinvestment Act, the DOE Biomass Program announced two multidisciplinary consortia charged with developing technologies to accelerate commercialization of advanced biofuels and bioproducts. The consortia model brings together researchers from universities, National Laboratories, and industry, to address both the foundational and applied research needs of the biofuels industry. Applied use of synthetic biology techniques is one example of how both consortia are utilizing foundational knowledge to improve organism performance, leading to improvements in fuel yield and process economics.

Driving Innovation with the Procurement Power of the Federal Government

Advancing Biofuels for Military and Commercial Transportation: As stated in its Blueprint for a Secure Energy Future, the Administration recognizes the need for the Federal government to lead by example to help move the Nation toward a clean energy economy, given the government's status as the largest energy consumer in the U.S. economy. In August 2011, the Secretaries of Agriculture, Energy, and the Navy announced the creation of a cooperative effort to develop drop-in advanced biofuels. Drop-in biofuels are direct replacements to existing gasoline, diesel, and jet fuels that do not require changes to existing fuel distribution networks or engines. This collaboration by the three Departments was developed in response to the Blueprint for a Secure Energy Future, and promises to advance U.S. efforts to reduce dependence on oil.

Driving Innovation and Creating Jobs in Rural America through Biobased and Sustainable Product Procurement: As part of a commitment to leading the way in procurement of biobased products to create jobs and open new markets in rural America, the President signed the Presidential Memorandum on Driving Innovation and Creating Jobs in Rural America through Biobased and Sustainable Product Procurement.[47] Biobased product materials are typically grown and manufactured in rural areas. Their increased procurement will lead to increased jobs in rural areas, benefits to the environment, and overall use of fewer petroleum-based products. The Presidential Memorandum provides guidance to increase and better track biobased procurement as well as expand the list of designated biobased products available to the Federal government.

47. http://www.whitehouse.gov/the-press-office/2012/02/21/presidential-memorandum-driving-innovation-and-creating-jobs-rural-ameri

Enhancing Entrepreneurial Activities at Universities

Accelerating Commercialization of University Research with Innovative New Funding Programs: While the knowledge gained from government-supported basic research frequently advances a particular field of science or engineering, some results also show immediate potential for impact in the business world. In support of the Administration's push to advance these promising discoveries to products, the NSF established in 2011 the Innovation Corps (I-Corps) program to spur transformation of fundamental research into useful technological innovation, to encourage collaboration between academia and industry in technology transfer, and to provide students with opportunities to learn about and participate in the process of transforming scientific and engineering discoveries into innovative technologies. Encouraging initial I-Corps activities by several NSF Directorates in 2011 provide a basis for expansion of I-Corps activities by NSF in 2012.

Improving Technology Transfer

Streamlining the Licensing of Intramural Research Inventions to Startup Companies: To speed the transfer of intramural technologies from the NIH to startup companies, the NIH developed new short-term, exclusive license agreements for companies that are less than five years old, with fewer than 50 employees and less than $5 million in capital raised. These new licenses will be offered to companies developing drugs, vaccines, or therapeutics from NIH-patented or patent-pending technologies. The start-up company must license at least one U.S. patent and commit to developing a product or service for the U.S. market.

Improving the Transfer of Technology from Federal Research Laboratories: A recent study suggested that transfer of technologies from Federal research laboratories to the private sector could be enhanced.[48] In October 2011, the President issued a memo asking agencies to streamline partnership processes, participate in regional innovation clusters and engage in public-private partnerships, and share Federal laboratory facilities with high-tech startup companies.[49] Each agency will design a five-year "lab to market" plan with tailored goals and metrics to measure progress.

Accelerating Technology Transfer through Knowledgeable Partners: Because Federal R&D agencies are limited in the services they can provide to U.S. businesses by their missions and resources, third parties are essential players in the transfer of government-owned technology. USDA's Agricultural Research Service established the Agricultural Technology Innovation Partnership Program (ATIP) to strategically form geographic partnerships with well-established economic development entities to encourage commercialization of USDA intramural research results. In June 2010, the first meeting of all ATIP intermediaries was held to plan and coordinate the transfer of technologies stemming from USDA intramural research. Also in 2010, USDA worked with EPA to develop a "first-of-its-kind" license agreement for distribution of a USDA intramural transgenic product, the HoneySweet plum.

48. Shipp, S., et al. *Technology Transfer and Commercialization Landscape of the Federal Laboratories.* Institute For Defense Analyses, Science & Technology Policy Institute, Arlington, VA. 2011.

49. http://www.whitehouse.gov/the-press-office/2011/10/28/presidential-memorandum-accelerating-technology-transfer-and-commerciali

Driving Innovation by Encouraging Entrepreneurship: The evidence supports and the Administration recognizes the role of entrepreneurs in American innovation and economic growth. In support of this role, November was designated as National Entrepreneurship Month. The 2009 Strategy for American Innovation[50] described approaches to promote competitive markets that spur and support productive entrepreneurship. In 2011, the updated Strategy for American Innovation built upon those approaches with additional detailed policy objectives, including support for innovative entrepreneurs and innovation hubs for entrepreneurial ecosystems http://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf. President Obama has called for the Research and Experimentation Tax Credit to be expanded, simplified,[51] and permanently extended, creating predictable, substantial incentives for U.S. businesses to innovate. In January 2011, the White House launched Startup America to accelerate high-growth entrepreneurship by unlocking access to capital and reducing barriers to entrepreneurship, among other objectives. Also in 2011, the President signed the America Invents Act to help American entrepreneurs and businesses patent inventions and get them to the marketplace more quickly, and to accelerate the creation of new products and new jobs.

> *"Entrepreneurs embody the promise of America: the idea that if you have a good idea and are willing to work hard and see it through, you can succeed in this country. And in fulfilling this promise, entrepreneurs also play a critical role in expanding our economy and creating jobs."*
>
> *-President Obama, January 31, 2011*

Facilitating Commercialization of Biomedical Discoveries through Improvements to the Small Business Grant Program: In addition to the modifications described in the SBIR reauthorization, NIH has undertaken steps to investigate how changes to its own SBIR efforts might accelerate translation of biomedical discoveries to the marketplace. For example, in 2011, the NIH initiated a new SBIR Technology Transfer Program, which includes efforts to develop new exclusive license agreements for startup companies interested in discoveries generated through NIH's intramural research efforts. In addition, NIH is initiating an assistance program to provide funds to help small businesses navigate the FDA regulatory approval processes for drugs and medical devices. More than 60 companies are expected to benefit from this assistance in the near future. Further, NIH's Scientific Management Review Board, an external advisory body, is expected to provide recommendations to NIH for additional SBIR program implementation and management modifications that may help accelerate the translation of biomedical discoveries to commercial markets, especially in light of the establishment of the NCATS.

Moving Forward: A dedicated commitment to translational efforts is needed to move bioinventions out of laboratories and into markets. Strategic, coordinated investments in translational and regulatory sciences will accelerate progress in many sectors of the bioeconomy. Additional programs, such as I-Corps, that enhance entrepreneurial activities at universities will help academic discoveries become commercial realities. To capitalize on the promise of the newly reauthorized SBIR program, agencies need to evaluate and update SBIR programs. Some relevant objectives include: reducing application response times, hiring/training program staff to enhance relevant in-house experience, and increasing the use of industry experts as peer reviewers to evaluate industry proposals. To drive the creation and growth of new bioeconomy markets, Federal agencies should increase procurement of biobased and

50. www.whitehouse.gov/assets/documents/SEPT_20__Innovation_Whitepaper_FINAL.pdf
51. http://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf

sustainable products, as authorized by law. Public input showed significant support for Federal efforts to identify and disseminate "best practices" for technology transfer.

Reducing Regulatory Barriers

"So you guys are leading the way, and we know there are some things government can do to help clear the way for your success. We can make sure America remains the best place on Earth to do business by knocking down barriers that stand in the way of your growth. That's why we passed 17 different tax cuts for small businesses, why I proposed lowering the corporate tax rate and eliminating unnecessary regulations to help larger businesses create jobs."

—President Obama, February 2011

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

Regulations governing our health products and services, energy production, national security, food, and environment are protections that necessarily reduce safety and security risks. However, some longstanding regulations have become inadequate or unnecessarily restrictive because technology and its associated products and services, as well as our national interests, have evolved and regulations may not have kept pace. Clear, predictable, and efficient regulations that ensure safety, security, and efficacy of products of biological research are powerful drivers of R&D investments by all sectors. In addition, because externalities and social attitudes influence market opportunities in the bioeconomy as they do in other economic arenas, a clear understanding of the benefits and risks of bioproducts is critical to the future bioeconomy.

An example of balancing concern for risks while maximizing benefits occurred in 2010. After a significant advance in synthetic biology, President Obama asked the Presidential Commission for the Study of Bioethical Issues to develop recommendations for Federal actions to ensure that America reaps the benefits of synthetic biology while identifying appropriate ethical boundaries and minimizing identified risks. As the bioeconomy and its underlying science advance, Federal agencies will adopt efforts accordingly to maximize public benefit and minimize public harm.

In 2011, President Obama issued two Executive Orders, Improving Regulation and Regulatory Review,[52] and Regulation and Independent Regulatory Agencies, to improve regulation and the regulatory review process. Under these Executive Orders, the President called on Federal agencies to design cost-effective, evidence-based regulations that are compatible with economic growth, job creation, and competitiveness while preserving safety. The Orders emphasize the principles of public participation, integration and innovation, flexible approaches, and scientific integrity. They also include a provision on retrospective review, which asks agencies to submit a plan to determine whether any regulations should be modified, streamlined, expanded, or repealed in order to make the agency's regulatory program more effective or less burdensome. Support for these important changes was highlighted in many of the public com-

52. http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf

ments received in response to a request for information issued by the Office of Science and Technology Policy about this Bioeconomy Blueprint.

In response to the Executive Orders, 26 agencies produced reform plans, and a small fraction of the initiatives described in the plans is predicted to save more than $10 billion over the next 5 years.[53] Highlighted here are actions agencies are taking to support a future bioeconomy while protecting human and environmental health through reforms that increase timeliness, predictability, and reduce costs.

Removing Barriers of Innovation in Biomedical Industries: The FDA will implement reforms that address immediate concerns to increase transparency, consistency, and predictability of the regulatory processes and help drive medical product innovation forward. Translating a new idea from discovery into a medical product is a complex process that involves an entire ecosystem of players, including researchers, government agencies, small businesses, large biotechnology, medical device and pharmaceutical companies, insurance providers or payers, physicians, patients, and the American public. To prepare for the challenges ahead in the biomedical industries, the FDA is conducting internal analyses and meeting with the major stakeholders to identify areas where the agency can improve its regulatory framework. In response, the FDA's new Innovation Initiative outlines major reforms within the FDA to address immediate concerns and drive American innovation forward. This agenda focuses on several different areas, such as strengthening the agency's relationship with the small business community, facilitating drug development and harnessing the potential of information sharing and data mining. Discussions with, and feedback from, major stakeholders are essential for these reforms and to increase the potential for new and better medical products to promote a healthier American public and world population.

Engaging External Scientific Experts to Improve the Regulation of Medical Devices: The FDA Center for Devices and Radiological Health (CDRH) is taking novel approaches for leveraging the expertise of the private sector to streamline and make more predictable the regulatory process for medical devices. In October 2011, CDRH announced the start of a pilot program with select health care professional and scientific professional organizations to rapidly identify appropriate experts to help CDRH staff resolve important scientific questions. In February 2011, CDRH proposed to establish an "Innovation Pathway," a new approach to reviewing important devices. For Innovation Pathway 2.0, the agency is taking a far broader approach. Rather than build onto the existing process, the agency is considering the entire regulatory system and developing a new pathway from the ground up based on experience and new expectations and through rapid pilot testing of new approaches. In addition, what CDRH creates for Innovation Pathway 2.0 will inform related improvements to other pathways to market. CDRH has assembled a team of entrepreneurs in residence—made up of external experts in medical device development, business process improvement, and information technology—who are working with FDA staff and leadership to rapidly improve the regulatory process for medical devices.

Reducing Bureaucratic Burdens for Low-Risk Medical Devices: The "*de novo* review" program for medical devices at the FDA is intended to provide a pathway to market for novel low-to-moderate-risk medical devices for which no similar device is available. Until now, the pathway has been underutilized because it is overly burdensome. In September 2011, the FDA CDRH issued draft guidance to make the *de novo* process less bureaucratic, more timely, more transparent and, thereby, a more viable pathway

53. http://www.whitehouse.gov/the-press-office/2011/08/30/letter-president-speaker-house-representatives

to market for novel low-to-moderate risk devices. By improving the de novo process, more devices that are novel will reach the market in a timely fashion.

Improving Human Subjects Research Protections while Reducing Unnecessary Burden: The Department of Health and Human Services (HHS) is working across the government to revise regulations governing federally-funded research involving human subjects to enhance protections and reduce burden, delay, and ambiguity for investigators. These regulations, known as the Common Rule, have not been significantly revised in more than 20 years, despite dramatic changes in the nature and terrain of the research enterprise. For example, by more precisely calibrating the level of review to the level of risk, review boards overseeing research protocols could focus their attention on protocols that pose greater than minimal risk to subjects. By considering revisions to the current rules, HHS is leading the way in modernizing, simplifying, and enhancing the current system that oversees human subjects' protections. This effort reflects the government's commitment to protecting participants in research while advancing biomedical and related research—and the public benefits that research makes possible. Public comments were sought on the proposed changes through an Advanced Notice of Proposed Rule Making published in the Federal Register on July 26, 2011.

Expanding the Coverage with Evidence Development Program to Drive Innovation: Reimbursement for medical treatments is a powerful driver of industry investment. Under the Coverage with Evidence Development (CED) program, Medicare reimburses for promising new technologies that do not currently meet the standard for full coverage. The CED program requires more evidence to be collected to determine full potential benefit of new technologies. The CED authority has existed for more than a decade but has been applied sparingly. The Centers for Medicare & Medicaid Services (CMS) is poised to implement the next phase of CED by better defining the parameters and guidance for CED so it can be used more widely and effectively as a driver of innovation. CMS believes that the lessons learned during the initial implementation of CED can inform its more frequent use and create predictable incentives for innovation while providing greater assurance that new technologies in fact fulfill their initial claims of benefit.

Reducing the Time to Market by Implementing Parallel Regulatory Reviews for Medical Products: FDA approval and CMS coverage significantly influence the development and commercial success of new medical products. The time required for FDA and CMS to sequentially review new medical products—often multiple years—is frequently cited as a disincentive for innovators and investors in the medical technology industry. A significant portion of this delay is due to the fact that most sponsors of new products approach each reviewing agency separately, first working to meet the evidentiary requirements of the FDA and only later focusing on the requirements of CMS. To address this problem, the FDA and CMS initiated a pilot program for the parallel review of medical devices, creating a pathway for new medical products to be simultaneously reviewed by both agencies. By engaging CMS earlier in the process, the parallel review program is expected to limit the duplication of effort on the part of

product sponsors and agency reviewers and reduce the time it takes new products to enter the market and receive payments from Medicare and other providers.

Developing tools to facilitate the continuity of business during a foreign animal disease outbreak: New DHS S&T programs on countermeasures and screening tools for foreign animal diseases are aimed at strengthening the defense of the U.S. agricultural infrastructure by developing new and next-generation countermeasures (vaccines, diagnostics, and screening tools) to protect the livestock industry against Foot and Mouth Disease and other high consequence foreign animal diseases. New and next-generation countermeasures will be developed and transitioned directly to veterinary biologic industry partners for commercialization and access by USDA. Current investments are focused on countermeasures for Foot and Mouth Disease, Rift Valley Fever, Classical Swine Fever, African Swine Fever, and Henipavirus.

Reforming Regulatory Processes to Accelerate Application Review and Open New Agricultural Markets: Regulatory processes can inhibit companies from initially investing in an area due to uncertain time delays and the lack of clear guidance for applicants. Consistent with the President's January 2011 Executive Order, Improving Regulation and Regulatory Review, USDA announced plans in November 2011 to dramatically streamline and improve several programmatic processes, including the USDA's processes for conducting risk assessments and rulemaking. The USDA expects time-savings of more than 70% by implementing improvements to project management and tracking, as well as assigning and meeting deadlines on required steps in the risk assessment process. Expected benefits of this effort include reduced government costs, improved relationships with foreign trade partners, and new market opportunities for U.S. products abroad, among many others. In addition, in August 2011, USDA announced that its Animal and Plant Health Inspection Service would conduct a two-year pilot project to improve the approval process for genetically engineered organisms.

Improving the Regulation of Emerging Technologies: Emerging technologies, including nanotechnology and synthetic biology, will provide exciting new products to enhance our lives, grow our economy, and preserve and restore the environment. A quarter century ago, the Federal government formulated the 1986 Coordinated Framework for the Regulation of Biotechnology to ensure a robust regulatory system for genetically engineered products www1.usgs.gov/usbiotechreg/read_file.nbii. Supported by studies that analyzed decades of research, genetic engineering has had a remarkable history of safe development and production of drugs, crops, foods,[54] and other products. In March 2011, the Administration released Principles for Regulation and Oversight of Emerging Technologies.[55] Under President Obama's Executive Order, Improving Regulation and Regulatory Review, federal regulatory agencies have already taken steps to make the regulatory process for emerging technologies more

54. http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf
55. http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf

transparent and predictable and will launch efforts to further improve the efficiency of the regulatory process while minimizing safety and security risks and removing unnecessary barriers to innovation.

Driving Industrial Innovation with International Standards: The bioeconomy is expanding within a rapidly developing global technology landscape, and international standards are a critical factor in driving industrial innovation and facilitating global trade. A January 2012 White House Memorandum[56] clarified the role of the Federal Government in working with the private sector in standards activities to address national priorities. With the benefit of close ties to both industry and the regulatory enterprise, NIST contributes to activities in international standards setting organizations such as the International Organization for Standardization. This participation helps ensure that international standards, which will play a critical role in realizing the benefits of the bioeconomy, are based on rigorous measurement science and technology.

Moving Forward: Public input reinforced the Administration's focus on improving regulatory processes to help achieve the promise of the future bioeconomy more rapidly and safely. Federal agencies should develop new, efficient regulatory processes and reform extant ones where necessary. This will reduce barriers to innovation and increase predictability and timeliness of regulatory processes to stimulate the bioeconomy in all sectors. Building and augmenting stakeholder collaborations and streamlining processes to reduce costs and response times while preserving safety are key objectives. When an emerging technology enters the regulatory process, Federal agencies must have a robust framework that identifies lead agency responsibility and its role in coordination, clarifies supporting agency roles, and delivers timely, specific guidance for applicants.

56. http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08_1.pdf

Developing a Bioeconomy Workforce

"When it comes to workforce development, one of the most important things that we've all learned is how important it is to get businesses in early with the universities and the community colleges—a hugely under-utilized resource—to develop the actual training program so that young people have confidence if they go through this training program, they've got a job; businesses have confidence that if they hire these young people who went through the training program, they are trained for those jobs."

—President Obama, February 2011

Strategic Objective: Update training programs and align academic institution incentives with student training for national workforce needs.

A vibrant bioeconomy depends on the education and skills of its workers. Therefore, directing resources to the training and development of specialized skills in the biological sciences, biotechnology, and bioengineering is one of the best investments the government can make. An expanding bioeconomy will require substantial biobased production of raw industrial materials such as oils and specialty chemicals, as well as products such as plastics, polymers, lubricants, and enzymes. These new raw materials and products will not only require a biotechnology/bioengineering workforce for their production, but also provide the basis for growth in manufacturing downstream products that use these items as building blocks.

While the manufacturing sector has faced challenges in recent years, it continues to be the lifeblood of the American economy. The manufacturing sector currently employs over 11 million Americans, and by itself, would be one of the 10 largest economies in the world. Recognizing the importance of the manufacturing sector, in 2010, the Administration launched the Skills for America's Future initiative in partnership with the Aspen Institute. This initiative brings together companies and community colleges around a simple idea: make it easier for workers to gain new skills that will make America more competitive in the global economy. Achieving this goal is especially important, given that 2.7 million manufacturing employees are nearing retirement and will likely leave the labor force within 10 years.

A January 2012 Department of Commerce report[57] highlighted the critical role that science, technology, engineering, and math (STEM) education plays in maintaining national competitiveness and growing the economy. Early in the Administration, the President

57. The U.S. Department of Commerce report is available at: http://www.commerce.gov/sites/default/files/documents/2012/january/competes_010511_0.pdf

announced a number of initiatives to improve and increase diversity in STEM education. In November 2009, the President launched the Educate to Innovate campaign for excellence in STEM education. The program aims to move American students from the middle to the top of international rankings in STEM achievements over the next decade. Its three priorities are (1) increasing STEM literacy to enable all students to think critically in STEM-related activities, (2) improving the quality of math and science teaching for American students, and (3) expanding STEM education and career opportunities for underrepresented groups, including women and minorities. The Administration's Race to the Top competition, an effort to create incentives for comprehensive state and local education reform, encourages making STEM education a priority in K-12 programs and specifically mentions addressing the needs of underrepresented groups and girls in STEM programs. These STEM education efforts are expected to contribute broadly to the development of a bioeconomy workforce for the 21st century.

Opportunities exist to improve training at the professional level as well. Approximately two-thirds of Federally-supported professional-level trainees are supported by research grants rather than training-type grants. When Federal funding for research increases, the number of research grants and the capacity to train more PhDs also increases, regardless of whether there is an increased demand in the workforce for individuals with such training. Moreover, most university departments that specialize in biomedical training provide little or no information about career outcomes for recent graduates who have been hired into relevant positions. In addition, the training provided to university students via research and training-type grants is generally directed toward academic positions. The number of tenure-track academic positions available to PhD biomedical trainees is far below the number of those so-trained.[58] Many biomedical doctorate recipients are being employed in positions other than those for which they were trained. A significant number of public comments in response to the Bioeconomy Blueprint Request for Information emphasized the importance of updating training programs to more effectively meet the needs of the careers into which trainees will eventually move. While the workforce needs within and outside of academia will continue to evolve as the bioeconomy develops, training programs and academic incentives should be aligned to meet the full spectrum of workforce demands.

As highlighted below, Federal agencies are making their own moves to prepare the next generation to compete successfully in a bioeconomy by improving STEM education and increasing diversity, preparing a bioeconomy workforce for academic and non-academic jobs, and leveraging community colleges and industry in workforce development.

58. http://www.nature.com/news/2011/110420/full/472276a.html

Improving STEM Education and Increasing Diversity

Investing in the Next Generation of Environmental Scientists: The Administration has stressed the importance of investments that will develop a strong, well-trained, and diverse workforce for a burgeoning bioeconomy. In direct response, the National Oceanic and Atmospheric Administration has awarded $10.8 million to four leading minority-serving institutions across the country to train students to conduct applied research in areas such as remote sensing, environmental science, marine resources, or atmospheric sciences. These areas are essential to understanding and predicting changes in our environment and to conserving and managing coastal and marine resources that are critically important to a bioeconomy. Furthermore, this funding recognizes the importance of STEM education and supports America's ability to innovate and compete in the global economy.

Enhancing Agricultural Sciences at Minority-Serving Institutions: By 2025, nearly one-quarter of the Nation's college-aged population will be Latino. To enhance the ability of Hispanic-Serving Institutions to support underserved students and develop a skilled bioeconomy workforce, the USDA committed $8.8 million in October 2011 to 18 Hispanic-Serving Institutions to support programs that address efforts focused on climate change, biobased energy development, childhood obesity, and food safety, among others. In addition, USDA provides support for other minority-serving institutions, particularly in capacity building and STEM education. USDA provides at least $51 million to underrepresented groups in STEM. It is projected that from 2010-2015 there will be 54,400 jobs available for agriculture graduates. Only half of these are likely to be filled by graduates in an agriculture discipline; the other half will be filled by allied disciplines. The programs mentioned above are important in responding to this shortage.

Expanding and Enhancing the Biomanufacturing Workforce: The Administration has taken a strong leadership role in manufacturing—a sector that has helped lead the economic recovery over the past two years by adding over 400,000 jobs since the beginning of 2010. In order to maintain forward progress, NSF has established two new programs to fund transformative research to address the national need for sustainable materials and chemicals and train the next generation of scientists and engineers to fill this expanding workforce. The Sustainable Chemistry Engineering and Materials (SUSCHEM) program will promote development of a workforce to support the growth of a new sustainable and environmentally friendly chemical and materials manufacturing sector. The Sustainable Energy Pathways (SEP) program, part of the NSF-wide initiative on Science, Engineering, and Education for Sustainability, will provide resources for training of the workforce that will lead the renewable energy industry. The new SUSCHEM program, as well as the existing SEP programs, emphasize the importance of building strong interdisciplinary networks and environments for workforce development.

Preparing a Bioeconomy Workforce for Academic and Non-Academic Jobs

Creating New Approaches to Bioeconomy Workforce Training: In 2011, the NIH's National Institute for General Medical Sciences released its Strategic Plan for Biomedical and Behavioral Research Training. The new plan recommends actions to improve student development and diversity and addresses several challenging realities of the current biomedical and behavioral research training landscape, including: changing career outcomes for trainees, increased time to scientific independence, and lack of diversity in the biomedical workforce. Also in 2011, the NIH assembled a Biomedical Workforce Task Force to make recommendations in 2012 for actions that NIH should take to support a sustainable biomedical training infrastructure that provides incentives for updated training programs to prepare trainees for academic and industry careers.

Building an Entrepreneurial Bioeconomy Workforce: In October 2011, the FDA announced an intention to train "Young Entrepreneurs" through the provision of fellowships for business, engineering, and science students with entrepreneurial interests. The FDA plans to work with university business schools to establish a four- to six-month internship or training course within FDA small business offices to provide future entrepreneurs, venture capitalists and inventors with first-hand access to information about regulatory review and FDA approval processes.

Training and Hiring the Next Generation of Innovators: In 2011, the FDA announced its new Future Innovators program to bring together regulatory sciences and policy training to meet the scientific and technological demands of the 21st century. Under this competitive program, the FDA will expose candidates to important topics such as regulatory affairs, manufacturing, diagnostics, biomedical device engineering, and computational science, and will hire qualified candidates who show outstanding promise in their fields for positions within the FDA. Retention of some of the Future Innovators will help the FDA maintain a cadre of highly trained experts to sustain the FDA as needs and technologies evolve.

Leveraging Community Colleges and Industry in Workforce Development

Inspiring Undergraduate Engineering Students for Biomedical Careers: In 2011, NIH founded Design by Biomedical Undergraduate Teams (DEBUT), a creative challenge program that engages engineering undergraduates (including community college students) to accelerate the design and application of biomedical technologies for human health. In 2012, the first teams will apply in three challenge categories: diagnostics, therapeutics, and technology to aid underserved populations and individuals with disabilities. Each winning team will receive a $10,000 prize and will be honored at an award ceremony during the 2012 Annual Meeting of the Biomedical Engineering Society in Atlanta, GA.

Building American Skills through Community Colleges: As the largest component of the Nation's higher education system, community colleges enroll more than 7.6 million students—many of whom are older, working, or in need of remedial classes. Community colleges work with businesses and government to create tailored training programs that meet economic needs in areas such as advanced manufacturing and health information technology.

> *"In the coming years, jobs requiring at least an associate degree are projected to grow twice as fast as jobs requiring no college experience. We will not fill those jobs – or keep those jobs on our shores – without the training offered by community colleges."*
>
> *– President Obama, October 5, 2010*

In his Fiscal Year 2013 budget request, President Obama proposed a new Community College to Career Fund that would provide $8 billion to the Departments of Education and Labor to support State and community college partnerships with businesses to build the skills of 2 million American workers. This new investment would build upon other Administration initiatives to strengthen community colleges' capacity to meet employers' need for skilled workers in high-growth sectors of the economy. The Trade Adjustment Assistance Community College and Career Training (TAACCCT) grant program, funded at $2 billion over four years, builds the capacity of community colleges, in collaboration with businesses, to create career pathways, create education partnerships, and develop online courses enabling participants to complete training in two years or less for high-wage, high-skill occupations. The first round of $500 million in TAACCCT grants from the Department of Labor, in collaboration with the Department of Education, was awarded in September 2011. Skills for America's Future, an industry-led initiative that the Administration helped to launch in 2010, matches major employers with community colleges in every state to develop curricula and programs that will prepare graduates to excel in the workforce.

Bringing Expertise into Federal Agencies to Drive the Bioeconomy: In parallel with many of the comments provided by the public, the Administration identified the importance of insourcing expertise to empower positive change in Federal agencies. In 2011, the FDA announced its Entrepreneurs-in-Residence pilot program, aimed to engage more than a dozen outside experts with state-of-the-art business and medical device expertise to work alongside FDA staff. This pilot effort will focus initially on building a priority premarket review program for technologies that demonstrate potential to revolutionize disease treatment, diagnosis, or health care delivery and that target unmet medical needs.

Moving Forward: Federal agencies should develop incentives for institutions to adapt training to meet the needs of the 21st century bioeconomy workforce. Increasing industry participation in the development of training programs and education is a priority. Informing students about placement rates for recent graduates allows them to make educated choices about career placement. Although public comment was divided on whether industry or government should support professional student internships, there was agreement that internship opportunities are essential components of the evolving needs of a future bioeconomy workforce. In addition, training programs for PhD-level professionals should formally promote student awareness of PhD-level career opportunities outside of academia, including but not limited to industry, policy, law, finance, and journalism. Agencies should consider convening industry stakeholders from various sectors to assess the success of training programs to meet the needs of employers.

Fostering Partnerships

"We're all familiar with clusters like Silicon Valley. When you get a group of people together, and industries together, and institutions like universities together around particular industries, then the synergies that develop from all those different facets coming together can make the whole greater than the sum of its parts."

—President Obama, February 2011

Strategic Objective: Identify and support opportunities for the development of public-private partnerships and precompetitive collaborations—where competitors pool resources, knowledge, and expertise to learn from successes and failures.

The Nation's economy has always depended, above all, on a continuous flow of new technologies and new ideas into the marketplace. Partnerships between companies, universities, and the Federal government are key to leveraging investments, knowledge and experience in emerging technologies required for, and generated by, a bioeconomy (see inset for models of collaborative partnerships. For instance, many companies do not invest in early ideas because they are unlikely to pay off immediately. This is where the government plays a crucial role. The President has emphasized that universities and companies must complement Federal efforts by working together to invent, deploy, and scale the cutting-edge technologies that will create new jobs, spark new breakthroughs, and reinvigorate America today and in the future.

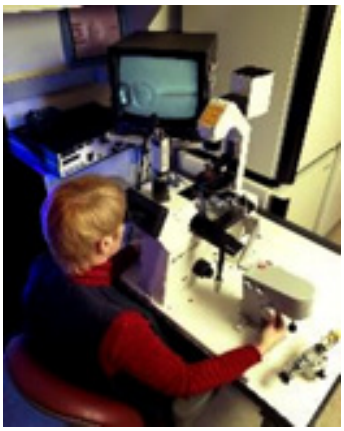
Models of Collaborative Relationships[54]

- Open-source initiatives
- Industry consortia for process innovation
- Discovery-enabling consortia
- Public–private consortia for knowledge creation
- Prizes
- Innovation incubators
- Industry complementors
- Virtual pharmaceutical companies

To advance this goal, President Obama launched the Advanced Manufacturing Partnership, a national effort that brings companies, universities, and the Federal Government together to invest in the emerging technologies that will create high-quality manufacturing jobs and enhance our global competitiveness. This concept is also driving the Startup America initiative's focus on building connections between established and new entrepreneurs. Through these efforts, the Administration is working to catalyze a new model of economic development

59. http://www.iom.edu/~/media/Files/Activity%20Files/Disease/NCPF/2009-FEB-Wkshp-on-Precompetitive-Collaboration/Altshuler.pdf

As shown below, Federal agencies are creating opportunities to support partnerships that will contribute to the bioeconomy.



Supporting Public-Private Partnerships to Find New Uses for Known Drug Compounds: The NIH plans to fund efforts to bring together industry and academic researchers to accelerate the "rescue" of abandoned pharmaceutical compounds and "repurposing" of approved products for novel therapeutic uses. In the proposed partnership, companies will provide previously proprietary compounds and their associated data to academic researchers who, with funding from NIH, will explore new uses to improve human health. This approach is bold in its scope in that it strives to identify novel uses for known industry compounds in preventing, treating, and curing disease.

Building Collaborations for Smarter Drug Design: Based on a successful 2011 NIH-industry workshop focused on developing a strategic approach to validating promising drug targets, NIH is organizing a joint NIH-Industry Target Validation Consortium, composed of experts from industry, academia, and NIH. NIH-supported scientists have created an impressively large collection of DNA and genome sequence data from diverse populations, including healthy people and disease patients. NIH and industry collaborators will use these data to better understand health and disease and provide high-value drug targets that companies can use for discovery and development of new diagnostics and therapeutics. Seventeen pharmaceutical and biotech companies attended the workshop and expressed enthusiasm for joining the consortium.

Collaborating to Develop Tools to Advance Whole Genome Sequencing from the Research Lab to the Clinic: At an international meeting of the American Society of Human Genetics in October 2011, NIST convened representatives from the FDA, CDC, and NIH with private-sector stakeholders to consider the tools needed to integrate DNA sequencing innovations into clinical practice. The future development of these tools, including reference materials, methods, and metrics, is envisioned to benefit from involvement by relevant stakeholders, such as regulators, producers, and consumers.

Supporting Innovation in Manufacturing of Biotherapeutics through Measurement Research: The NIST and the FDA are working with the biopharmaceutical industry to develop measurements and standards to support development, manufacturing, and regulatory approval of new protein therapeutics. NIST is working to develop fundamental measurement science, standards, and reference data to enable more accurate characterization of key attributes of protein drugs that are directly linked to their safety and efficacy. These tools are expected to promote improved manufacturing processes for protein products and more firmly underpin regulatory decisions.

Collaborating to Combat Alzheimer's Disease: The NIH, FDA, other Federal agencies, more than 20 pharmaceutical companies, and many others from the private sector created the Alzheimer's Disease Neuroimaging Initiative (ADNI), a groundbreaking study to identify subtle changes that take place in brains of older people before symptoms of Alzheimer's disease appear. Alzheimer's disease is a neurodegenerative disease that affects more than 5 million Americans, and there is currently no cure for this devastating disease. The first stage of the study has already produced valuable outcomes: pharmaceuti-

cal companies have begun using ADNI-validated disease markers, cutting down on clinical trial expense and length compared to the less precise cognitive measures that have traditionally been used in trials of Alzheimer's disease. As a continuation of the ADNI study, a team of researchers from the NIH, FDA, academia and pharmaceutical companies are collaborating to expedite the diagnosis and treatments of Alzheimer's disease using biomarker panels in both plasma and cerebrospinal fluid samples from patients. In February 2012, the Administration announced new investments in Alzheimer's research, including an additional $50 million for cutting-edge Alzheimer's research in Fiscal Year 2012 and an $80 million boost in funding for Alzheimer's research in the President's Fiscal Year 2013 budget.

Establishing Public-Partnerships for Food Security: The Administration supports approaches that address the root causes of hunger and poverty and forge long-term solutions to chronic food insecurity and under-nutrition. Through its new Feed the Future initiative (United States Agency for International Development, USDA and NIH), the Administration is helping developing countries transform their agricultural sectors to sustainably grow enough food to feed their people. In a complementary effort through its Basic Research to Enable Agricultural Development (BREAD) program, NSF partnered with the Bill and Melinda Gates Foundation to invest a total of $48 million over 5 years to support research carried out at U.S. academic institutions, while the Gates Foundation supports international partners via sub-awards from the U.S. awardees. Of the first round of projects announced in 2010, one project is already revolutionizing genome-wide selection of plants with desirable traits, and a 2011 award will affect cassava and banana breeding. These new tools can be applied to any crop, so while they benefit smallholder farmers in developing countries through BREAD, they will have similar impacts here in the United States.

Developing Innovative Approaches to New Biofuels Feedstock: Forecasting a need for improved genetic diversity for the biomass industry, USDA and DOE launched a new three-year public-private partnership in 2011 to improve biomass feedstock. Because sugarcane is one of the most efficient grasses in converting sunlight into sugar and biomass, the USDA focused efforts on developing a new sugarcane crop with additional desired traits, including increased yields in U.S. climates. A near-term aim of this public-private partnership is the planting of 3.1 million acres of cane crop worth $120 million on marginal lands in the southern regions of the United States.

Increasing Bioeconomy Agricultural Exports: President Obama supported the Renewable Energy and Energy Efficiency Export Initiative to spur the creation of millions of new jobs by 2015 and improve U.S. export competitiveness in renewable energy. One such industry whose exports expanded quickly is the wood pellet industry. In 2010, the United States exported $128 million of wood pellets. To further facilitate this export growth, in 2011 the USDA's Market Access Program committed to identifying and growing additional market

opportunities for wood pellet exports in the European Union. Additionally, the USDA recently expanded one of its regular international market reports to include production, consumption, and trade statistics for wood pellets with the goal of increasing knowledge of the global biomass industry.

Moving Forward: Federal agencies should provide incentives for precompetitive collaborations to benefit the bioeconomy broadly. Federal agencies should also identify public-private partnerships in health, energy, agriculture, and manufacturing to leverage Federal investments and industry investments and expertise. Public input supported the creation of new public-private partnerships with shared risk, defined responsibilities, and deliverables to achieve mutual benefit and grow the bioeconomy. In addition, to promote the bioeconomy, universities should be encouraged to partner with industry to advance the scientific enterprise and reward faculty researchers who do so.

Conclusion

The Administration has made great strides in harnessing biological research innovations to address national challenges in health, energy, food, environment, and manufacturing via the commercial economy. But there is much more to be done. The Administration plans to explore additional creative ideas for promoting U.S. leadership in the bioeconomy, such as innovative financing for translational research, increasing the impact of the SBIR program, and improving the ability of faculty and students to move from "idea to IPO," and will continue to accept public input by email at bioeconomy@ostp.gov.

By strategically shaping future R&D investments, improving commercialization of bioinventions, updating workforce training programs for new bioeconomy careers, reforming regulatory processes, and building new bioeconomy public-private partnerships, the Administration will help stimulate the growth of a high-wage, high-skill sector while improving the lives of all Americans.