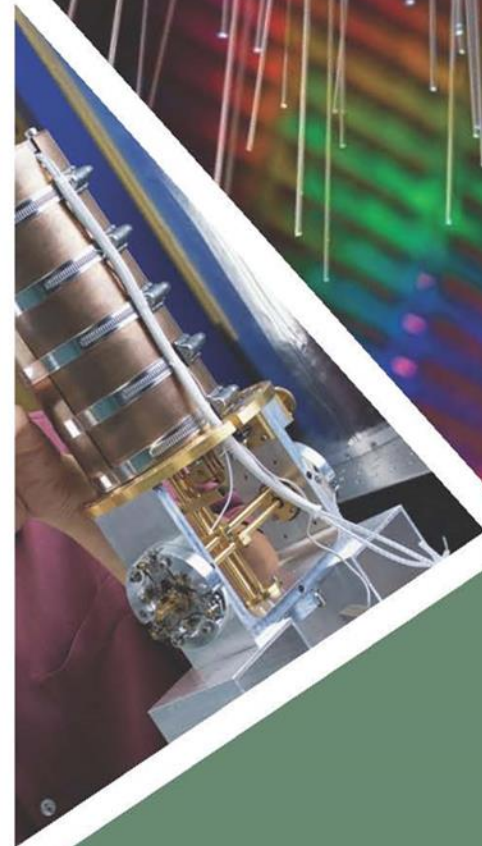
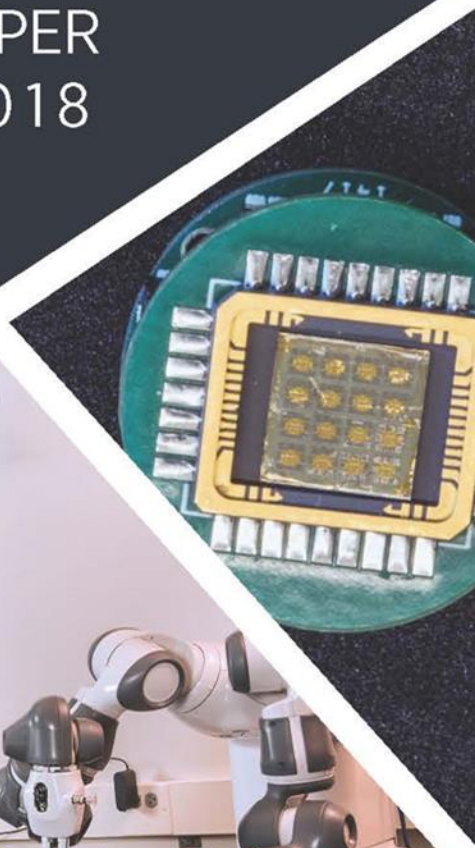


RETURN ON INVESTMENT INITIATIVE

TO ADVANCE
THE PRESIDENT'S
MANAGEMENT
AGENDA

DRAFT GREEN PAPER
DECEMBER 2018



UNLEASHING
AMERICAN
INNOVATION

NIST Special Publication 1234



PRESIDENT'S
MANAGEMENT
AGENDA

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Return on Investment Initiative for Unleashing American Innovation

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December 2018



U.S. Department of Commerce
Wilbur L. Ross, Jr., Secretary

National Institute of Standards and Technology
Walter Copan, NIST Director and Undersecretary of Commerce for Standards and Technology

DISCLAIMER STATEMENT

Any mention of companies or commercial products within this document is for information only; it does not imply recommendation or endorsement by NIST or the other Federal agencies participating in the Lab-to-Market cross agency priority goal of the President's Management Agenda.

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PREFACE

MESSAGE FROM UNDER SECRETARY OF COMMERCE FOR STANDARDS AND TECHNOLOGY

The Return on Investment (ROI) Initiative for Unleashing American Innovation is part of a national conversation that is designed to advance the Lab-to-Market cross agency priority (CAP) goal of the President's Management Agenda (PMA). The ROI Initiative's vision is to unleash American innovation into our economy. The goal is to maximize the transfer of Federal investments in science and technology into value for America in ways that will (a) meet current and future economic and national security needs in a rapidly shifting technology marketplace and enhance U.S. competitiveness globally, and (b) attract greater private sector investment to create innovative products, processes, and services, as well as new businesses and industries.

The PMA's Lab-to-Market CAP Goal is co-led by the U.S. Department of Commerce (DOC) via the National Institute of Standards and Technology (NIST) and the White House Office of Science and Technology Policy (OSTP). By statute, DOC is the lead Federal agency for technology transfer policy and practice. The Secretary of Commerce has delegated to NIST the stewardship for technology transfer policy, to promote and advance technology transfer, and to report on its progress to the Nation. Indeed, NIST's mission is to promote U.S. innovation and industrial competitiveness, serving also as the host organization for the Federal Laboratory Consortium for Technology Transfer (FLC) in convening America's Federal Laboratories. In these capacities, NIST is a partner with the Nation's R&D enterprise in seeking continued advancement of U.S. innovation.

As part of the ROI Initiative, NIST implemented an open, inclusive, and collaborative process to identify and assess options for supporting the ROI Initiative's overall goal and objectives. NIST's outreach efforts were designed to ensure that Federal R&D, intellectual property, and technology transfer stakeholders had an opportunity to provide inputs to inform this Green Paper. Our outreach included a Request for Information (RFI) published in the Federal Register, four public meetings, a summit hosted by NIST, and multiple stakeholder engagement sessions. The Green Paper also integrates findings from an extensive review of prior reports and studies related to federally funded R&D technology transfer policies and practices.

This Green Paper is a discussion document based on an assessment of the feedback from the U.S. stakeholder community. It provides an initial summary of key stakeholder inputs and identifies short-term and long-term actions to further enhance the U.S. innovation engine at the public-private interface. Implementation of any of the intended actions that require specific policy, legislative, and/or regulatory actions will be advanced via formal proposals subject to appropriate interagency review, and public comment. Our goal is to remove barriers to innovation, modernize partnering models and tools, expand entrepreneurial ecosystems, and create increased opportunities for returns to the American people from investment in R&D.

I am grateful to all stakeholders, especially those who submitted oral and written comments in response to the RFI and at ROI public forums throughout 2018, to the outstanding, dedicated team at NIST and the Office of Science and Technology Policy, to all the U.S. Federal science and technology agencies represented in the National Science and Technology Council and its Lab-to-Market Subcommittee, and to the Science and Technology Policy Institute (STPI) for your many contributions thus far.

Thank you for your continuing engagement in helping to chart this important course of action for the Nation.

Sincerely,

Walter G. Copan, Ph.D.
Under Secretary of Commerce for Standards and Technology
Director, National Institute of Standards and Technology



Senior Executive Branch Policy Officials at the Unleashing American Innovation Symposium, held at U.S. Institute of Peace, Washington, D.C. on April 19, 2018.

Shown: Michael Kratsios, Deputy Assistant to the President and Deputy U.S. Chief Technology Officer; Dr. Walter Copan, Under Secretary of Commerce for Standards and Technology, and Director, National Institute of Standards and Technology; United States Secretary of Commerce Wilbur L. Ross; Margaret Weichert, Deputy Director for Management, Office of Management and Budget; and Andrei Iancu, Under Secretary of Commerce for Intellectual Property and Director, United States Patent and Trademark Office.

EXECUTIVE SUMMARY

The United States (U.S) has led the world in innovation, research, and technology development since World War II, but that leadership is being challenged on a global scale. At risk is America's leadership in industries of the future such as artificial intelligence, quantum computing, and robotics. In combination with the rapid, foundational advances in technology, innovation has never been more critical to U.S. economic competitiveness and national security than it is today.

The President's Management Agenda (PMA), released March 20, 2018, lays out a long-term vision for modernizing the Federal Government for the 21st Century. The Return on Investment (ROI) Initiative directly supports the PMA and is designed to unleash American innovation. ROI refers here to the economic and national security return to the Nation based on the investment in Federal research and development (R&D) by the American people.

The U.S. innovation system is substantially fueled by the discoveries and inventions arising from federally funded R&D at the Nation's universities, research institutes, and Federal Laboratories. The Bayh-Dole and Stevenson-Wydler Acts were transformational for the U.S. when enacted in 1980, providing clarity of intellectual property ownership for the public good, and incentivizing the commercial development of inventions for U.S. economic impact. These landmark pieces of legislation, as well as their subsequent updates, have served America well.

The Bayh-Dole Act predominantly deals with ownership of inventions made with Federal funding. Specifically, it allows companies, nonprofits, and universities to retain title to federally funded R&D inventions to facilitate their further development. With the Stevenson-Wydler Act, each Federal agency that carries out and sponsors R&D has been given the mandate, as part of its agency's mission, to secure intellectual property rights and to contribute directly to U.S. innovation through technology transfer. Federal agencies are obligated to communicate the benefits of those inventions having potential economic value to the private sector, and to effectively transition them for use by American companies and entrepreneurs. With these legislative acts, the technology transfer profession was born—and the results for the U.S. economy have continued to grow ever since.

The competitive environment for the U.S. has changed dramatically since implementation of the Bayh-Dole and Stevenson-Wydler Acts and their amendments in subsequent technology transfer legislation. This legislative framework has been widely emulated around the world and further adapted. Technology transfer and its practices have advanced substantially as the pace of innovation continues to accelerate globally. Shorter product life cycles, disruptive business models, new partnering strategies, and globalized R&D and supply chains are enabled by revolutionary advances in digital, communications, biological, materials, and quantum technologies.

As part of ROI Initiative, this Green Paper addresses the critical need to modernize the U.S. system of technology transfer and innovation for the 21st Century. Although Federal technology transfer laws and activities have served the Nation well over nearly four decades and continue to support innovation, the U.S. is continuing to lose ground to competition.

U.S. economic competitiveness is strengthened by the ability of private sector-companies to advance the new technologies resulting from basic R&D, and to deliver the products and services that drive the Nation's economy forward. This ecosystem has allowed the U.S. to enjoy the economic benefits of advancing science and technology and has kept the Nation prosperous and strong. The partnership between Federal R&D and the private-sector has proven to be an effective model. In 2017 alone, the Federal Government invested approximately \$150 billion in R&D—about one-third at Federal Laboratories across the country and two-thirds at universities and private-sector R&D institutions. Federal R&D funding represents about one-third of all U.S. R&D spending.

Measures of technology transfer in the U.S. from 1996 to 2015 demonstrate over \$1 trillion in economic growth and millions of new jobs. Critical technologies such as life-saving drugs, vaccines, and medical devices, the internet, global positioning system or GPS, and countless other innovations underpinning every aspect of the American way of life are traceable to groundbreaking work at Federal Laboratories, federally funded universities, and private sector R&D organizations. Removing impediments to effective technology transfer and collaboration will accelerate economic value creation.

The PMA includes the Lab-to-Market (L2M) cross agency priority (CAP) goal, which aims to improve the transfer of technology from federally funded R&D to the private sector to promote U.S. economic growth and national security. The L2M CAP Goal is organized around the five strategies, which also serve as the organization for the chapters in this green paper:

1. Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices;
2. Increase engagement with private sector technology development experts and investors;
3. Build a more entrepreneurial R&D workforce;
4. Support innovative tools and services for technology transfer; and
5. Improve understanding of global science and technology trends and benchmarks.

Each of the strategy chapters is organized to provide an introductory background, note the challenges, and explain intended actions to streamline Federal technology transfer policies and practices and accelerate the transfer of technology to the private sector. The intended actions include best practice sharing, policy guidance, statutory improvements, and clarification of statutory provisions through regulatory changes, which are directed at reducing government bureaucracy and cutting red tape to accelerate innovation. A succinct summary of the intended actions is in the following table.

Return on Investment Initiative – Summary of Intended Actions

Strategy 1 Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices
Government Use License: Define the scope of the “government use license”
March-In Rights: Define the circumstances under which the government may exercise march-in rights to license further development of an invention to achieve practical application
Preference for U.S. Manufacturing: Protect and strengthen U.S. manufacturing; streamline waiver process in accordance with statute
Software Copyright: Establish copyright for software products of Federal Government R&D
Trade Secrets: Expand authority to protect trade secrets
Strengthen Technology Transfer at Federal Laboratories: Streamline Federal Laboratory technology transfer policies and practices
Presumption of Government Rights to Employee Inventions. Provide for a present assignment of invention rights and streamline rights determination processes
Strategy 2 Increase engagement with private sector technology development experts and investors
Streamline Partnership Mechanisms: Establish consistency in legislative interpretation and use of best practices
New/Expanded Partnership Mechanisms: Authorize new and expanded mechanisms to establish partnership agreements and nonprofit foundations
Technology Maturation Funding: Allow limited use of R&D funding awards for intellectual property protection; work with Small Business Administration for Small Business Innovation Research
Strategy 3 Build a more entrepreneurial R&D workforce
Technology Entrepreneurship Programs: Establish technology entrepreneurship programs at Federal R&D agencies government-wide
Managing Conflicts of Interest: Implement government-wide requirements to better manage conflicts of interest to promote entrepreneurship
Strategy 4 Support innovative tools and services for technology transfer
Federal IP Data Reporting System(s): Establish a modern platform for reporting data on intellectual property resulting from Federal R&D
Access to Federal R&D Assets: Establish a federated data portal that is easy for the public to access, use, and analyze
Strategy 5 Improve understanding of global science and technology trends and benchmarks
Benchmarking and Metrics: Establish metrics to better capture, assess, and improve Federal R&D outcomes, impacts, and operational processes

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INTRODUCTION

Since the 19th Century, American economic prosperity and national security have been based upon innovation—the process of invention and commercialization of new ideas into products and services in the marketplace. Victory in World War II was enabled by technological pre-eminence—radar, atomic weapons, gyroscopic bomb sights—and the production of goods on a mass scale.

The United States (U.S.) has led the world in innovation, research, and technology development since World War II, but that leadership is being challenged on a global scale.¹ Unlike many of its global competitors, the U.S. economic system relies on the strength of private sector companies to produce the new technologies that result from research and development (R&D) to deliver the goods and services that drive the nation’s economy forward. The partnership between Federal R&D, through Federal Laboratories and Federal funding for R&D at external organizations, and the private sector has proven to be an effective model.

The intimate connection between a competitive economy and national security is recognized at the highest level. In the Administration’s “National Security Strategy of the United States,”² President Donald J. Trump states “Economic security is national security.” Pillar II of the Strategy, “Promote American Prosperity,” highlights the need to “Lead in Research, Technology, Invention, and Innovation” as a key goal and identifies four objectives:

- Understand worldwide science and technology trends,
- Attract and retain inventors and innovators,
- Leverage private capital and expertise to build and innovate, and
- Rapidly field inventions and innovations.

America’s future competitiveness will be driven in part by our ability to capture the economic and national security benefits of emerging technologies. U.S. leadership in advanced technology development, however, is threatened by a number of converging factors including declining domestic manufacturing, the relocation of technology-intensive R&D abroad, and the changing rules around intellectual property development.³ American leadership in industries of the future

¹ National Science Foundation. 2018. “Science and Engineering Indicators 2018.”
<https://nsf.gov/statistics/2018/nsb20181/digest/sections/introduction>

² The White House, Washington, D.C. December 2017.

³ Department of Defense. 2018 “Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States.”
<https://defense.gov/StrengtheningDefenseIndustrialBase>

such as artificial intelligence, quantum computing, Internet-of-Things, advanced manufacturing, and robotics is at risk. Over the remainder of this century, these emerging industries will help redefine the battlefield of the future as well as how Americans live.

The Federal Government’s continued investment in a broad range of fundamental and mission-oriented scientific and engineering R&D is a crucial innovation driver for the Nation, supporting job creation, national security, economic growth, and global competitiveness. These investments, along with continued collaboration and partnerships with private sector businesses, are critical for the U.S. to remain the preeminent world leader of scientific discovery, invention, and globally competitive innovations. Reliable and predictable intellectual property rights are essential to incentivize innovation and encourage private sector investment in R&D.⁴ In combination with the rapid, foundational advances in technology, innovation has never been more critical to U.S. economic competitiveness and national security than it is today. The “American system” of technology transfer is a distinctive comparative advantage in the global marketplace, and America must extract all possible value from its significant investment of human and capital resources.

To ensure that American taxpayers are reaping the full benefit of R&D investments and that the United States is strengthening its economic competitiveness and national security, the Federal Government is working to move the Nation to a new level of innovation performance that will increase the taxpayers return on *their* investment in federally funded R&D. This green paper identifies critically needed actions to “unleash American innovation” by removing systemic barriers and strengthening partnerships between government, industry, and academia.

AMERICAN INNOVATION FRAMEWORK

The American innovation ecosystem is the envy of the world, advancing science and technology and making the Nation prosperous and strong. The essence of the innovation process involves bringing inventions arising from Federal investment in science and technology (S&T) to the private sector, attracting private capital to further invest in their development, and then launching and advancing them successfully in practical commercial use. Excellence in each stage of R&D—discovery, translation, and innovation—is vital to America’s global competitiveness.

⁴ National Science and Technology Council, Committee on Technology, Subcommittee on Advanced Manufacturing. 2018. “Strategy for American Leadership in Advanced Manufacturing.”

In 2017, the Federal Government invested approximately \$150 billion in R&D—about one-third at Federal Laboratories across the country and two-thirds at universities and private sector R&D institutions.⁵ Federal R&D funding represents about one-third of all U.S. R&D spending.⁶ The Federal Government fills a crucial gap in the innovation process by funding R&D in areas of critical importance to the Nation. Often, these R&D topics do not carry a strong enough immediate financial incentive for R&D investment by the private industry sector. Federal R&D investment priorities adapt to changing National needs and Administration priorities, with the expectation that this investment will strengthen the Nation's innovation base and position the United States for unparalleled job growth, continued prosperity, and national security.⁷ For example, current Administration R&D priorities include security; artificial intelligence (AI), quantum information sciences, and strategic computing; connectivity and autonomy; manufacturing; space exploration and commercialization; energy; medical innovation; and agriculture.

The discoveries that result from American R&D efforts must be transferred from the laboratory to the marketplace through innovations that bring products and services to consumers more quickly. Protection of intellectual property rights is often necessary to achieve this transfer by establishing partnerships with industry for commercial adoption. The U.S. Constitution enshrined the critical importance of private rights in innovation as an enduring, foundational principle that would sustain and guide the Nation:

“Congress shall have power...to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”⁸

⁵ There are over 300 Federal Laboratories, including Government-Owned, Government-Operated (GOGO) Laboratories, Government-Owned, Contractor-Operated (GOCO) Laboratories, and Federally Funded Research and Development Centers (FFRDCs). For further information, see Analytical Perspectives, Budget of the United States Government, Fiscal Year 2019, Ch. 18, <https://www.gpo.gov/fdsys/pkg/BUDGET-2019-PER/pdf/BUDGET-2019-PER.pdf>.

⁶ National Science Board. 2018. “Science and Engineering Indicators 2018.”

⁷ Office of Management and Budget & Office of Science and Technology Policy, FY 2020 Administration R&D Budget Priorities, Memorandum for the Heads of Executive Departments and Agencies, M-18-22, July 31, 2018.

⁸ Article I, Section 8 of the U.S. Constitution establishing the Legislative Branch.

Since then, the Federal Government has provided the framework for technology transfer through several laws, executive orders, and regulations.⁹ Federal technology transfer laws and activities have served the Nation well over nearly four decades, and continue to support U.S. innovation.¹⁰ From 1996 to 2015, contributions to the U.S. economy from academic technology transfer alone included up to \$1.3 trillion in gross industrial product, \$591 billion in gross domestic product, and 4.3 million jobs.¹¹ Critical technologies such as life-saving drugs, vaccines, and medical devices, the internet, global positioning system or GPS, and countless other innovations underpinning every aspect of the American way of life are traceable to groundbreaking work at Federal Laboratories and at federally funded universities and private sector R&D organizations.

While substantial positive benefits continue to accrue from Federal R&D investments, the United States can do better to resolve barriers that inhibit realizing the largest and broadest commercial, economic, and national security returns possible from these investments. There are significant challenges in effectively transferring the technology, knowledge, and capabilities resulting from Federal R&D investments to the private sector. Potentially valuable technologies, created at taxpayer expense, can remain in laboratories due to systemic barriers that limit opportunities to move these innovations to the commercial marketplace. The intended actions described in this green paper aim to enhance the American innovation framework and maximize the ROI to the American taxpayer.

⁹ The term “technology transfer” refers to the broad range of mechanisms used to transfer technology, knowledge, and capabilities resulting from federally funded R&D to productive uses, and, where appropriate, commercialization.

¹⁰ For further information on relevant technology transfer legislation, see Federal Laboratory Consortium for Technology Transfer (FLC). 2013. FLC Technology Transfer Desk Reference, <https://www.federallabs.org/media/publication-library/flc-technology-transfer-desk-reference>; and FLC. §2013. The Green Book, <https://www.federallabs.org/media/publication-library/federal-technology-transfer-legislation-and-policy-the-green-book>.

¹¹ Estimates based on contributions of patent licensing activity; estimates do not include broad-based spillover benefits to the U.S. economy, see Association of University Technology Managers (AUTM). 2016. Driving the Innovation Economy, <https://www.autm.net/AUTMMain/media/SurveyReportsPDF/AUTM-FY2016-Infographic-WEB.pdf>.

THE PRESIDENT'S MANAGEMENT AGENDA

The President's Management Agenda (PMA), released March 20, 2018, lays out a long-term vision for modernizing the Federal Government for the 21st Century in key areas that will improve the ability of Federal agencies to deliver mission outcomes, provide excellent service, and effectively steward taxpayer dollars on behalf of the American people.¹² This green paper establishes a framework for enacting the vision put forth in the PMA through intended actions that will result in real improvements in how Federal Laboratories and federally funded universities and private sector R&D organizations support economic development through research and innovation.

THE PMA VISION

The PMA's vision for reform is to enable the Federal Government to adapt to changing needs over time, with a focus on pursuing deep-seated transformation rather than short-term fixes. The reform agenda identifies five root cause challenges facing the Federal Government to meet the needs of the 21st Century: 1) accumulated regulatory burden, 2) structural issues, 3) decision-making and processes, 4) leadership and culture, and 5) capabilities and competencies. To get traction on these complex and interconnected challenges, the PMA recognizes the need for broader, system-level thinking across agencies and functional disciplines for a whole-of-government effort to tackle barriers to change.

The PMA established Cross-Agency Priority (CAP) Goals targeting 14 specific areas in which multiple agencies must collaborate to effect change and report progress in a manner that the public can easily track. Each CAP Goal is expected to move from vision to action by acknowledging shortcomings, setting a modern vision, and delivering on concrete goals that adapt Federal programs, capabilities, and the Federal workforce to efficiently, effectively, and, through an accountable approach, meet mission demands and public expectations. CAP Goals report quarterly, providing the public an open and transparent assessment of the progress being made on milestones and key performance indicators.¹³

THE LAB-TO-MARKET CAP GOAL

The Lab-to-Market (L2M) CAP Goal aims to improve the transfer of technology from federally funded R&D to the private sector to promote U.S. economic growth and national

¹² White House. 2018. President's Management Agenda, <https://www.whitehouse.gov/wp-content/uploads/2018/03/The-President%E2%80%99s-Management-Agenda.pdf>.

¹³ Quarterly CAP Goal reports publish in March, June, September, and December at <https://www.performance.gov/>

security. The L2M CAP Goal is designed to enable the United States to adapt to a rapidly changing global innovation landscape by:

- Improving the transition of federally funded innovations from the laboratory to the marketplace by reducing the administrative and regulatory burdens for technology transfer and increasing private sector investment in later-stage R&D;
- Developing and implementing more effective partnering models and technology transfer mechanisms for Federal agencies; and
- Enhancing the effectiveness of technology transfer by improving the methods for evaluating the investment returns and economic and national security impacts of federally funded R&D and using that information to focus efforts on successful approaches.

The L2M CAP Goal charges agencies to develop and implement stakeholder-informed action plans, which may include improved Federal practices and policies, regulatory reform, and legislative proposals; increased interactions with private-sector experts; identification, sharing, and adoption of best practices for technology transfer; and increased transfer of federally funded innovations from laboratory to market.

The L2M CAP Goal is co-led by the Department of Commerce (DOC) via the National Institute of Standards and Technology (NIST) and the White House Office of Science and Technology Policy (OSTP). Other participating agencies include the Office of Management and Budget (OMB), the Departments of Agriculture, Defense, Commerce, Education, Energy, Health and Human Services, Homeland Security, Interior, Transportation, and Veterans Affairs, the Environmental Protection Agency, the National Aeronautics and Space Administration (NASA), the National Science Foundation (NSF), and the Small Business Administration (SBA). The National Science and Technology Council (NSTC), through its Lab-to-Market Subcommittee (L2M SC), is working to coordinate, review, and implement interagency priorities related to the L2M CAP Goal. Other supporting interagency groups include the Interagency Working Group on Technology Transfer (IAWGTT), the Interagency Working Group on Bayh-Dole (IAWGBD), the Federal Laboratory Consortium for Technology Transfer (FLC), the Small Business Innovation Research (SBIR) Project Managers Working Group, and the Innovation Corps™ (I-Corps™) Community of Practice.¹⁴

¹⁴ For further on the L2M CAP Goal supporting organizations, see NIST. Lab to Market, <https://www.nist.gov/tpo/lab-market>.

RETURN ON INVESTMENT INITIATIVE

On April 19, 2018, NIST, in coordination with OSTP, launched the Return on Investment (ROI) Initiative to advance the PMA and its L2M CAP Goal. The ROI Initiative was formally announced at the Unleashing American Innovation Symposium, in which leaders from across government, industry, and academia exchanged views on current obstacles, best practices, and potential solutions to address systemic barriers to catalyze the full potential of American innovation (Figure 1).

The ROI Initiative's vision is to “unleash American innovation” into our economy and its goal is to “maximize the transfer of Federal investments in science and technology into value for America in ways that will (a) meet current and future economic and national security needs in a rapidly shifting technology marketplace and enhance U.S. competitiveness globally, and (b) attract greater private sector investment to create innovative products, processes, and services, as well as new businesses and industries.”



Figure 1. Federal panelists at the Unleashing American Innovation Symposium, held at U.S. Institute of Peace, Washington, D.C. on April 19, 2018.

Shown: Michael Kratsios, Deputy Assistant to the President and Deputy U.S. Chief Technology Officer; Dr. Christopher Austin, Director, National Center for Advancing Translational Sciences, National Institutes of Health; Dr. France Córdova, Director, National Science Foundation; Andrei Iancu, Under Secretary of Commerce for Intellectual Property, and Director, United States Patent and Trademark Office; and Dr. Walter Copan, Under Secretary of Commerce for Standards and Technology, and Director, National Institute of Standards and Technology.

The objectives of the ROI Initiative are to “assess and, where appropriate, streamline and accelerate the transfer of federally funded technology by (a) identifying critically needed improvements to Federal technology transfer policies, practices, and efforts; and (b) seeking broad input from Federal R&D, intellectual property (IP), and technology transfer stakeholders.”

THE ROI GREEN PAPER

As part of the ROI Initiative, NIST implemented an open, inclusive, and collaborative process to identify and assess options for supporting the ROI Initiative’s objectives. This green paper identifies a set of intended actions—based on careful consideration of stakeholder input—to reduce or remove barriers and facilitate accelerated technology transfer in ways that will improve the return on federally funded R&D investment as well as further the missions of Federal agencies.

INPUTS TO THE GREEN PAPER

NIST engaged in several outreach efforts to ensure that Federal R&D, intellectual property, and technology transfer stakeholders had an opportunity to provide inputs to inform this green paper. This outreach included a Request for Information (RFI) published in the *Federal Register*, four public meetings, a summit hosted by NIST, and multiple stakeholder engagement sessions:

- The RFI requested responses on topics related to Federal technology transfer principles and practices, challenges, and solutions to improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D investments.¹⁵
- Four public meetings were held to gather stakeholder feedback and comments: San Jose, CA (May 17, 2018); Denver, CO (May 21, 2018); Chicago, IL (May 31, 2018); and Gaithersburg, MD (June 14, 2018).
- The Maryland Technology Transfer Summit, held on April 20, 2018, was organized by the Maryland Department of Commerce and hosted by NIST. The event included

¹⁵ 83 FR 19052. *Request for Information Regarding Federal Technology Transfer Authorities and Processes*, May 1, 2018, <https://www.federalregister.gov/documents/2018/05/01/2018-09182/request-for-information-regarding-federal-technology-transfer-authorities-and-processes>.

Federal and State policy makers, industry leaders, technology managers, and universities and research institutes, among others.¹⁶

- NIST hosted multiple stakeholder engagement sessions.¹⁷

In addition, this green paper integrates findings from an extensive review of prior reports and studies related to federally funded R&D technology transfer policies and practices (refer to References).

DEFINITIONS USED IN THE GREEN PAPER

In this green paper, ROI is not intended to be defined in classic economic terms. Instead, ROI as used here takes a broad approach that emphasizes the underlying social and public mission inherent in the development of Federal research into products and services benefiting American taxpayers. The “return” is interpreted to encompass a wide variety of benefits of technology transfer, both tangible and intangible to the investor, namely American citizens. It should not be viewed in the narrow context of revenue generation, but rather as contributions to broader economic prosperity, national security, and societal impact. The “return” is to the American society as a whole in accordance with each agency’s statutory mission. “Investment” refers to federally funded R&D both performed by the government (intramural) and by universities and the private sector (extramural).

In the context of Federal activities, technology transfer often refers to the movement of knowledge and results—such as products, techniques, tools, data, and inventions—from intramural Federal R&D out of laboratories and into practical application.¹⁸ Given that about two-thirds of Federal R&D expenditures support research by non-Federal scientists and engineers,

¹⁶ Maryland Department of Commerce and National Institute of Standards and Technology. “2018 Maryland Technology Transfer Summit.” <https://www.nist.gov/news-events/events/2018/04/2018-maryland-technology-transfer-summit>.

¹⁷ Including the NIST Visiting Committee on Advanced Technology, the Association of University Technology Managers, the Licensing Executives Society, the Council on Government Relations, the Council on Competitiveness (Technology Leadership and Strategy Initiative), the State Science and Technology Institute, FLC, the Association of Public and Land Grant Universities (Commission on Innovation, Competitiveness, and Economic Prosperity), the Association of American Universities (Council on Federal Relations), and the American Chemical Society (Chief Technology Officers Summit).

¹⁸ NAS. 1997. *Enabling America: Assessing the Role of Rehabilitation Science and Engineering*, <https://www.nap.edu/read/5799/chapter/1>

technology transfer, for the purposes of this green paper, also encompasses the activities of these extramural partners. In addition, throughout this green paper, “the process by which existing knowledge, facilities, or capabilities developed under Federal research and development (R&D) funding are used to fulfill public and private need” is referred to as technology transfer.¹⁹

STRUCTURE OF THE GREEN PAPER

The L2M CAP Goal is executed through five strategies that also form the foundation for how this green paper is organized:

1. Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices;
2. Increase engagement with private sector technology development experts and investors;
3. Build a more entrepreneurial R&D workforce;
4. Support innovative tools and services for technology transfer; and
5. Improve understanding of global science and technology trends and benchmarks.

Each chapter in this green paper provides an introductory background, notes the challenges, and explains intended actions to streamline and accelerate Federal technology transfer policies and practices. Implementation of any of the intended actions that require specific policy, legislative, and/or regulatory actions will be advanced via formal proposals subject to appropriate interagency review, and public comment. The final chapter of the green paper summarizes the intended actions to overcome systemic challenges raised by technology transfer stakeholders that will unleash American innovation and provide even greater return on investment to the American taxpayer.

¹⁹ Federal Laboratory Consortium for Technology Transfer (FLC). 2013. *FLC Technology Transfer Desk Reference: A Comprehensive Introduction to Technology Transfer*. Cherry Hill: Federal Laboratory Consortium for Technology Transfer.

STRATEGY 1. IDENTIFY REGULATORY IMPEDIMENTS AND ADMINISTRATIVE IMPROVEMENTS IN FEDERAL TECHNOLOGY TRANSFER POLICIES AND PRACTICES

The first of the five strategies of the L2M CAP Goal is focused on identifying and reducing regulatory impediments and administrative barriers in Federal technology transfer policies and practices.²⁰ The intended actions are designed to make it easier for industry to work with Federal Laboratories and access federally funded R&D by removing both real and perceived barriers.

The ownership and transfer of federally funded science and technology developed at government institutions, universities, and corporations is governed by a series of laws and associated regulations and policy that originally date back to the 1980s. While the basic structure is still strong, the environment has changed dramatically, and updates are needed. Federal agencies and their laboratories are responsible for managing intellectual property and research partnerships independently based on the overall framework, thereby facilitating the transfer of technology through a distributed approach. The distributed approach allows Federal agencies to align their technology transfer efforts with the mission focus of their R&D, but this mission-based variability between agencies makes it more difficult to identify and address systemic barriers.

This chapter describes ways to address the first L2M CAP Goal strategy to address barriers that slow or prevent technology transfer. While the Bayh-Dole Act and Stevenson-Wydler Act provide essential authorities that facilitate the transfer and translation of federally funded R&D to innovative products, processes, and services for the American people, there are numerous provisions that would benefit from clarification. A common concern noted throughout the RFI responses are the variations across agency technology transfer policies and practice because of differing authorities between agencies as well as differing interpretations of shared legislation guiding technology transfer efforts.

²⁰ President's Management Agenda (PMA), *Cross-Agency Priority Goals: Improve Transfer of Federally-Funded Technologies from Lab-to-Market*; released March 20, 2018. https://www.performance.gov/CAP/CAP_goal_14.html

A. INTRODUCTION

In the early 1980s, Congress passed the first two of a series of laws that are designed to enable the further development of federally funded inventions: the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480)²¹ and the Bayh-Dole Act of 1980 (P.L. 96-517).²² Stevenson-Wydler Act, as amended, governs how Federal Laboratories transfer technology to non-Federal entities, and enables Federal entities to provide access to Federal Laboratory assets (both researchers and facilities) to outside organizations through research partnerships and other means.²³ These laws require each laboratory with 200 or more technical staff to have an office dedicated to technology transfer,²⁴ mandate that technology transfer be a responsibility of all science and engineering professionals consistent with their mission responsibilities,²⁵ and establish a principle of royalty sharing for Federal inventors.²⁶ Congress also encouraged access to government researcher expertise and laboratory facilities by establishing a mechanism called a Cooperative Research and Development Agreement (CRADA), which can be used to form public-private partnerships with other Federal agencies, State or local governments, industrial organizations, and nonprofit organizations including universities.²⁷ To encourage commercial development of products developed under a CRADA, the CRADA partners receive preferential rights to license intellectual property developed under the partnership.²⁸

The Bayh-Dole Act established uniform rules that allow companies, nonprofits, and universities to retain title to federally funded research inventions in order to facilitate their further

²¹ P.L. 96-480, codified at 15 U.S.C. §§ 3701-15.

²² P.L. 96-517, codified at 35 U.S.C. §§ 201-14, Also known as the University and Small Business Patent Procedures Act of 1980.

²³ Trademark Clarification Act of 1984 (P.L. 98-620); Federal Technology Transfer Act of 1986 (P.L. 99-502); National Competitiveness Technology Transfer Act of 1989 (P.L. 101-189); National Technology Transfer and Advancement Act of 1995 (P.L. 104-113); Technology Transfer Commercialization Act of 2000 (P.L. 106-404)

²⁴ 15 U.S.C. § 3710(b) Establishment of Research and Technology Applications Offices

²⁵ 15 U.S.C. §3710(a)(2)

²⁶ 15 U.S.C. §3710c – Distribution of royalties received by Federal Agencies

²⁷ 15 U.S.C. § 3710a – Cooperative research and development agreements

²⁸ 15 U.S.C. § 3710a(b)(1)

development.²⁹ This right is limited to patentable inventions that arise from federally funded research and is subject to a few limitations to protect U.S. taxpayer investment, namely U.S. manufacturing preference, government use licenses, and march-in rights to ensure commercialization.³⁰ Through this law and amendments, Congress also incentivized the commercialization of federally funded inventions by requiring that the inventor get a share of the royalties.³¹ Bayh-Dole and amendments also allow Federal agencies and Government-Owned, Government-Operated (GOGO) Laboratories to issue exclusive licenses to government-held patents for the full life of the patent.³² Bayh-Dole and amendments allow the contractors who operate Government-Owned, Contractor-Operated (GOCO) Laboratories to hold title and make commercialization decisions to patents of GOCO Laboratory-developed inventions.

The *Economist Technology Quarterly* called Bayh-Dole, “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half century...this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers’ money.”³³

Private investment, practical application of innovations, and economic growth depend on a strong system of IP protection. The Leahy-Smith America Invents Act³⁴ (AIA) was enacted in 2011 to modernize the U.S. patent system and, among other things, better align it with other systems by instituting a first-inventor-to-file system rather than the former first-to-invent system. Several RFI comments were received about updating the AIA and its implementation by U.S. Patent and Trademark Office (USPTO). (Refer to “What We Heard: America Invents Act.”) NIST will communicate the RFI input received to the USPTO. All supporting interagency groups related to technology transfer will assist USPTO as needed to evaluate the received input and work collaboratively to support a strong IP system in the U.S.

²⁹ 35 U.S.C. § 202 – Disposition of rights.

³⁰ 35 U.S.C. § 204 – Preference for United States Industry, 15 U.S.C. § 3710a(b)(1)(A) government use license, 35 U.S.C. § 203 – March-in rights

³¹ 35 U.S.C. § 202(c)(7)

³² 35 U.S. Code § 209 - Licensing federally owned inventions

³³ *Innovation’s golden goose*. The Economist Technology Quarterly. Dec. 2002.
<https://www.economist.com/technology-quarterly/2002/12/12/innovations-golden-goose>

³⁴ Public Law 112–29 https://www.uspto.gov/sites/default/files/aia_implementation/20110916-pub-l112-29.pdf

What We Heard: America Invents Act

There were numerous suggestions and data presented related to AIA and its implementation through USPTO rules. Below is a summary of what we heard from the RFI:

- Allow Small Entity Status (SES) for university or small business entities leading patent prosecution of jointly-owned inventions with Federal agency or agencies.
- Consider changes to the Patent Trial and Appeal Board Proceedings, particularly around Inter Partes Review (IPR).
 - Address perception that IPR introduces asymmetries into the patent system that disadvantage patent holders and create uncertainty that discourages investment.
 - Address perception that IPR treats patent review as a hybrid form of continued examination and generally denies the due process that patents were supplied in the courts.
 - Harmonize the IPR claim construction standard with the Federal courts and International Trade Commission; and apply the same the burden of proof standard in IPR proceedings that is applied by the Federal district courts.
 - Consider comments that IPR implementation deprives patent owners of basic due process, exposes patent claims to varying and inconsistent standards of review as between USPTO and Article III proceedings, unduly restricts amendment of claims under review, and denies patent owners quiet title in this important property right.
- Remedy situations where inventors prevail against infringers but cannot secure injunctions halting unauthorized sales of their discoveries.
- Address concerns that the grace period under the AIA has been negated by the implementing regulations.
- Clarify the scope of patent eligible subject matter based on AIA and Supreme Court rulings.
- Explore actions to reduce the burden of patent owners facing serial challenges brought by parties having no standing in court; without freedom from the cloud of challenge throughout the entire patent life, patent owners face diminishing confidence, investment, product development and commercialization, and new business formation.
- Restore the right of patent holders to sue for damages if their patents are subject to reexamination based on false evidence or other abuse, harmed by fraud on the court, or abuse of process.

B. GOVERNMENT USE LICENSE

1. BACKGROUND

The government use license refers to the “nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government,” that applies to any federally funded invention. While there are slight differences in statutory language, the government use license applies to inventions stemming

from research partnerships with Federal Laboratories (15 U.S.C. § 3710a(b)(1)(A)),³⁵ Federal employee inventions (15 U.S.C. § 3710d(a)),³⁶ and federally funded inventions produced by contractors and grantees (35 U.S.C. §202(c)(4)).³⁷ The primary benefit of the government use license is that the government can use research that it funded for its mission-driven purposes without a threat of legal challenges for patent infringement.³⁸ It has been long recognized that government use includes direct use by the agency for its own acquisition purposes, even if this may involve a different contractor.^{39,40}

2. CHALLENGES

RFI respondents commented that the purpose of the government use license needed to be clarified and its use should be construed consistently and narrowly. It was also noted that an overly broad interpretation of this right was contrary to the stated intent of the Bayh-Dole Act to allow rights to be elected and retained by the contractor. In addition, GAO found that there were few statistics on how often Federal agencies exercise their use rights.⁴¹ While disseminating statistics on Government use would be helpful, it is nevertheless important to better define the circumstances under which use of the government use license would be appropriate consistent with the original legislative intent.

³⁵ “A nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.”

³⁶ “...subject to reservation by the Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.”

³⁷ “...the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world...”

³⁸ U.S. Government Accountability Office (GAO). 1999. “Reporting Requirements for Federally Sponsored Inventions Need Revision.” <https://www.gao.gov/assets/230/227817.pdf>

³⁹ Night Vision Corp v. United States, No. 06-5048. U.S. Court of Appeals <https://caselaw.findlaw.com/us-federal-circuit/1393887.html>

⁴⁰ U.S. Government Accountability Office (GAO). 2009. “Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions.” <https://www.gao.gov/assets/300/293020.pdf>

⁴¹ U.S. Government Accountability Office (GAO). 1999. “Reporting Requirements for Federally Sponsored Inventions Need Revision.” <https://www.gao.gov/assets/230/227817.pdf>

An issue that has been noted is the use of the government use license to obtain discounts on products developed from federally funded R&D, primarily pharmaceuticals. A 2003 GAO report concluded that the government use license does not bestow the broader right to purchase royalty-free (i.e., discounted) products that happen to incorporate a federally funded invention if not produced under the government's license.⁴²

3. INTENDED ACTION

Intended Action 1. Define the scope of the “government use license” for use directly by the government—or a government contractor in the performance of an agreement with the government—for a government purpose only, including continued use in research and development by the government. The scope of the government use license should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use or consume those goods and services.

A. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR EXTRAMURAL R&D PROGRAMS

Implement regulatory change under the Bayh-Dole Act to (i) update the definition of government use license and its use directly by the government—or a government contractor in the performance of an agreement with the government—for government purpose only and not for the

⁴² U.S. Government Accountability Office (GAO). 2003. “Agencies’ Rights to Federally Sponsored Biomedical Inventions.” <https://www.gao.gov/new.items/d03536.pdf>

use of a third party,⁴³ and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.⁴⁴

B. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR INTRAMURAL AND PARTNERSHIP R&D PROGRAMS

Implement regulations under the Stevenson-Wydler Act⁴⁵ (consistent with the Bayh-Dole regulatory change) to (i) update the definition of government use license and its use directly by the government for government purpose only and not for use by a third party, and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.

C. MARCH-IN RIGHTS

1. BACKGROUND

The Bayh-Dole Act is based on the idea that inventions resulting from federally funded research should benefit the American people through the practical application of products and services through commercialization, and that sufficient protections are available to achieve this result. The Federal Government reserves the right to ensure that a contractor, an assignee, or exclusive licensee of intellectual property developed with Federal funding is taking effective steps

⁴³ Two regulatory changes suggested:

- Insert new definition in 37 CFR 401.2: “The term **government use** is defined as use directly by the government for a government purpose and the direct benefit of an agency, not to the benefit of a third party even if related to the government mission. Continued use in research and development by the government is included.”
- Insert new language into existing standard patent rights clause in 37 CFR 401.14(b) “Allocation of Principal Rights” clause: “The government use license is restricted by the following conditions: (A) for use directly by the government or on behalf of the government for its own consumption or practice for its own direct benefit. (B) to continue to perform research. (C) This right does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product where the government is not procuring the goods or services for its own direct use or consumption through a contract.”

⁴⁴ 37 CFR 401.14

⁴⁵ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

to further develop the invention for the benefit of the public. In limited circumstances the government may compel action, or *march in*, to, “require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants,” and, if the contractor, assignee, or exclusive licensee refuses, then the Federal Government can grant such a license itself.⁴⁶

Congress specified the conditions that must be met in order for the Federal Government to exercise its march-in rights: (1) effective steps have not occurred, or are not expected to occur, within a reasonable time to achieve “practical application” of the subject invention; (2) health and safety needs are not being reasonably satisfied; (3) public use requirements specified by Federal regulations must be met; and (4) agreements for U.S. manufacturing have not been met or have been breached.⁴⁷ Implementing regulations established rigorous administrative processes for agencies to initiate and exercise march-in rights.⁴⁸ The Government Accountability Office (GAO) noted that this process is detailed, time-consuming, and complex, making it difficult for agencies to initiate and exercise the march-in right.⁴⁹ The use of march-in is typically regarded as a last resort, and has never been exercised since the passage of the Bayh-Dole Act in 1980.

Although the march-in right has not been used, the National Institutes of Health (NIH) has received six formal petitions to initiate march-in proceedings.⁵⁰ In each case, NIH determined the criteria to exercise march-in rights were not met. Petitioners argued that march-in rights should be used to curtail high drug prices and ensure U.S. citizens receive public health benefits from accessible and affordable drugs. Ultimately, for each petition, NIH determined that the use of march-in to control drug prices was not within the scope and intent of the authority.⁵¹ While there is no government-wide repository of information related to march-in petitions and determinations, NIH published several of its march-in petitions online to demonstrate

⁴⁶ 35 U.S.C. § 203 – March-in rights; 35 U.S. Code § 209 - Licensing federally owned inventions

⁴⁷ 35 U.S.C. § 203 – March-in rights

⁴⁸ 37 CFR 401.6 – Exercise of march-in rights

⁴⁹ U.S. Government Accountability Office (GAO). 2009. Federal Research: Information on the Government’s Right to Assert Ownership Control over Federally Funded Inventions. Washington, D.C.: GAO.

⁵⁰ Thomas, John. 2016. March-In Rights under the Bayh-Dole Act. Washington, D.C. CRS.

⁵¹ For summaries of NIH petitions and determinations, *see* Ibid.

transparency in their process, and other relevant petition materials were made available via the NIH Freedom of Information Act Office.⁵²

As seen in the petitions to NIH, much of the discussion of march-in rights focuses on the definition in the statute for “practical application,” which includes the idea of “reasonable terms.” The meaning of “reasonable terms” has proven to be ambiguous. In requests for the government to exercise the march-in right, “reasonable terms” has been interpreted as a reasonable price to the consumer or use to control price.⁵³ To date, the government has not taken march-in action deferring to a different interpretation based on reasonable licensing terms. The original sponsors of the Bayh-Dole Act have noted that their intent was to ensure that products were licensed for reasonable terms rather than being used as a price control. (Refer to “Statements by Senators Bayh and Dole on March-In.”)

Statements by Senators Bayh and Dole on March-In

The “Bayh-Dole [Act] did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government...The ability of the government to revoke a license granted under the [Act] is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from [federally] funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product,” among other circumstances.

Source: Birch Bayh and Robert Dole, “Our Law Helps Patients Get New Drugs Sooner,” Washington Post, April 11, 2002.

RFI respondents pointed to potential consequences from using march-in rights as a price control. These reasons include impeding the creation of new drugs and discouraging university and medical school licensees from making the substantial additional investments necessary to develop and commercialize new drug discoveries. The RFI respondents had generally positive views of the NIH’s march-in determinations and thought NIH’s approach appropriate. Overall, respondents agreed that the march-in authority should not be broadened, and that doing so would

⁵² For example, see the NIH FOIA Office’s documentation on the CellPro petition at NIH, “First-Party Correspondence Documents,” <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/cellpro-march-petition-documents>.

⁵³ Peter S. Arno and Michael H. Davis. 2001. “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research,” *Tulane Law Review*, vol. 1, pgs. 631-692, <http://www.cptech.org/ip/health/bd/arnodavis012001.pdf>.

create uncertainties in the U.S. innovation system. Some respondents called for the elimination of the march-in provision, citing the track record on its lack of use as a proxy for ineffectiveness. However, according to GAO, multiple agencies support the existence of march-in rights because it acts as leverage to promote commercialization of federally funded inventions.⁵⁴

2. CHALLENGES

RFI respondents stated that prospective licensees are often not satisfied with obtaining anything less than exclusive licensing rights to federally sponsored inventions. Industry stakeholders have noted their concern that the Federal Government's march-in right is a risk to consider in making the business decision to take a license for a federally funded technology. RFI respondents elaborated that despite the fact that march-in rights have never been exercised by the government under the Bayh-Dole Act, there continues to be a general misunderstanding from prospective licensees that march-in rights take ownership rights away from inventors and licensees.⁵⁵ The existence of march-in might lead to a lack of confidence that patents will be enforceable in fair court proceedings or the U.S. Patent and Trademark Office's Patent Trial and Appeal Board. RFI respondents report that the threat of march-in has prevented licensing deals that would have otherwise occurred, leading to technologies languishing in contravention to the law's stated purpose.

The National Academies recommended that agencies review their actions with respect to "Determinations of Exceptional Circumstances, government use rights, and exercise of march-in rights."⁵⁶ RFI respondents argued that proper and consistent determination and application of march-in rights across Federal agencies is critical for a clear, predictable, and reliable technology transfer system. Specifically, they referenced language in the march-in statute under the definition of "practical application" including "reasonable terms" and whether that applies to creating government price controls, particularly for pharmaceuticals. Pricing is covered by other statutes, e.g., Drug Price Competition and Patent Term Restoration Act (P.L. 98-417), which encourages the development of generic drugs by the pharmaceutical industry. Prescription drug

⁵⁴ U.S. Government Accountability Office (GAO). "Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions." <https://www.gao.gov/assets/300/293020.pdf>

⁵⁵ NIST public meeting at Chicago, IL on May 31, 2018

⁵⁶ National Research Council. 2011. *Managing University Intellectual Property in the Public Interest*. Washington, DC: The National Academies Press. 82.

pricing is also covered in a recent policy blueprint.⁵⁷ In addition, there is a general need to identify and further define the exceptional circumstances that must be met to appropriately exercise march-in rights.⁵⁸

RFI respondents mentioned further ideas including explicit criteria for the technologies that are and are not subject to march-in, such as export-controlled items; stipulation of a time limit for the Federal Government to exercise march-in rights; or defining investment limits in which significant resources have been spent on technology after transfer.

3. INTENDED ACTION

Intended Action 2. Define the circumstances under which the government may exercise march-in rights consistent with the uses of march-in specified in statute and not as a regulatory mechanism for the Federal Government to control the market price of goods and services.

A. DEFINE CIRCUMSTANCES UNDER WHICH MARCH-IN RIGHTS MAY BE EXERCISED

Implement regulatory change under the Bayh-Dole Act to make explicit that the use of march-in rights specified in statute is reserved for a compelling national issue or declared national emergency when other remedies have failed. When a Federal agency receives information that it believes might warrant march-in, regulation will require that the agency first conduct an informal consultation with the contractor, grantee, or licensee to understand the nature of the issue and consider other potential alternatives to remedy the concern. The agency will summarize the efforts made to correct the non-compliance when notifying the contractor or licensee if it intends to proceed with a potential march-in action.

B. CLARIFY AMBIGUITIES IN MARCH-IN RIGHTS PROCESSES AND TERMINOLOGY

Implement regulatory change under the Bayh-Dole Act by specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services. Provide a clear and consistent definition for “reasonable terms” contained within the existing statutory definition of “practical application.” Clarify the intent of reasonable licensing terms to

⁵⁷ Department of Health and Human Services. 2018. “American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.”

⁵⁸ NIST public meeting at Gaithersburg, MD on June 14, 2018

allow a product or service to reach the marketplace but not as terms (i.e., price control mechanism) for consumer use.⁵⁹ ⁶⁰ Clarifications for “reasonable terms” and “practical application” should allow flexibility in crafting commercial or other terms in license agreements to achieve effective technology transfer.

D. PREFERENCE FOR U.S. MANUFACTURING

1. BACKGROUND

Under Bayh-Dole, any recipient of an exclusive license to a federally funded invention must agree to manufacture it substantially in the United States in order to use or sell it domestically.⁶¹ The intent of the provision is “to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.”⁶² According to the Manufacturing USA 2017 Annual Report, the manufacturing sector makes up 8.5 percent of U.S

⁵⁹ 37 CFR 401.14(j) details the march-in rights in standard Bayh-Dole Act patent rights. The four enumerated circumstances that the government would elect to assert march-in rights are: 1) contractor has not taken or is not expected to take effective steps to achieve practical application of the subject invention, 2) there is a health or safety need which is not reasonably satisfied by contractor or its licensees, 3) there is a public use requirement specified by Federal regulations that are not reasonably satisfied by contractor or its licensee, and 4) march-in is necessary because of preference of U.S. manufacturing has not been met, a waiver was not granted or obtained, or licensee is in breach of such agreement. Suggested changes to the enumerated circumstances may include language that makes clear that march-in will not be used for anti-competitive reasons such as price control.

37 CFR 401.6 details the procedures that govern the exercise of march-in rights. Language may be added to this section to provide procedural guidance regarding march-in right proceedings, fact-finding, and determination.

⁶⁰ 37 CFR 401.2 is the definitions section for Bayh-Dole Act rights regulation. The current definition of practical application, per 401.2(e), is “The term *practical application* means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being used and that its benefits are, to the extent permitted by law or government regulations, available to the public **on reasonable terms**.” The bolded text has been used to support the use of march-in rights as a price control mechanisms as reasonable terms has been interpreted to mean “low price.”

⁶¹ 35 U.S.C. § 204 – Preference for United States industry. U.S. Manufacturing Preference also applies to inventions produced under CRADAs, but it is a recommendation rather than a requirement. *See* 15 U.S.C. § 3710a(c)(4)(A).

⁶² 35 U.S.C. § 200 - Policy and objective

employment, 11.7 percent of the Nation's GDP, 35 percent of productivity growth, 60 percent of exports, and 70 percent of private-sector R&D.⁶³

The September 2018 Department of Defense report to the President "Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States"⁶⁴ in response to Executive Order 13806⁶⁵ makes the case for protecting American manufacturing. This report notes that it is imperative to maintain domestic manufacturing capability to meet more than current production needs with the conclusion that: "Above all, America's manufacturing and defense industrial base must support economic prosperity, be globally competitive, and have the capabilities and capacity to rapidly innovate and arm our military with the lethality and dominance necessary to prevail in any conflict."

In certain cases, institutions can request a waiver⁶⁶ to the U.S. manufacturing requirement from the Federal agency that sponsored the research. Federal agencies can issue waivers in instances where "upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible."⁶⁷ For example, if manufacturing in the U.S. would cause a significant delay or is prohibitively expensive for a primarily overseas market, then the requirement could potentially be waived. Other technology-specific factors are also considered when agencies issue waivers, such as whether the technology

⁶³ Manufacturing USA 2017 Annual Report. <https://nvlpubs.nist.gov/nistpubs/ams/NIST.AMS.600-3.pdf>

⁶⁴ <https://media.defense.gov/2018/Oct/05/2002048904/-1/-1/1/assessing-and-strengthening-the-manufacturing-and%20defense-industrial-base-and-supply-chain-resiliency.pdf>

⁶⁵ <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-assessing-strengthening-manufacturing-defense-industrial-base-supply-chain-resiliency-united-states/>

⁶⁶ In the majority of cases, the U.S. manufacturing requirement will not be waived completely. Rather, the requirement will be modified to include specific, enforceable commitments that will provide a net benefit to the U.S. economy.

⁶⁷ 35 U.S.C. § 204 – Preference for United States industry; *see also* 37 C.F.R. § 401.14(i) – Preference for United States industry

will create new U.S.-based jobs that have a positive impact on the U.S. trade balance, even if it is manufactured overseas.⁶⁸

In addition to requirements in licensing, agencies are also directed to “give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States.”⁶⁹ Although this requirement does not have the potential to trigger march-in as under the Bayh-Dole requirement, it is still built into the terms of the resulting CRADA licensing agreement and may result in termination of the license.

2. CHALLENGES

RFI respondents who have attempted to comply with the requirement have been confused by the meaning of the phrase “manufactured substantially in the United States.” Specifically, respondents did not understand the term “substantially.” This ambiguity may not allow businesses to properly assess whether they should apply for a waiver or continue with the risk of developing a new technology. The lack of clarity can lead companies not to license technologies, which ultimately prevents new inventions and discoveries from reaching the public.

While the phrase “manufactured substantially in the United States” may be seen as ambiguous, the term is intentionally flexible.⁷⁰ The intent is to strike a balance between encouraging other countries to open their markets for American businesses and protecting American taxpayers’ interests in United States Government-funded technologies. Furthermore, satisfying “substantial manufacture” will vary, depending on factors such as the developmental state of the technology and domestic supply chain.

Institutions that decide to apply for a waiver can experience a long and opaque process within each agency. Some institutions that have requested waivers have found that the responses are slow to come if they ever come at all. Further, there are agency-to-agency differences in preference for U.S. industry manufacturing waiver process due to differences in the missions and technology focus areas of the different agencies.

3. INTENDED ACTION

⁶⁸ U.S. National Institutes of Health. “NIH Procedures for Request for Waivers of the U.S. Manufacturing Requirement in Licenses to Extramural Inventions.”
<https://public.era.nih.gov/iedison/public/utilization/ManufacturingWaiver.jsp>

⁶⁹ 15 U.S.C. § 3710a(c)(4)(B)

⁷⁰ See https://www.wto.org/english/docs_e/legal_e/22-roo_e.htm

Intended Action 3. Protect and strengthen the statutory requirement that products embodying or using federally funded inventions be manufactured substantially in the United States. Streamline and implement a uniform waiver process government-wide in accordance with statutory requirements.

A. STREAMLINE THE WAIVER PROCESS FOR EXTRAMURAL R&D PROGRAMS

Implement regulatory change under Bayh-Dole Act to support the preference for U.S. manufacturing by implementing a more transparent, government-wide, uniform, streamlined waiver process. These revisions could include identifying common requirements for granting waivers across government agencies⁷¹ and a government-wide point of application for requesting waivers. Although each agency would still have responsibility for reviewing the requests and issuing waivers, as appropriate, this action will strengthen public access to the waiver process and the ability to obtain a more consistent, timely decision.

B. STREAMLINE THE WAIVER PROCESS FOR INTRAMURAL R&D PROGRAMS

Implement regulations under the Stevenson-Wydler Act⁷² (consistent with the Bayh-Dole regulatory change) to support the preference for U.S. manufacturing by implementing a more transparent, government-wide, uniform process for implementing the U.S. manufacturing preference for CRADAs. This may include only extending rights and protections to domestic CRADA partners.

C. IDENTIFY THE PATHWAY TO EXTEND PREFERENCE FOR U.S. MANUFACTURING TO NON-EXCLUSIVE LICENSES

Identify the pathway for expanding the preference for U.S. manufacturing to all licenses rather than limiting this preference to exclusive licenses as it is in current statute. While the majority of RFI commenters indicated that eliminating rather than expanding the manufacturing requirement would accelerate transfer, the need to support and expand the U.S. domestic manufacturing base cannot be ignored so that the American people benefit fully from the R&D

⁷¹ 35 U.S.C. § 209(b) contains language on preference of the government for licensees of federally owned inventions to manufacture in US.

37 CFR § 401.14(i) details the preference for U.S. industry. The waiver language is as follows: “However, in individual cases, the requirement for such an agreement may be waived by the Federal agency upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.”

⁷² Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The intended action is discussed under Strategy 1, Section G.

they support. The expansion of the need for a waiver to all licenses must be coupled to a more reliable and speedy mechanism to request and obtain appropriate waivers.

D. IDENTIFY THE PATHWAY TO EXPAND PREFERENCE FOR U.S. MANUFACTURING TO ALL CONTRACTORS

Identify the pathway for expanding the preference for U.S. manufacturing to contractors, in addition to all licensees. This will ensure that the preference for U.S. manufacturing extends to (i) all products embodying or using federally funded inventions, and (ii) contractors at any tier, and all sales, regardless of geographic location.

E. SOFTWARE COPYRIGHT

1. BACKGROUND

Since the passage of the foundational technology transfer statutes in the 1980s, the digital age has resulted in major changes in many of the products and services that result from R&D and the way in which they are used by the public. The ubiquitous use of computers and personal digital devices has revolutionized major parts of our daily lives. The reliance on embedded computing capability is also found within ordinary products.⁷³ Technology transfer law and policy does not adequately address technological development in the 21st Century; the technology landscape and marketplace has been dramatically reconfigured since the foundational laws were enacted in the 1980s. This is particularly true for software, which has changed fundamentally in the ensuing 40 years. Software is commonly defined as a set of computer readable language that serve as directions, procedures, rules, and associated documentation for the operation of a computer system. Intellectual property protection for digital goods and services is critical for competing in the global high-tech marketplace.

U.S. copyright law protects “original works of authorship” fixed in a tangible medium of expression by granting to authors certain exclusive rights⁷⁴ subject to a number of exceptions and limitations.⁷⁵ Computer programs, video games, photographs, films, journal publications, and

⁷³ United States Copyright Office, “Software-Enabled Consumer Products.” December 2016. <https://www.copyright.gov/policy/software/software-full-report.pdf>

⁷⁴ 17 U.S.C. §106.

⁷⁵ See, e.g. 17 U.S.C. §§107-122. <https://www.copyright.gov/title17/>

databases are examples of works eligible for copyright protection. Copyright protects not only software source code, but also protects software structure, sequence, and organization.⁷⁶ Copyright protection automatically attaches upon fixation of the work in a tangible medium of expression, and extends from at least 70 years to approximately 120 years from creation.⁷⁷

Copyright registration confers some additional benefits to copyright protection and establishes a public claim with the United States Copyright Office.⁷⁸ Copyright registration is required to file a lawsuit in the United States for U.S. works, and registration confers on copyright holders the opportunity to obtain remedies for infringement of proprietary software. Companies are likely to invest in taking computer software to the marketplace when it is registered with the Copyright Office because of the damages that can be obtained in the case of copyright infringement. The lack of certainty surrounding the rights has contributed to the lack of lab-to-market commercialization activity of non-copyrighted or unregistered software.

Although copyright protects computer software, there is an exception that provides that a works falling into the statutory definition of “Government Works,” are not subject to copyright protection in the United States. Under 17 U.S.C. § 105, works created by government employees are not eligible for copyright protection.⁷⁹ The effect of section 105 is that all government works, including software developed by Federal employees, enter the public domain without commercial consideration whether published or unpublished.

Some software produced by government researchers is patented, but this is a relatively lengthy process that is not ideally suited to the fast-paced software industry. In addition, a recent Supreme Court case, *Alice v. CLS Bank International*, threw into question the validity of hundreds of thousands of patents for computer-implemented inventions.⁸⁰ Agencies and Federal Laboratories have developed various work-arounds to deploy software for commercial use in the absence of a copyright or patent, such as invention licensing agreements or limited-purpose

⁷⁶ “Copyright Registration of Computer Programs.” Circular 61.
<https://www.copyright.gov/circs/circ61.pdf>

⁷⁷ 17 U.S.C. § 302 – Duration of copyright: Works created on or after January 1, 1978 and 17 U.S.C. §303 – Duration of copyright: Works created but not published or copyrighted before January 1, 1978

⁷⁸ <https://www.copyright.gov/circs/circ01.pdf>

⁷⁹ 17 U.S.C. § 105 – Subject matter of copyright: United States Government works

⁸⁰ *Alice v. CLS Bank International*, 573 U.S. ___, 134 S.Ct. 2347 (2014).

CRADAs, but these have limited utility.⁸¹ Certain exemptions have been carved out from the Government Works copyright exception; for example, NIST is permitted to secure copyright on Standard Reference Data under 15 U.S.C. § 290e,⁸² and the U.S. Postal Service is permitted to secure copyright for its designs on postage stamps, stamped envelopes, souvenir cards, and other philatelic publications.^{83,84} In addition, works that are produced or funded by the Federal Government may not fall under the strict limits of the statutory definition of “Government Works” and may be protected by copyright or other legal mechanisms.⁸⁵

2. CHALLENGES

Government researchers have reported that the exception for copyrighting government works that are software has led to a lack of control over potentially sensitive code; the diminished commercial potential for partners seeking to further develop government work due to its lack of exclusivity; third parties asserting copyright in some cases, thus requiring the government to pay

⁸¹ Hughes, Mary E., Susannah V. Howieson, Gina Walejko, Nayanee Gupta, Seth Jonas et al. 2011. *Technology Transfer and Commercialization Landscape of Federal Laboratories*, Washington, DC: IDA Science and Technology Policy Institute; Howieson, Susannah V., Stephanie S. Shipp, Gina K. Walejko, Pamela B. Rambow, Vanessa Peña, et al. 2013. *Exemplar Practices for Department of Defense Technology Transfer*. Washington, DC: Science and Technology Policy Institute.

⁸² 15 U.S. Code § 290e – United States copyright and renewal rights

- (a) Notwithstanding the limitations under section 105 of title 17, the Secretary may secure copyright and renewal thereof on behalf of the United States as author or proprietor in all or any part of any standard reference data which he prepares or makes available under this chapter and may authorize the reproduction and publication thereof by others.
- (b) The publication or republication by the Government under this chapter, either separately or in a public document, of any material in which copyright is subsisting shall not be taken to cause any abridgment or annulment of the copyright or to authorize any use or appropriation of such material without the consent of the copyright proprietor.

⁸³ Postal Reorganization Act of 1970, Public Law 91-375, enacted in Title 39 of the U.S. Code. <https://www.law.cornell.edu/uscode/text/39>

⁸⁴ U.S. Postal Service G013 Trademarks and Copyrights. <https://pe.usps.com/archive/html/dmmarchive20030810/Go13.htm>

⁸⁵ For example, there are criminal statutes against the reproduction of U.S. currency in 18 U.S.C. Chapter 25 – Counterfeiting and Forgery. 18 U.S.C. § 501(1) permits color illustrations of U.S. currency under specific conditions, and 18 U.S.C. § 504 permits black and white reproductions of currency.

to use its own inventions;⁸⁶ and difficulty applying the *standard terms* of free use licenses for software that is freely disseminated or open source software.⁸⁷

Federally funded R&D that are not “Government Works,” including research performed at universities and other organizations are eligible for copyright protection. However, embedded portions of code written by Federal employees working with these organizations must be excluded, creating an overly complicated framework. Software that have commercial value do not have the protections needed to provide a license that can maintain quality, such as ensuring software code integrity and version control, and can lead to further private investment and development to result in commercial products. RFI respondents indicated that this lack of the ability to protect research innovations through copyright led to lost opportunities to transfer software developed by Federal researchers and created a disincentive for them to envision and develop software with potential for commercial use.⁸⁸ The ability to identify and transfer software is generally more limited, unlike the system that is in place for patented inventions resulting from the lack of copyright protection for federally developed software.

The ineligibility of the government to copyright software has frustrated endeavors to release and participate in open source development. Open source software is a type of computer software where the software code is released under a copyright license where the copyright holder grants to users the rights to modify and share to promote public accessibility. There is a need for the legal right for government software works to be protected by copyright in order to grant public users an open source license that helps define the terms of use.

The marketplace, however, is increasingly digital. The Bureau of Economic Analysis (BEA) noted in 2016 that 6.5 percent of the U.S. Gross Domestic Product is digital amounting to over \$1.2 trillion of trade.⁸⁹ The rate of growth for this sector of the economy likewise showed a 5.6 percent growth compared to the overall growth of 1.3 percent. The respondents to the RFI supported enabling Federal entities to secure software ownership rights. (Refer to “RFI Response on Protection Limitations for Software.”)

⁸⁶ Hughes, Mary E., Susannah V. Howieson, Gina Walejko, Nayanee Gupta, Seth Jonas et al. 2011. *Technology Transfer and Commercialization Landscape of Federal Laboratories*, Washington, DC: IDA Science and Technology Policy Institute; Howieson, Susannah V., Stephanie S. Shipp, Gina K. Walejko, Pamela B. Rambow, Vanessa Peña, et al. 2013. *Exemplar Practices for Department of Defense Technology Transfer*. Washington, DC: Science and Technology Policy Institute.

⁸⁷ An example of an open content license for copyright is Creative Commons license, see <https://creativecommons.org/licenses/>.

⁸⁸ GAO Report “Copyright Law Constrains Commercialization of Some Federal Software.” <https://www.gao.gov/assets/150/149097.pdf>

⁸⁹ See <https://www2.ntia.doc.gov/node/1090>

RFI Response on Protection Limitations for Software

“The inability for works created by Federal employees to be protected under copyright has acted as a significant deterrent in the field of software innovation. Due to the short duration of software product lifecycles, the speed of software development, and limitations around patenting software, it is often copyright that provides the primary intellectual property protection for software. Without copyright, Federal Laboratories have no asset to license, and technology transfer may be blocked. Further, if software is co-developed between a Federal Laboratory and a university, the university may license its copyright, but the Federal Laboratory will be unable to participate in the license agreement. Implications include lost opportunities to transfer software developed in Federal laboratories, lost licensing revenue, and a lack of incentive for Federal employees to develop commercially-relevant software.”

Source: RFI response, University of Colorado Boulder

RFI respondents also stressed that there is a great deal of confusion about software rights in Government Works and argued for establishing uniform policy and procedures to enable transfer and licensing of federally developed software. The inconsistency in agency approaches to software rights,⁹⁰ among other issues, can hinder the development of federally sponsored technology. For example, agencies use other technology transfer mechanisms to approximate copyright protection, but not all agencies use the same mechanisms and not all government attorneys agree on the validity of such mechanisms. This has created confusion in the private sector and served as an obstacle to commercialization.

3. INTENDED ACTION

Intended Action 4. Establish copyright for software products of Federal Government R&D.

A. PROTECT SOFTWARE PRODUCTS OF FEDERAL R&D

Legislative change is required to allow agencies to register a copyright to establish protection for the commercialization of “software” that are products of R&D for which the Federal Government owns a right, title, or interest.⁹¹ This narrowly tailored change will maintain the

⁹⁰ See, e.g. Pamela B. Rambow, Vanessa Peña, et al. 2013. *Exemplar Practices for Department of Defense Technology Transfer*. Washington, DC: Institute for Defense Analysis (IDA) (noting that the Department of Commerce interprets the Stevenson-Wydler Act to permit licensing of copyright, but that Department of Defense attorneys disagree with this approach).

⁹¹ Changes could be made to:

original intent of the Bayh-Dole Act to use IP to create a means to transfer results to the private sector to develop marketable goods and services. The change will not affect most Government Works since they are usually not software and are not R&D inventions under the meaning of the Bayh-Dole Act.⁹²

F. TRADE SECRETS

1. BACKGROUND

Trade secrets represent a type of intellectual property which “consist of information and can include a formula, pattern, compilation, program, device, method, technique, or process”⁹³ that provides an economic advantage over competitors or consumers, is generally not known, and is subject to efforts reasonable under the circumstances to maintain its secrecy.⁹⁴ Unlike patents and copyrights which are enforceable throughout the length of time of the issued protection, a trade secret is tenuous in that the protection is lost in the event that a trade secret holder fails to maintain secrecy or if the information is reverse engineered or independently developed by a competitor. Small businesses receive disproportionately greater benefits from trade secret protections than larger businesses as larger businesses can generally afford to maintain and enforce more costly patent and other intellectual property protections.⁹⁵ However, trade secrets

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- 35 U.S.C. § 207 authorizes each federal agency to apply for, obtain, and maintain domestic and foreign protection of federally owned inventions. Software copyright may be accomplished with a revision to 35 U.S.C. § 207(a)(1).
 - 15 U.S.C. § 3710c authorizes distribution of royalties received by Federal agencies. Software copyright may be accomplished with a revision to 15 U.S.C. § 3710c(a)(1) to explicitly state that technology transfers outside of a traditional invention license are equally eligible for the collection and disbursement of royalties.
 - 17 U.S.C. § 105 orders that copyright protection is not available for any work of the United States Government. Works by government scientists and engineers performing federal R&D can be exempted from this law through revision.

⁹² 35 U.S.C. § 201(d) definition of “invention.”

⁹³ U.S. Patent and Trademark Office. 2018. “Trade Secret Policy.” Last modified July 11, 2018. <https://www.uspto.gov/patents-getting-started/international-protection/trade-secret-policy>

⁹⁴ Ibid.

⁹⁵ David S. Almeling. 2009. “Four Reasons to Enact a Federal Trade Secrets Act, 19.” *Fordham Intell. Prop. Media & Ent. L. J.* 769, 786-87.

have some benefits over patents in that trade secrets have a potentially unlimited duration, no territorial limits, and no applications to file or fees to pay.⁹⁶ While trade secrets are often used by businesses, working with a Federal Laboratory creates barriers to maintaining trade secrets for the resulting products, as government functions are generally geared toward publication to disseminate research results and, when applicable, patenting as the means of protecting research results without unduly restricting publication. Additionally, government practice includes Freedom of Information Act (FOIA) requirements,⁹⁷ which makes keeping trade secrets difficult for Federal Laboratories. Patents by their conception in the U.S. Constitution are a means of disclosing information in exchange for a limited period of protection.

Federal Laboratories, which do not have the authority to create and protect their own trade secrets, already have requirements to protect incoming trade secrets. Beginning in 1948 with the Federal Trade Secrets Act, there has been federal protection against the disclosure of proprietary information provided to the government.⁹⁸ There are now both civil and criminal remedies for misappropriation of trade secrets under Federal law,⁹⁹ and the U.S. is obligated to provide trade secret protection under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹⁰⁰ Trade secrets and commercial and financial information are also exempted from mandatory disclosure under FOIA. Federal trade secret protections decrease the likelihood that the government will disclose proprietary information when entering into R&D collaborations with the private sector. In addition, these protections provide a signal to the private sector that they can rely on robust legal enforcement for violations disclosing their intellectual property and, in

⁹⁶ U.S. Patent and Trademark Office. “Trade Secrets Protection in the U.S.”
<https://www.nist.gov/sites/default/files/documents/mep/marinaslides.pdf>

⁹⁷ 5 U.S.C. §552(b)(4)— Public Information; Agency Rules, Opinions, Orders, Records, Land Proceedings, amended by OPEN Government Act of 2007, Pub. L. No. 110 175, 121 Stat. 2524; Executive Order 12600 – Pre-disclosure Notification Procedures for Confidential Commercial Information; Presidential Memorandum on Administration of Freedom of Information Act, Oct. 4, 1993; Attorney General memorandum for heads of Department and Agencies, Freedom of Information Act, Oct 4, 1993.

⁹⁸ 18 U.S.C. §1905 – Disclosure of confidential information generally

⁹⁹ Procurement-related laws (1994)—provide both civil and criminal penalties for the Federal Government disclosure of non-government information gained through procurement (41 U.S.C. § 423); The Economic Espionage Act (1996)—regulates the theft or misappropriation of trade secrets for the benefit of any foreign government (18 U.S.C. §§ 1831-1839); The Defend Trade Secrets Act (2016)—creates Federal civil cause of action for the disclosure of trade secrets (P.L. 114–153).

¹⁰⁰ The TRIPS Agreement binds all members of the World Trade Organization, *see* World Intellectual Property Organization, http://www.wipo.int/wipolex/en/other_treaties/details.jsp?treaty_id=231

turn, spur R&D investments and collaborations that would otherwise have been viewed by industry collaborators as too risky to pursue.¹⁰¹

The rapidly changing landscape of information and communication technologies and the growing availability of information in the digital public domain are challenges to maintaining secrecy and protection of trade secrets. Since it is easier to store, access, and disseminate trade secrets in the digital environment, there is an increased risk of disclosure or misappropriation.¹⁰²

2. CHALLENGES

RFI respondents commented on industry stakeholders' general perceptions that the Federal Government does not sufficiently protect and enforce trade secrets, and that this situation is one of the major obstacles to private sector engagement and establishing public-private R&D collaborations. There is a perceived lack of transparency and consistency in the Federal Government's protection and enforcement of trade secrets. For instance, Federal employees may inadvertently disclose information, e.g., through FOIA requests. The processes to notify R&D collaborators when relevant information is requested via a FOIA request differs across agencies and Federal Laboratories. It was noted that government may lack access to new cybersecurity technology and applications that could provide proof of information ownership and ensure that information exchanged through R&D collaborations is secure.

Authorities under CRADAs provide protection of information "obtained in the conduct of research or as a result of activities" and provides a 5-year time limit for that protection.¹⁰³ (For more information on CRADAs see Strategy 2 Section C). However, the 5-year limit is likely inadequate when dealing with technologies that take a long time to reach maturity. For example, technology development occurs in the nuclear sector over decades, and collaborators and industry may find the 5-year limit insufficient to meet their needs to bring a developed product to market.

There are serious liabilities and consequences for mishandling trade secrets and related proprietary information that may discourage agencies from accepting the risk associated with trade secret protection. Some agencies, such as the Department of Energy (DOE), have issued

¹⁰¹ Png, Ivan P. L. 2012. "Law and Innovation: Evidence from State Trade Secrets Laws" June 15, 2012, <http://dx.doi.org/10.2139/ssrn.1755284>

¹⁰² U.S. Patent and Trademark Office. "Trade Secrets Protection in the U.S." <https://www.nist.gov/sites/default/files/documents/mep/marinaslides.pdf>

¹⁰³ 15 U.S.C. § 3710a(c)(7)(A) Cooperative research and development agreements contract considerations

standard procedures for the submission and protection of trade secrets and commercial or financial information that is privileged or confidential, where such information is submitted by applicants for DOE assistance including research partnerships.¹⁰⁴ However, there is a lack of clear, Federal-wide guidance or regulation for accepting and managing this information for technology transfer activities.

3. INTENDED ACTION

Intended Action 5. Establish clear and consistent definition as well as authorities required to protect the trade secrets of companies involved in R&D collaborations with Federal Laboratories.

A. CLARIFY THE DEFINITION OF *TRADE SECRET*

Implement regulations under the Stevenson-Wydler Act¹⁰⁵ to establish a clear and consistent definition of *trade secret*¹⁰⁶ and the use of trade secrets in technology transfer.

B. EXTEND CRADA INFORMATION PROTECTION PERIOD

Legislative change is required to extend the potential CRADA information protection period to 10 years (from 5 years specified in current statute) in cases where there is a demonstrable need to protect the information for a business collaborator to achieve practical application of products that result from CRADA work.

¹⁰⁴ Procedures for Submitting to the Department of Energy Trade Secrets and Commercial or Financial Information That Is Privileged or Confidential, 76 FR 26579 (2011).

¹⁰⁵ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

¹⁰⁶ See definition provided in the Defense Trade Secrets Act, codified at 18 U.S.C. §§ 1839(3)

G. STRENGTHEN TECHNOLOGY TRANSFER AT FEDERAL LABORATORIES

1. BACKGROUND

The Stevenson-Wydler Act of 1980, as amended, is the key foundational legislation that defines and delineates how the technology transfer function will be conducted by Federal Laboratories—including GOGO and GOCO Laboratories. Among its key features, the Stevenson-Wydler Act:

- Establishes the technology transfer function and describes the role and responsibilities of technology transfer at all federal R&D agencies and laboratories,^{107,108}
- Authorizes a mechanism for public-private partnerships through Cooperative Research and Development Agreements,¹⁰⁹
- Provides for policies that describe distribution and use of royalties from Federal Laboratory inventions,¹¹⁰
- Requires annual reporting on federal technology transfer,¹¹¹ and
- Creates the Federal Laboratory Consortium for Technology Transfer.¹¹²

2. CHALLENGES

Unlike the Bayh-Dole Act, for which the Secretary of Commerce is given authority to develop implementing regulations, there are no companion regulations for technology transfer under the Stevenson-Wydler Act. The lack of regulation requires that clarifications for minor items must be enacted by the Congress rather than implemented through the promulgation of regulations. The

¹⁰⁷ 15 U.S.C. § 3710 (b) Establishment of Research and Technology Applications Offices and (c) Functions of Research and Technology Applications Offices

¹⁰⁸ Federal Laboratories with 200 or more full-time equivalent scientific, engineering, and related technical positions are required to dedicate at least one full-time equivalent professional to staff an ORTA.

¹⁰⁹ 15 U.S.C. § 3710a

¹¹⁰ 15 U.S.C. § 3710c

¹¹¹ 15 U.S.C. § 3710(f) and (g)

¹¹² 15 U.S.C. § 3710(e)

ability to further describe the meaning of the statute in a regulation would allow for greater consistency and a more flexible response to provide updated processes.

The process and procedures related to granting this authority are well understood through the regulations that implement licensing under the Bayh-Dole Act by the Secretary of Commerce. Although it is a clear objective of the Administration to reduce regulation and regulatory burden on businesses, regulation under this Act would be directed at streamlining government operations rather than increasing a reporting or compliance burden on citizens. The process of promulgating a regulation is also very collaborative across agencies and requires public input. The technology transfer offices across the Federal Laboratories have developed and maintained a strong network across the federal enterprise via both well-established interagency committees and working groups as well as other less formal mechanisms. These mechanisms work well in identifying and implementing best practices, however, policies do not have the ability to impact legal interpretations of the statute.

Regulations are a primary vehicle used by the Federal Government to implement laws. Outdated, unnecessary, and burdensome regulations are market-dampening burdens that require streamlining. Updating regulations that ensure optimal performance by federal agencies can serve to address market failures, reduce entry barriers, encourage greater competition, and spur innovation.

In 2007, the DOC delegated responsibility to NIST for implementing the Bayh-Dole regulations (37 C.F.R. §§ 401 and 37 CFR §§ 404). In 2018, NIST updated the regulations to synchronize the rules with changes in the America Invents Act, incorporate provisions from Executive Order 12591 that have been in effect since 1987, and address provisional patent applications and other related issues. The Stevenson-Wydler Act does not grant regulatory authority to any federal agency. This omission has contributed to a measure of uncertainty for the public due to the inconsistent interpretation of the law's requirements by different federal agencies.

Royalties collected by Federal agencies are disbursed in accordance with provisions in the Stevenson-Wydler Act that are codified in 15 U.S.C. § 3710c. The royalties are shared with all inventors of the licensed invention, with a maximum amount not to exceed \$150,000 per year to any one person, unless the President approves a larger award.¹¹³ The National Defense

¹¹³ 15 U.S.C. § 3710c(a)(3)

Authorization Act (Public Law 115-91)¹¹⁴ authorized an increase for Department of Defense employees up to \$500,000 per year subject to approval at the level of the Secretary, unless the employee leaves the laboratory, which reduces the amount back to the \$150,000. Additionally, the statute related to royalties states that royalties shall be retained and disbursed to inventors for “inventions.” This has led to confusion and uncertainty among several agencies as to whether royalties can be collected and disbursed for transfers of technology that do not meet the definition of an “invention,” such as software and biological materials.

3. INTENDED ACTION

Intended Action 6. Implement consistent and streamlined policies and practices government-wide under the Stevenson-Wydler Act.

A. REGULATORY AUTHORITY FOR STEVENSON-WYDLER ACT

Legislative change is required to grant the DOC authority to implement regulations for the Stevenson-Wydler Act, confirming the mission requirement of contributing to U.S. innovation for all government entities engaged in research and development. This green paper identifies the need for consistent and streamlined regulations government-wide that will reduce the inconsistency and burden on the American people. Many of the areas of discussion of Bayh-Dole Act regulation for federal licensing that have been granted to the Secretary of Commerce have a companion component in partnership agreements under the Stevenson-Wydler Act. The government use license, preference for U.S. manufacturing, technology transfer agreements, and the ability to measure and report progress are all examples of areas that could be addressed in regulation instead of requiring new legislation. Additional areas include consistent policies for appropriate use of international intellectual property protections, such as international patents, in support of U.S. innovation, manufacturing, and export.

B. CONSISTENCY IN ROYALTIES FROM LICENSED INTELLECTUAL PROPERTY

Legislative change is required to authorize royalty payments to federal employees for non-invention forms of licensed intellectual property and to extend to federal employees at all agencies

¹¹⁴ In Public Law 115-91, Section 233, Congress approved a pilot program to improve incentives for technology transfer from DoD laboratories. In Section 233(b)(2)(A), inventor share of royalties is capped at \$500,000 per year to any one person, unless a larger award is approved by the respective DoD branch Secretary. Section 233(b)(2)(B) caveats that an inventor leaving the laboratory shall be capped at \$150,000 unless the head of the agency approves a larger award. It should be noted that the pilot program will terminate 5 years after the date of the enactment of the Act, per Section 233(e).

the increase in royalty cap of up to \$500,000 per year authorized in the FY 2018 National Defense Authorization Act (Public Law 115-91).

H. PRESUMPTION OF GOVERNMENT RIGHTS TO EMPLOYEE INVENTIONS

1. BACKGROUND

Like many employers, the Federal Government does have a presumed assignment of intellectual property rights for work related inventions. Executive Order 10096 signed January 23, 1950 by President Harry Truman ¹¹⁵ includes provisions that “The Government shall obtain the entire right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.” The provisions of this Executive Order are included in 37 C.F.R. 501 et seq. for the purposes of determining federal employee invention rights.

In the *Stanford v. Roche* case,¹¹⁶ the U.S. Supreme Court found that the Bayh-Dole Act states that a contractor may “elect to claim title,” and therefore the Act does not automatically vest title to the contractor. While this case applies to contractors, action was taken to amend the Bayh-Dole Act implementing regulations¹¹⁷ to require that a contractor acquire a present assignment of rights from the employee in order to ensure the government interest is protected. Although not directly tested by the court, this same consideration is needed to protect the government right to employee inventions under Executive Order 10096. The Executive Order does contain a provision that it is *presumed* that the Federal Government will retain the entire right, title, and interest to federal employee inventions:

[I]t shall be presumed that an invention made by an employee who is employed or assigned (i) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (ii) to conduct or perform research, development work, or both, (iii) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (iv) to act in a liaison capacity among governmental or nongovernmental

¹¹⁵ <https://www.archives.gov/federal-register/codification/executive-order/10096.html>

¹¹⁶ (No. 09-1159) 583 F. 3d 832, <https://www.law.cornell.edu/supct/html/09-1159.ZS.html>

¹¹⁷ 37 C.F.R. 401.14(f)(2), see <https://www.federalregister.gov/documents/2018/04/13/2018-07532/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions>

agencies or individuals engaged in such work, or made by an employee included within any other category of employees specified by regulations issued pursuant to section 4(b) hereof, falls within the provisions of paragraph (a), above, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b), above. Either presumption may be rebutted by the facts or circumstances attendant upon the conditions under which any particular invention is made and, notwithstanding the foregoing, shall not preclude a determination that the invention falls within the provisions of paragraph (d) next below.

In addition to the requirements in the Executive Order, Congress clarified in a policy statement that “Technology Transfer, consistent with mission responsibilities, is the responsibility of each laboratory science and engineering professional.”¹¹⁸

2. CHALLENGES

The current practice described in the implementing regulations for employee inventions in 37 C.F.R 501 requires an affirmative action to prove that the government right exists rather than following the presumption in Executive Order 10096. This requires an attorney to examine and make a finding as an administrative action, adding time and cost to each invention disclosure. This is a considerable amount of burden and expense considering that 4,830 inventions were reported in FY 2015.¹¹⁹ Given the broad applicability of this presumption as stated by Congress in the statutory policy statement in the Steven-Wydler Act, the vast majority of inventions should be presumed to require assignment to the U.S. Government without further review. In cases where there is a question of rights, a rights determination could be performed by the agency and the current appeal rights retained.

In addition to the administrative cost associated with inventions, the requirement of assignment still relies on an executive order and regulations, rather than a firm basis in statute. Although the Executive Order has been in place for nearly seven decades, there are still questions about ownership of rights from employees in certain professions and in cases where employees hold additional positions outside the Federal Government. While the test in the Executive Order has been useful, there have been claims that employees developed inventions related to government work while on a dual appointment or in another work arrangement. Since the *Stanford v. Roche* case has moved employers to obtain a present assignment of rights, the order of these claims is not established.

¹¹⁸ 15 U.S.C. 3710(a)(2)

¹¹⁹ NIST. 2018. “Federal Laboratory Technology Transfer Fiscal Year 2015.”
https://www.nist.gov/sites/default/files/documents/2018/04/30/fy2015_fed_tt_report.pdf

3. INTENDED ACTION

Intended Action 7. Provide for a present assignment of invention rights by federal employees to the Federal Government and provide for streamlined rights determination processes for federal employee inventions.

A. UPDATE REGULATIONS THAT APPLY TO RIGHTS IN INVENTIONS BY GOVERNMENT EMPLOYEES

Implement regulatory change under Executive Order 10096 for a present assignment of invention rights by federal employees to the Federal Government and provide for streamlined rights determination processes with a presumption of assignment of all rights title and interest in government-related inventions by federal employees.

B. UPDATE LEGAL BASIS FOR INVENTION RIGHTS FOR GOVERNMENT EMPLOYEES

Legislative change is required to codify the federal employee's requirement to report inventions and assign all right, title, and interest in work related inventions to the Federal Government.

STRATEGY 2. INCREASE ENGAGEMENT WITH PRIVATE SECTOR TECHNOLOGY DEVELOPMENT EXPERTS AND INVESTORS

The second of five strategies of the L2M CAP Goal is focused on increasing engagement with private sector technology development experts and investors. The intended actions are designed to make it easier for the private sector to partner with Federal agencies and to attract private sector investment for translational R&D, technology maturation, and commercialization. This chapter discusses actions to streamline existing partnership mechanisms for technology transfer and to accelerate technology transfer through new/expanded partnership mechanisms. The actions also help build and leverage innovation ecosystems that include incubators, accelerators, public-private co-location, personnel exchange, and university-based research parks.

A. INTRODUCTION

For the Nation to see significant return on its investment in R&D, the science and technology developments must be transferred to the private sector to enable practical application through further development and/or commercialization. There are critical components that enable this transfer to occur, including: (1) availability of effective legal mechanisms to actualize the partnership and transfer of potentially impactful innovation from the lab to the private sector; (2) an ability to make connections between the federally funded R&D performer and private industry so that industry is aware of existing technologies, expertise, and capabilities; and (3) a sufficient level of technology readiness to be of interest to private industry. Informing the right private sector partner with such information increases the chance of impact in the American marketplace.

A significant number of RFI responses addressed the importance of R&D tax credits to stimulate private investment. Changes to the tax code, however, might be difficult at this time since major tax legislation was enacted into law very recently.¹²⁰ NIST will communicate these suggestions to appropriate policy making bodies for their consideration and action. (Refer to “What We Heard: Tax Incentives.”)

¹²⁰ Public Law No: 115-97 (12/22/2017)

What We Heard: Tax Incentives

There were numerous suggestions and data presented regarding tax incentives. Below is a summary of what we heard from the RFI:

- Provide tax incentives to investors to encourage them to take more risk early on in a technology project or tech startup.
- Remove restrictions placed on public-private use of tax-exempt bond financed facilities through IRS Procedure 2007-047.
- Need for an improved R&D tax credit.
- Provide incentives for companies to partner with universities for R&D.
- Broaden basic research definition.
- Expand the corporate R&D tax credit.

B. STREAMLINE PARTNERSHIP MECHANISMS

1. BACKGROUND

Government-wide and agency-specific legislation provides a variety of legal mechanisms to facilitate engagement with the private sector. These mechanisms can be grouped into the following categories:

- Intellectual property protection, such as patents and copyrights;
- Property transfers, such as material transfer agreements;
- Research partnership agreements, such as CRADAs;
- Resource use agreements, such as those for use of facilities;
- Educational agreements, such as training;
- Personnel exchange mechanisms, such as for guest researchers and fellows; and
- Agreements with intermediaries, such as partnership intermediary agreements.

The use of these mechanisms varies across agencies, reflecting the differences in agency missions as well as legislative authorities and practices across Federal Laboratories (Appendix 1).

Standard and required terms for these agreements vary based on legislation, regulations, and other governing policies. For instance, comparing the main partnering agreements used by the DOE's National Laboratories—Strategic Partnership Projects (SPPs), CRADAs, and

Agreements for Commercializing Technology (ACT) ¹²¹—demonstrates differing technology transfer mechanisms used to provide flexibility depending on the project, intellectual property ownership and indemnification concerns, among other contract terms (Appendix 2).

2. CHALLENGES

RFI respondents remarked that private companies and universities perceive collaboration with Federal Laboratories to be difficult due to differing authorities, processes, and required terms across agencies. Agency terms vary regarding intellectual property rights, financial terms, and indemnification, among others. The lack of standardized technology transfer mechanisms can frustrate potential partners and have a negative impact on technology transfer. Additionally, the base templates for developing CRADAs differ significantly across agencies. This situation causes inefficiency and frustration for institutions that are attempting to partner with multiple agencies. Adding to the lack of uniformity, there is contradictory statutory language. For example, there is a discrepancy in statute on who can be a CRADA partner in the CRADA authority (e.g., CRADA partner can be one or more non-Federal parties) versus the CRADA definition (e.g., CRADA partner can be other Federal agencies in addition to non-Federal parties).¹²²

A 2018 GAO report similarly stated that, “some stakeholders had concerns about consistency in licensing practices both within the labs and across labs.”¹²³ GAO also reported that stakeholders found the licensing process “lengthy and uniquely regulated, which can deter companies from licensing federal inventions.”¹²⁴ RFI respondents noted the added burden of navigating technology transfer processes and high transaction costs related to negotiating intellectual

¹²¹ DOE announced the ACT as a pilot program in December 2011, for further on the basis for development of the ACTs see Susannah V. Howieson, Brian J. Sergi, and Stephanie S. Shipp. 2013. Department of Energy Agreements for Commercializing Technology. IDA, Science and Technology Policy Institute.

¹²² 15 U.S.C. 3710a(a)(1) identifies the following organizations as potential CRADA partners: “other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency).”

15 U.S.C. 3710(d)(1) defines a CRADA as an “agreement between one or more Federal laboratories and one or more non-Federal parties...”

¹²³ U.S. Government Accountability Office (GAO). 2018. Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions, <https://www.gao.gov/assets/700/692606.pdf>.

¹²⁴ Ibid.

property terms. It was noted that successful technology transfer of Federal Government R&D investment is impeded by administrative bottlenecks and roadblocks posed by multiple, time-consuming layers of agency review and processing as well as difficulty communicating the purpose and rationale of agreement requirements to prospective licensees.

3. INTENDED ACTION

Intended Action 8. Establish consistency in legislative interpretation and use of best practices government-wide and implement streamlined, transparent partnership agreements, including licensing and indemnification terms.

A. LEGISLATIVE INTERPRETATION OF TECHNOLOGY TRANSFER AUTHORITIES

Implement regulations under the Stevenson-Wydler Act¹²⁵ to establish consistency in legislative interpretation of technology transfer authorities government-wide.¹²⁶

B. USE OF BEST PRACTICES FOR TECHNOLOGY TRANSFER

Develop, adopt, and use “speed-of-business”-based best practices and tools for technology transfer that deliver modern, streamlined, and responsive customer-experience government-wide.¹²⁷

C. CONSISTENT LICENSING POLICIES AND PRACTICES

Establish consistent, transparent licensing policies and practices for federally funded intellectual property—while maintaining flexibility to tailor the specific financial terms of each license, consistent with the statutory goal to promote commercial use of inventions.¹²⁸

¹²⁵ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

¹²⁶ Including agreements such as CRADAs, consortia, license agreements, materials transfer agreements, non-disclosure agreements, facility use agreements, and FFRDC agreements.

¹²⁷ Including, for example, technology transfer taxonomy, standardized menu-based customizable model agreements and templates; mission-aligned strategic portfolio-based intellectual property management; performance incentives and expectations for researchers/managers and technology transfer/licensing professionals; and training for R&D executives/officials as well as technology transfer/licensing professionals.

¹²⁸ Responsive to May 2018 GAO Report (GAO-18-327) titled “Additional Actions Need to Improve Licensing of Patented Federal Inventions” (<https://www.gao.gov/assets/700/692606.pdf>): The Secretary of Commerce should instruct NIST to (1) fully report the range of challenges in federal

Implementation of consistent government-wide licensing policies and practices will require regulatory change under the Bayh-Dole Act and implementation of regulations under the Stevenson-Wydler Act.¹²⁹

D. CONSISTENCY IN USE OF INDEMNIFICATION PROVISIONS IN AGREEMENTS

Establish consistent indemnification terms government-wide for agreements ¹³⁰ with Federal research and development contractors, grantees, and collaborators. Alternative indemnification terms should be considered, including disclaiming liability to the extent of the Federal Tort Claims Act.^{131,132}

E. PURPOSE OF GOVERNMENT LICENSE ROYALTIES

Implement regulatory change under the Bayh-Dole Act to clarify that license royalties are used primarily to promote compliance by the licensee to the terms of development and achieve practical application of technology.¹³³

F. CONFLICTING LANGUAGE IN CRADA AUTHORITY

patent licensing, such as those outlined in this report, by, for example, leveraging its survey of practices at federal technology transfer offices, past FLC studies, and agency reports and including that information in its summary reports to Congress; (2) clarify the link between establishing patent license financial terms and the goal of promoting commercial use, through appropriate means, such as the upcoming rule-making process and updating relevant guidance; and (3) facilitate formal information sharing among the agencies to provide Federal Laboratories with information on financial terms in comparable patent licenses, as appropriate.

¹²⁹ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

¹³⁰ Including contracts, grants, cooperative agreements, cooperative research and development agreements, and other agreements.

¹³¹ 28 U.S.C. Chapter 171

¹³² Suggested language: No indemnification for any loss, claim, or liability is intended or provided by any Party under this Agreement. Each Party will be liable for any claims or damages it incurs in connection with this Agreement, except that {insert name}, as an agency of the Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Chapter 171.

¹³³ In response to May 2018 GAO Report (GAO-18-327) Recommendation 2 in footnote 60. Language changes can be made in applicable sections of 37 CFR § 404.2 to describe the government policy on license royalties. It has generally been accepted that the government will use royalties to promote practical application of an invention as a method to ensure compliance by the licensee, promote fairness, and encourage invention to promote economic growth. It is not viewed as an alternative to appropriated funding or as funding mechanism.

Legislative change is required to fix the statutory discrepancy regarding who can be a CRADA partner.¹³⁴ This fix will address difficulties executing CRADAs between federal agencies, for example, between a federal agency and another agency's GOCO Laboratory.

C. NEW/EXPANDED PARTNERSHIP MECHANISMS

1. BACKGROUND

New and expanded mechanisms may be designed to establish partnership agreements at the speed of business and to attract private sector investment for translational R&D, technology maturation, and commercialization efforts. They also provide the means to build and leverage innovation ecosystems that include incubators, accelerators, public-private co-location, personnel exchange, and university-based research parks. Examples of such partnership mechanisms include the use of nonprofit foundations, partnership intermediaries, Agreements to Commercialize Technology (ACT), and Other Transaction Authority (OTA).

Nonprofit foundations support Federal R&D agencies by employing mechanisms that Federal agencies cannot always readily pursue, such as receiving and actively seeking gifts and other monetary donations from private donors and organizations. For example, the Foundation for the National Institutes of Health (FNIH) can raise nonfederally appropriated funds that support agency R&D activities.¹³⁵ In addition, foundations sponsored or initiated by Federal and State entities have facilitated technology commercialization and generated revenue to reinvest in R&D. Foundations act synergistically with agency and Federal Laboratory technology transfer offices and serve to increase the capacity for identifying collaborative R&D and other opportunities.

Federal Laboratories may also use Partnership Intermediary Agreements (PIAs)¹³⁶ to perform services that support cooperative or joint activities with small businesses, institutions of higher education, and other defined educational institutions. PIAs are a legal agreement between

¹³⁴ 15 U.S.C. § 3710a(a)(1) identifies the following organizations as potential CRADA partners: "other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency)." 15 U.S.C. § 3710(d)(1) defines a CRADA as an "agreement between one or more Federal laboratories and one or more non-Federal parties..."

¹³⁵ "The FNIH manages the solicitation of funds by private donors for NIH research projects with appropriate firewalls." <https://www.nih.gov/news-events/news-releases/nih-end-funding-moderate-alcohol-cardiovascular-health-trial>

¹³⁶ 15 U.S.C. § 3715 – Use of partnership intermediaries

a Federal agency and an agency of—or nonprofit entity affiliated with—a State or local government as defined in statute.

Nonprofit private foundations that operate on behalf of a Federal agency can be congressionally mandated or created within an agency to advance its mission. Most foundations for federal agencies are established via acts of Congress. A few, including USDA’s Agricultural Technology Innovation Partnership (ATiP) Foundation, are PIA arrangements. The main differences include: foundations have broad application, including technology transfer, while PIAs are narrowly focused to technology transfer functions; and foundations are essentially “start-ups” based on congressional action, while a PIA is a legal agreement between an agency and an existing nonprofit or State entity. Nonprofit foundations may enter into R&D collaboration and service agreements with industry and with nonprofit, state, and local organizations.

One congressionally mandated example is FNIH, authorized under Public Law 101-613 titled “The National Institutes of Health Amendments of 1990.” The FNIH’s primary duties include: (a) raising private funds to support the NIH mission; (b) creating innovative public-private biomedical partnerships that complement the NIH mission; providing a neutral forum to engage all partners to work together between NIH, Federal partners, industry, academia, and the philanthropic community; (c) accelerating transition of basic research findings into biomedical interventions and public health applications; and (d) enabling private partners to expand the number of funded NIH grants, among others. According to its 2017 Annual Report, FNIH has raised more the \$1 billion since its inception.¹³⁷

University research parks and open campuses represent initiatives in which geographic proximity to local, State, and regional ecosystems can be leveraged to increase collaborative R&D and technology maturation. A university research park is a property-based venture with numerous responsibilities: developing property master plans for research and commercialization; creating partnerships with universities and other research institutions; encouraging the growth of new companies; translating technology; and driving technology-led economic development.¹³⁸

¹³⁷ Foundation for the National Institutes of Health. “2017 Annual Report: Shaping the Future of Human Health.” Accessed October 9, 2018. <https://fnihi.org/2017-annual-report/about-us/>

¹³⁸ Association of University Research Parks, n.d. “What is a Research Park?” Accessed Oct 11, 2018. <https://www.aurp.net/what-is-a-research-park>

In a 2012 survey of university research parks, 88 percent of the respondents indicated that research parks provide access to business and commercialization services.¹³⁹

Similarly, an open campus is a business model that facilitates collaborative engagement between Federal and private sector researchers through access to researchers, unique facilities, and additional collaboration resources.¹⁴⁰ Open campuses aim to extend an organization's R&D activities to other dispersed geographic facilities and organizations. Research and development is typically focused on the originating organization's mission priorities. Participating organizations and facilities receive a unique opportunity to collaborate face-to-face with researchers working on state-of-the-art problems and potentially benefit from the transfer of the results into commercial markets.

One Federal example is the Army Research Laboratory's (ARL) Open Campus initiative.¹⁴¹ Through the Open Campus initiative, ARL leverages regional expertise and facilities to accelerate the discovery, innovation, and transition of science and technology of relevance to the Army. Partner researchers and institutions are given access to unique ARL facilities; real data sets and expertise; generation of joint intellectual property; incubation of spin-off companies for the pursuit of science and technology innovations; and maturation and rapid transition of intellectual property rights and technologies to the industrial marketplace. As of March 2017, the ARL open campus had 105 active CRADAs, 234 CRADA projects, and 775 visiting researchers; there was \$29.9 million of in-kind research in FY 2016.¹⁴² Another example is the DOE Oak Ridge National Laboratory's Manufacturing Demonstration Facility (MDF).¹⁴³ The MDF is the DOE's first facility established to provide affordable and convenient access to R&D expertise, facilities, and tools to facilitate rapid adoption of advanced manufacturing technologies to enhance the competitiveness of the U.S. workforce.

Open campuses associated with Federal Laboratories can help facilitate researcher and knowledge exchange by enabling prospective private and other R&D collaborators to have access to state-of-the-art research facilities and other collaborative space. Open campuses tend to be

¹³⁹ Driving Regional Innovation and Growth, Results of the 2012 Survey of North American Research Parks, Prepared for Association of University Research Parks (AURP), by Battelle Technology Partnership Practice, August 2013, https://aurp.memberclicks.net/assets/documents/aurp_batelllereportv2.pdf

¹⁴⁰ United States Army. 2014. "Army Research Lab Open Campus Opportunities" Accessed 10/3/2018. https://www.arl.army.mil/www/pages/2357/ARL_Open_Campus_Opportunities.pdf

¹⁴¹ United States Army. "Army Research Lab, Extended." Accessed Oct 1, 2018. <https://www.arl.army.mil/opencampus/ARLExtended>

¹⁴² Tien Pham, n.d. "ARL Open Campus – A New Model for Army Science and Technology." https://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_180834.pdf

¹⁴³ <https://www.ornl.gov/mdf>

“outside the fence,” meaning R&D collaborators experience streamlined facility access and security procedures than would otherwise be in place for “inside the fence.”

One approach to grant non-Federal researchers access to unique government facilities is through outleasing, often called Enhance Use Lease Authority (EULA), leasing underutilized government property to the private sector. These agreements often occur when agencies hold land that is vital to their mission in the long-term, but they are currently not utilizing the facility or property at full capacity. Through these leases, private industry can work in close proximity to Federal researchers, which might enhance the outcomes of associated research partnerships. This has been used to establish open campuses and research parks at multiple Federal Laboratories, including 2008 Planetary Ventures Bay View at NASA Ames Research Center, the Rolls-Royce Outdoor Jet Engine Testing Facility at John C. Stennis Space Center, Falcon Hill National Aerospace Research Park at Hill Air Force Base, and the USDA Agriculture Research Service Beltsville Agricultural Research Center. There is also interest from Federal Laboratories to outlease non-excess property to the private sector.

The Agreement for Commercializing Technology (ACT)¹⁴⁴ is an innovative DOE partnering mechanism for GOCO Laboratories, using as authorization the Atomic Energy Act.¹⁴⁵ DOE authorized the use of ACTs as a permanent mechanism in October 2017 after piloting the program for 6 years. The ACT enables (i) DOE Laboratory contractors to engage in partnerships with terms that are more compatible with industry practices (e.g., business-friendly intellectual property rights, indemnification terms, best-effort performance, advance payments); (ii) supports Industry-Lab Partnerships that leverage Federal assets; and (iii) complements SPP, CRADA and User Agreements.¹⁴⁶ DOE is currently piloting an extension of the ACT, called FedACT, that expands the use of ACT to allow organizations to partner with DOE’s National Laboratories on federally funded projects.

The explicit expansion of the ACT authority to all GOCO Laboratories would open the unique knowledge, capabilities, and facilities at these laboratories to greater commercial development without hampering their intended government mission and function. The ACT authority could also be used by GOGO Laboratories through partnership intermediaries that are authorized under the Stevenson-Wydler Act. The ACT authority is not intended to replace other technology transfer

¹⁴⁴ See <https://www.energy.gov/technologytransitions/frequently-asked-questions-about-act>

¹⁴⁵ The Atomic Energy Act of 1954 (Public Law 83-703), codified in Title 42 of the U.S.C.

¹⁴⁶ ACT: Mechanism that allows DOE GOCO National Laboratories to partner with businesses and other non-Federal entities with greater flexibility than CRADAs or Strategic Partnership Projects (SPP) agreements. ACT allows a GOCO contractor to negotiate terms and conditions that are more consistent with private industry practice, such as IP rights, payment arrangements, indemnification, and development of multi-party R&D partnerships. ACT is a contractual agreement based specifically on DOE statutory authorities.

mechanisms. Rather, it is intended to provide an alternative mechanism for creating partnerships in cases where standard DOE terms could not be negotiated.

2. CHALLENGES

Legislative modification of CRADAs to a more flexible agreement called the Research Transaction Authority (RTA) will enable Federal agencies to pursue faster agreement negotiations and reduce the risks for businesses that seek to partner with the government. The RTA would extend the ability of all Federal Laboratories to enter into an arrangement similar to “Other Transaction Authority,” but strictly limited to R&D and not for use in procurement or financial assistance actions.¹⁴⁷ Other Transaction Authority allows for agreements that offer greater speed, flexibility, and accessibility in performing research and prototyping activities, and can be used to design and implement innovative business models within the government that would otherwise not be feasible.¹⁴⁸ This authority is envisioned to parallel the Space Act Agreements¹⁴⁹ used by NASA to win the space race with the Soviet Union and still in use today. Regulatory authority is required to exercise implementing regulations for RTA to guide the adoption of uniform policy and practice.

There are few foundations currently supporting Federal agencies, which is potentially due to confusion over whether agencies have the authority to establish foundations. Possibly another point of confusion may be whether agencies can use appropriated dollars to support a foundation if the foundation was not explicitly authorized by Congress. In general, congressionally established foundations have benefited from appropriated agency funding to partially support their operations.

3. INTENDED ACTION

Intended Action 9. Authorize new and expanded mechanisms to establish partnership agreements at the speed of business and to attract private sector investment for translational R&D, technology maturation, and commercialization.

¹⁴⁷ RTAs may be viewed as modified and modernized version of CRADAs.

¹⁴⁸ https://www.transform.af.mil/Portals/18/documents/OSA/OTA_Brief.pdf?ver=2015-09-15-073050-867

¹⁴⁹ National Aeronautics and Space Act of 1958 Public Law 85-568, see <https://www.nasa.gov/partnerships/about.html>

A. EXPAND USE OF ACT AUTHORITY

Implement regulations under the Stevenson-Wydler Act¹⁵⁰ to extend the ACT authority¹⁵¹ to all GOCO Laboratories. Legislative change is required to extend the use of the ACT authority by GOGO Laboratories through partnership intermediaries authorized under the Stevenson-Wydler Act.

B. ESTABLISH NEW RESEARCH TRANSACTION AUTHORITY

Legislative change is required to establish the *Research Transaction Authority*¹⁵² to support translational R&D collaborations¹⁵³ by simplifying, accelerating, tailoring, and executing partnership agreements at the speed of business. The new authority is modeled after the OTA and will not be used for procurement or financial assistance actions. Implement regulations under the Stevenson-Wydler Act¹⁵⁴ with uniform government-wide policies and practices to ensure proper stewardship for use of the RTA authority and appropriate conveyance of intellectual property rights consistent with the Bayh-Dole Act. The RTA is a new partnering mechanism to for Federal Laboratories and is not intended to change or limit existing authorities.

C. EXPAND USE OF NONPROFIT FOUNDATIONS

Legislative change is required to authorize all Federal R&D agencies to establish nonprofit foundations that will advance their missions by attracting private sector investment to accelerate technology maturation, transfer, and commercialization efforts of an agency's R&D outcomes.¹⁵⁵

¹⁵⁰ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

¹⁵¹ See <https://www.energy.gov/technologytransitions/frequently-asked-questions-about-act>

¹⁵² Add a new section to 15 U.S.C. § 3710a to create “research transactional authority” which would expand to all applicable agencies the ability to use Other Transaction Authority (OTA). Only a few agencies are authorized to use OTAs. The RTA would exclude procurement and financial assistance actions.

¹⁵³ To also include incubators, accelerators, public-private co-location, personnel exchange, and university-based research parks.

¹⁵⁴ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

¹⁵⁵ 15 U.S.C. 3705 details cooperative research centers. Language can be added to extend the authority for agencies to develop nonprofit foundations. Agencies that require appropriated funding for a foundation will require direct action by Congress.

Develop, adopt, and use consistent policies and practices to establish and operate nonprofit foundations at Federal R&D agencies.

D. EXPAND USE OF OUTLEASING AUTHORITY

Legislative change is required to authorize all Federal Laboratories to outlease real property to the private sector for use to support technology transfer and commercialization activities.¹⁵⁶ The ability to make the most use of existing real property assets through EULA, or other mechanisms for non-excess property, while retaining the potential for future government use is a potential way to increase interactions with Federal Laboratories. In addition, if lease revenue is retained by the laboratory, it can create an incentive to ensure full use of existing capacity and boost research outcomes.

D. TECHNOLOGY MATURATION FUNDING

1. BACKGROUND

Developing early-stage research discoveries into products for Federal or commercial use requires significant investment in capital and labor. Additional funding is often needed to mature the technology before a private sector investor will be willing to take the risk on a potential product. RFI respondents reported that it can be difficult to attract prospective private sector licensees for federally funded patents. “The chasm between the immature state of the work emerging from the research laboratory and the level of maturity needed to attract a large corporate transferee was identified as one of the largest barriers to technology transfer.”¹⁵⁷ According to GAO, “potential industry partners are often reluctant to assume the risks of investing in technologies whose potential has not been demonstrated with a prototype, performance data, or similar evidence.”¹⁵⁸ Technology maturation funding can be used to produce a proof of concept,

¹⁵⁶ Expansion of this authority could be included in 15 U.S.C. § 3710 as an additional section (section “j”).

¹⁵⁷ Wang, M., S. L. Pfleeger, D. M. Adamson, G. Bloom, W. Butz, D. Fossum, M. Gross, A. Kofner, H. Rippen, T. K. Kelly, and C. T. Kelley Jr. 2003. *Technology Transfer of Federally Funded R&D*. Santa Monica, CA: RAND Science and Technology Policy Institute.

¹⁵⁸ U.S. Government Accountability Office (GAO). 2009. *Technology Transfer: Clearer Priorities and Greater Use of Innovative Approaches Could Increase the Effectiveness of Technology Transfer at Department of Energy Laboratories*. Washington, D.C.: GAO. GAO-09-548. <http://www.gao.gov/assets/300/290963.pdf>

prototype, additional data, or validation studies; scale-up a technology; or enhance intellectual property protection.¹⁵⁹

The Federal Government supports a variety of technology maturation programs, some of which require a cost-sharing arrangement between an agency and a private company or other organization. Federal technology maturation programs involve both cross-cutting programs, such as those supporting small businesses, and agency-specific programs that support specific sectors:

- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs—the Nation's largest source of early-stage technology financing—are administered by the Small Business Administration through 11 Federal agencies with about \$2.5 billion¹⁶⁰ annual set aside and about 160,000 awards granted;¹⁶¹ STTR requires collaboration with a research institution¹⁶²
- The Department of Defense (DOD) Rapid Innovation Program aims to transition technologies into applications that can be used on defense weapon systems and focuses on more mature technologies that would have an immediate impact.¹⁶³
- The DOD Manufacturing Technology (ManTech) Program aims to advance the state-of-the-art for defense-essential manufacturing capabilities and supports manufacturing innovation institutes, which provide companies with access to facilities and risk sharing to bring new products to market and increase U.S. manufacturing competitiveness.¹⁶⁴

¹⁵⁹ Howieson, Susannah V., Elaine M. Sedenberg, Brian J. Sergi, and Stephanie S. Shipp, 2013. Department of Energy Technology Maturation Programs. IDA Paper P-5013, May 2013

¹⁶⁰ SBIR is funded with 3.2% of extramural research budget for all agencies with a budget greater than \$100 million per year; STTR is funded with 0.45% of extramural research budget for all agencies with a budget greater than \$1 billion per year. SBA Office of Investment & Innovation presentation on December 2016, slide 8 and 10. <https://www.sbir.gov/sites/default/files/SBIR%20Overview-%20DEC%202016.pptx>.

¹⁶¹ Ibid, slide 4.

¹⁶² Small Business Innovation Research (SBIR). “About SBIR.” Accessed October 1, 2018. <https://www.sbir.gov/about>

¹⁶³ U.S. Department of Defense (DOD), n.d. “Rapid Innovation Fund.” Accessed Oct 11, 2018. <https://defenseinnovationmarketplace.dtic.mil/business-opportunities/rapid-innovation-fund/>

¹⁶⁴ U.S. Department of Defense (DOD), n.d. “Manufacturing Technology Program.” Accessed Oct 11, 2018. <https://www.dodmantech.com/>

- DOE Energy Innovation Hubs include five innovation hubs that focus research on fuels from sunlight, nuclear energy modeling and simulation, energy storage, and critical materials and involve R&D collaborations among scientists from Federal Laboratories, universities, and private companies.¹⁶⁵
- DOE Technology Commercialization Fund is funded via a set-aside of 0.9 percent of DOE's budget for applied energy research, development, demonstration, and commercial application and matches funds with private partners.^{166,167}
- NIH through its National Center for Advancing Translational Sciences programs, an institute of the NIH, funds transition via its Clinical and Translational Science Awards¹⁶⁸
- NSF requires, through cooperative agreements, cost-sharing with academic and other organizations for its Engineering Research Centers,¹⁶⁹ Industry-University Cooperative Research Centers (IUCRC), and Partnerships for Innovation¹⁷⁰ programs
- NIST, with DOD and DOE, supports the U.S. manufacturing sector through its Manufacturing Extension Partnership¹⁷¹ and Manufacturing USA program.¹⁷²

RFI responses noted the difficulty of fulfilling the patent and licensing requirements to patent and license inventions. This was particularly notable for small businesses and small institutions that do not have resources to invest. The comments noted the need to allow a

¹⁶⁵ U.S. Department of Energy (DOE), n.d. "Hubs." Accessed Oct 11, 2018. <https://www.energy.gov/science-innovation/innovation/hubs>

¹⁶⁶ U.S. Department of Energy (DOE), n.d. "Technology Commercialization Fund." Accessed Oct 11, 2018. <https://www.energy.gov/technologytransitions/services/technology-commercialization-fund>

¹⁶⁷ Section 1001 of the Energy Policy Act of 2005

¹⁶⁸ National Institutes of Health (NIH), n.d. "Clinical and Translational Science Awards (CTSA) Program." Accessed Oct 11, 2018.

¹⁶⁹ National Science Foundation (NSF), n.d. "Engineering Research Centers (ERC)." Accessed Oct 11, 2018. https://www.nsf.gov/funding/pgm_summ.jsp?pims_id=5502

¹⁷⁰ National Science Foundation (NSF), n.d. "Partnerships for Innovation (PFI)." Accessed Oct 11, 2018. https://www.nsf.gov/funding/pgm_summ.jsp?pims_id=504790

¹⁷¹ National Institute of Standards and Technology (NIST) and U.S. Department of Commerce, n.d. "Manufacturing Extension Partnership (MEP)." Accessed Oct 11, 2018. <https://www.nist.gov/mep>

¹⁷² Manufacturing USA, n.d. "Manufacturing USA." Accessed Oct 11, 2018. <https://www.manufacturingusa.com/>

portion of award funds to be allocated to properly protect and sustain the government’s investment in the R&D. Since the government retains a use license while placing the full cost on the contractor, it was noted that there is an imbalance in the requirement.

2. CHALLENGES

Technology maturation requires a significant amount of funding, time, and energy to facilitate the adoption of the new technology by commercial entities.¹⁷³ The Congressional Research Service found that university-developed technologies are not at a technology maturation level that is suitable for adoption by industry and are “doomed to remain in the laboratory unless incentives are added to induce ongoing collaboration between the inventors and the entrepreneurs seeking to take them to market.”¹⁷⁴ RFI responses echoed the same sentiment. (Refer to “Perspectives on a New Approach for Federal R&D Funding.”)

Perspectives on Federal R&D Funding Approach

“The federal government has played a long and foundational role in funding basic and applied scientific research that has produced tremendous commercial and social benefits for the United States. This role must persist. However, in the post-World War II era the U.S. science, technology, and innovation system pursued a “linear model” of innovation that pumped seemingly limitless funding for basic research into U.S. universities and government labs on the front-end with the expectation that industry virtually alone would conduct the applied and translational work needed to transform the basic research into technologies and products that could be commercialized (and manufactured at scale in the United States) on the back-end. That approach also viewed all scientific research as essentially equal and didn’t prioritize scientific research funding based on its ability or likelihood to help support U.S. economic competitiveness, which was taken as a given. While this model worked for a time—when many fewer other nations had the technological capabilities to translate basic research into commercial products—it’s ill-suited to today’s intensely competitive global economy. Thus, a new approach is needed to guide federally funded R&D and its impact on the U.S. innovation system, and it should focus on two key areas of importance: what research is funded and how that research is commercialized.”

Source: NIST public meeting at Gaithersburg, MD on June 14, 2018

¹⁷³ Schacht, W. H. 2012. *The Bayh-Dole Act: Selected issues in patent policy and the commercialization of technology*. Library of Congress, Washington DC: Congressional Research Service, 2009.

¹⁷⁴ Mary Elizabeth Hughes, Susannah Vale Howieson, Gina Walejko, Nayanee Gupta, Seth Jonas, Ashley T. Brenner, Dawn Holmes, Edward Shyu, and Stephanie Shipp. 2011. *Technology Transfer and Commercialization Landscape of the Federal Laboratories*. IDA.

Funding support is also needed to support non-technical aspects of the commercialization process. For example, companies, particularly startups and small businesses, need capital to perform customer discovery and validation, which involve a substantial number of interviews and follow up meetings, and to iterate on their prototypes based on feedback. Startups, particularly those that may be interested in SBIR and STTR programs, may lack the capital to perform these essential functions for successful commercialization of their products. In addition, funding is needed for filing patents and for identifying potential commercial partners (Refer to “RFI Response on the Need for Resources for the Intellectual Property Process”). In order to work with federally funded technologies, small companies also need assistance on patenting and licensing, commercialization planning, and market assessments.¹⁷⁵ (Refer to “What We Heard: SBIR.”)

RFI Response on the Need for Resources for the Intellectual Property Process

“It is challenging for universities and other recipients of federal research funding to independently pay for technology and product research and development, as well as for preparation, filing, prosecutions and maintenance of patents and applications...Lack of funding for patenting and commercialization activities poses a fundamental challenge to a university’s ability to transfer federally funded technologies.”

Source: RFI—State University of New York

Many RFI comments noted that a new technology commercialization appropriation is needed. While a new technology maturation fund would be useful, this green paper generally attempts to maintain a budget neutral posture.

¹⁷⁵ Federal Laboratory Practices Contributing to Economic Development DOC

What We Heard: SBIR

There were numerous suggestions and very strong data presented as evidence to support the SBIR/STTR Program as “America’s Seed Fund.” Below is a summary of what we heard from the RFI:

- Ensure the continued funding and sustainment/increase of the SBIR and STTR programs.
- Develop broader and more flexible approach to include translational research.
- Initiate an SBIR for Federal Laboratories.
- Expand "Phase zero" proof-of-concept pilot program (already implemented by NSF).
- Provide for additional flexibility in how SBIR/STTR funds can be used including market assessment, customer discovery, and technology transfer.
- Expand connections between SBIR and I-Corps™ to provide training.
- Promote the protection and use of Phase II inventions to Phase III.
- Better align FAR/DFARS with SBIR.
- Increase geographic dispersion of awards.
- Reduce paperwork – consider shorter or modified Phase I applications.
- Further study SBIR metrics to inform how updates can maximize effectiveness.

3. INTENDED ACTION

Intended Action 10. Allow the limited use of R&D funds awarded through government grants, contracts, and cooperative agreements for intellectual property protection; and provide a summary of public comments on SBIR/STTR technology maturation funding and related improvements¹⁷⁶ to the U.S. Small Business Administration (SBA) for consideration and development of follow up actions.

A. LIMITED USE OF FUNDS FOR PATENTING

Implement regulatory change under the Bayh-Dole Act to allow for a reasonable amount of awarded R&D funds up to a specified maximum to be used by the contractor to secure the government’s right and interest to a patented invention.¹⁷⁷

¹⁷⁶ For example, expanded support for technology entrepreneurship and commercialization involving startups and small businesses including commercial viability assessment, market analysis, and proof-of-concept/prototyping.

¹⁷⁷ A change to 37 CFR 401.14(f) could be used to note that up to 3% of the award could be used to protect the government’s right and interest in an invention through the contractor’s election to patent. This action would not increase the size of any award.

STRATEGY 3. BUILD A MORE ENTREPRENEURIAL R&D WORKFORCE

The third of five strategies of the L2M CAP Goal is focused on building a more entrepreneurial R&D workforce to unleash American innovation. The intended actions are designed to promote start-ups, job creation, and economic growth by facilitating technology transfer activities through an R&D workforce more knowledgeable about the needs of industry and with the flexibility to support industry's needs. This chapter discusses actions to stimulate a more entrepreneurial mindset for the Federal R&D workforce through targeted programs in areas such as skill building, mentoring, training, professional development, education, and personnel exchange. It also describes actions to address constraints to entrepreneurial activities posed by restrictive conflict of interest policies.

A. INTRODUCTION

The R&D workforce is the foundation of the American R&D enterprise and the greatest asset for U.S. innovation and industrial competitiveness. Federally funded researchers, engineers, and managers develop new innovative technologies, identify commercialization opportunities, and transfer technology to industry, or start companies themselves. Further, since passage of the Federal Technology Transfer Act of 1986, which amended the Stevenson-Wydler Act of 1980, “technology transfer, consistent with mission responsibilities, [has been] a responsibility of each laboratory science and engineering professional.”¹⁷⁸ By empowering both the intramural and extramural R&D workforce to be more entrepreneurial, the Federal Government ensures that its funds will be used with an eye towards practical application and commercialization, resulting in a greater return on investment to the American taxpayer.

At its core, technology transfer is a person-to-person “contact sport” requiring robust engagement between motivated researchers and engaged industry representatives. Innovators need to be knowledgeable about the needs of industry, while those in industry need to be flexible and responsive, to effectively transfer technology. Truly revolutionary technologies can languish if a strong business acumen is not available to meet the challenges of bringing a technology to market. The skills needed to develop a value proposition and assemble a team to run a business are not within the classical training of researchers. Training and flexible solutions are needed whether it will be the inventor taking the new product to market, or for inventors to communicate

¹⁷⁸ 15 U.S.C. § 3710 (a) - Utilization of Federal Technology, Policy

the discovery and its implications to a business that will eventually translate the new ideas into tomorrow's products and services.

B. TECHNOLOGY ENTREPRENEURSHIP PROGRAMS

1. BACKGROUND

Training and professional development programs are mechanisms used across government, business, and education to teach specific skills or areas of knowledge. These programs impart important competencies that are not necessarily learned on the job. The Federal Government uses entrepreneurial training and professional development to give the R&D workforce the tools they need to be more enterprising.

Researchers play a critical role in technology transfer because they have the best understanding of the technology itself and the way in which it might be used. However, most scientists and researchers lack experience in business formation,¹⁷⁹ may be unaware of how to collaborate with industry, and may not understand the commercial viability of their innovations.¹⁸⁰ This skill gap can lead to an inability to balance basic research and the identification of commercialization opportunities, and can hinder the effective transfer of technology.¹⁸¹ In general, entrepreneurial training programs teach researchers to understand the needs of industry, to commercialize technology, and to recognize their potential to add to the technology transfer and start-up ecosystem. Federally funded training programs not only educate researchers on how to navigate this balance, but also establish an avenue for product development.

Federal agencies use training and professional development in diverse ways to achieve their unique goals and needs. Some agencies use mentoring as a complement to other entrepreneurial

¹⁷⁹ West, Darrell. 2012. "Improving University Technology Transfer and Commercialization." *Issues in Technology Innovation*, Num 20. <https://www.brookings.edu/research/improving-university-technology-transfer-and-commercialization/>

¹⁸⁰ U.S. Government Accountability Office (GAO). 2014. "Federal Laboratory Commission Should Increase Communication with Potential Customers to Improve Initiatives." <https://www.gao.gov/products/GAO-15-127>

¹⁸¹ Hughes, Mary E., Susannah V. Howieson, Gina Walejko, Nayanee Gupta, Seth Jonas et al. 2011. *Technology Transfer and Commercialization Landscape of Federal Laboratories*, Washington, DC: IDA Science and Technology Policy Institute.

programs. For example, the NIST N-STEP program provides mentors to researchers and associates affiliated with NIST to evaluate research for business potential and helps develop new businesses that can commercialize the research results.¹⁸² The DOE Lab-Embedded Entrepreneurship Programs (LEEP) takes top entrepreneurial scientists and engineers and embed them within National Laboratories to perform early-stage R&D that may lead to the launch of energy or manufacturing businesses in the future.¹⁸³ Other agencies have established mentoring networks to counsel entrepreneurs, such as the SBA SCORE program, which consists of 13,000 volunteer businessmen and businesswomen. Additional programs are designed to directly provide innovation training and professional development, most notably the NSF Innovation Corps™ (I-Corps™).¹⁸⁴

I-Corps™ is an accelerated version of the Stanford University's Lean Launchpad course.^{185,186} Founded in 2011, the experiential learning program seeks to give federally funded extramural researchers a course in start-up entrepreneurship. I-Corps™ teams—composed of a technical lead, entrepreneurial lead, and business (or industry) mentor—engage in a seven-week curriculum¹⁸⁷ to understand customer problems that their technology may address, potential addressable markets, and the potential pathways forward to commercialize their technology concepts. I-Corps™ teams are exposed to feedback from potential customers with the goals of understanding their markets and learning how to identify fail-fast issues and pivot to alternative paths forward. I-Corps™ teams also develop regional networks, engage in customer discovery work, and receive hands-on training on entrepreneurship and ecosystem development.

¹⁸² TEDCO. "Providing opportunities to Maryland researchers." Website accessed 9/26/2018. <https://www.tedcomd.com/funding/tech-transfer/n-step>

¹⁸³ <https://www.energy.gov/eere/amo/lab-embedded-entrepreneurship-programs>

¹⁸⁴ National Science Foundation (NSF). "I-Corps™." Website accessed 9/26/2018. https://www.nsf.gov/news/special_reports/I-Corps™/

¹⁸⁵ Stanford. 2014. "Stanford's Lean LaunchPad Course Sets Students on Entrepreneurial Trajectory." Accessed 9/26/2018. <https://stvp.stanford.edu/blog/stanfords-lean-launchpad>

¹⁸⁶ National Science Foundation (NSF) was directed by Congress to continue funding I-Corps™ and encouraged to expand the program in Section 601 of the American Innovation and Competitiveness Act of 2017, Public Law 114-329.

¹⁸⁷ The I-Corps™ 2016 Teaching Handbook is available for download and view at <https://venturewell.org/wp-content/uploads/I-Corps™-Teaching-Handbook-Jan16.pdf>

I-Corps™ started at NSF, but some agencies, such as DHS, DOD,¹⁸⁸ and NASA¹⁸⁹ partner with NSF to send awardees through NSF I-Corps™ programs, while other agencies developed their own programs based on I-Corps™ and adapted the curriculum for their research communities. Examples of agency-based programs include I-Corps™@NIH,¹⁹⁰ National Security Agency’s (NSA) version of I-Corps™ for the Intelligence Community,¹⁹² I-Corps™ at ARPA-E,¹⁹³ Energy I-Corps™ at DOE,¹⁹⁴ and the USDA I-Corps™ Agricultural Research Service (ARS) pilot program.¹⁹⁵ Some States have also collaborated with NSF to create I-Corps™ programs, such as I-Corps™@Ohio.¹⁹⁶ Most agencies provide entrepreneurial training for extramural researchers funded under their research programs, while some programs, such as NIH’s Clinical and Translational Science Awards (CTSA), train professionals working on translating science into practical applications.¹⁹⁷ For example, the University of Michigan created

¹⁸⁸ U.S. Department of Defense (DOD). 2018. “I-Corps™ @ DoD Funding Announcement.” <https://basicresearch.defense.gov/News/Articles/News-Display/Article/1490285/I-Corps™-dod-funding-announcement/>

¹⁸⁹ National Aeronautics and Space Administration. 2018. “I-Corps™ Program.” Accessed 10/1/2018. <https://sbir.nasa.gov/content/I-Corps™>.

¹⁹⁰ National Institutes of Health (NIH). 2018. “The I-Corps™ at NIH.” Accessed 10/1/2018. <https://sbir.cancer.gov/programseducation/icorps>.

¹⁹¹ Domain focused programs include the I-Corps™@NIH, which includes cross-cohort learning on sector-specific topics like regulatory strategy for therapeutic candidates, and a National I-Corps™ NSF Cohort, which may focus topics of a more granular nature, such as business model differences between a manufactured product versus a business service. NSF also has built a relationship with Science Foundation Ireland (SFI) to send their teams through the NSF program. The program is called I-Corps@SFI. Additionally, the DOE also has an I-Corps program called Energy I-Corp, that DoE manages and is separate from the NSF program, and is specialized for energy opportunities.

¹⁹² The White House. 2015. “Fact Sheet: President Obama Announces New Commitments from Investors, Companies, Universities, and Cities to Advance Inclusive Entrepreneurship at First-Ever White House Demo Day.” <https://obamawhitehouse.archives.gov/the-press-office/2015/08/04/fact-sheet-president-obama-announces-new-commitments-investors-companies>

¹⁹³ ARPA-E. “I-Corps™ at ARPA-E.” Accessed 10/1/2018. <https://arpa-e.energy.gov/?q=site-page/I-Corps™-arpa-e>.

¹⁹⁴ <https://www.energy.gov/eere/technology-to-market/energy-i-corps>

¹⁹⁵ Bahar, Mojdeh. “I-Corps™ ARS—A New Twist on NSF’s I-Corps™ Model.” https://meeting.federalallabs.org/wp-content/uploads/2018/04/I-Corps™-at-ARS-I-Fast-at-NIFA-M.Bahar_.pptx

¹⁹⁶ I-Corps™ Ohio. Accessed 10/1/2018. <https://icorpsohio.org/> .

¹⁹⁷ NIH. “About the CTSA Program.” Accessed 10/1/2018. <https://ncats.nih.gov/ctsa/about>.

a supplementary training program for CTSA called Fast Forward Medical Innovation (FFMI) fastPACE to accelerate entrepreneurial training.¹⁹⁸

RFI respondents perceived government entrepreneurial training and professional development programs, especially I-Corps™, to be very successful. RFI respondents remarked on the success of I-Corps™ in preparing scientists, engineers, and graduate students to extend their focus beyond the laboratory. From 2011 to June 2018, I-Corps™ trained 1,223 teams representing 248 universities from 47 States, D.C., and Puerto Rico.^{199,200} NSF has also used I-Corps™ programs to promote inclusion in science and technology entrepreneurship through efforts such as funding targeted I-Corps™ sites,²⁰¹ and to promote a more entrepreneurial mindset.²⁰² Teams that went through I-Corps™ raised \$300 million in follow-on funding and started 583 start-up companies, with six of those start-ups being successfully acquired by a larger company.²⁰³

Federal agencies also use accelerator and incubator programs to stimulate entrepreneurship. A seed accelerator is defined as “a fixed-term, cohort-based program, including mentorship and educational components, that culminates in a public pitch event or demo-day.”²⁰⁴ Accelerator programs typically offer funding and other support services to potential startup companies in return for a share of equity in the company. Accelerators generally attempt to expedite the growth of an existing company in a few weeks or months. Alternatively, incubators recruit individuals

¹⁹⁸ Servoss, Jonathan et al. 2017. “fastPACE Train-the Trainer: A scalable new educational program to accelerate training in biomedical innovation, entrepreneurship, and commercialization.” *Journal of Clinical and Translational Science*, Volume 1, Issue 5.

¹⁹⁹ NSF. “I-Corps™ Curriculum and Resources.” Accessed 10/1/2018.
https://www.nsf.gov/news/special_reports/I-Corps™/resources.jsp.

²⁰⁰ In addition to the nine NSF I-Corps Nodes, there are also 99 sites that contribute to the national infrastructure of I-Corps™ – providing additional geographic reach beyond the nine Nodes. Link to a recent map of sites: https://www.nsf.gov/news/special_reports/i-corps/sites.jsp

²⁰¹ NSF. 2017. “NSF promotes inclusion in tech entrepreneurship through eight I-Corps™ Sites.”
https://www.nsf.gov/news/news_summ.jsp?cntn_id=190921

²⁰² VentureWell. 2016. “How an Entrepreneurial Mindset Can Make Research More Effective: Reflections from an I-Corps™ Alumnus.” <https://venturewell.org/entrepreneurial-mindset-can-make-research-effective-reflections-corps-alumnus/>

²⁰³ National Science Foundation (NSF). “I-Corps™ Curriculum and Resources.” Website accessed 9/26/2018. https://www.nsf.gov/news/special_reports/I-Corps™/resources.jsp

²⁰⁴ Susan G. Cohen, University of Richmond, and Yael V. Hochberg (Massachusetts Institute of Technology and the National Bureau of Economic Research, “Accelerating Startups: The Seed Accelerator Phenomenon,” March 2014, <http://seedrankings.com/pdf/seed-accelerator-phenomenon.pdf>

with promising ideas and nurture them over a longer period of time with the hope of establishing a business model and company based on a particular innovation.²⁰⁵

Federal accelerator programs include the SBA Growth Accelerator Fund Program launched in 2014. From 2014 to 2017, SBA funded approximately 235 accelerators and incubators.²⁰⁶ Cyclotron Road, embedded within DOE's Lawrence Berkeley National Laboratory, is an example of an incubator that recruits entrepreneurial technology fellows. Fellows receive access to laboratory scientists and equipment to pursue technology development, raise capital, build a business case, and ideally commercialize their products. Since 2015, Cyclotron Road has awarded more than \$15 million to 41 fellows who have generated an additional \$75 million in early stage funding from varied sources to support their projects.²⁰⁷

2. CHALLENGES

RFI respondents overwhelmingly provided positive evaluations of I-Corps™ and indicated that these successes could be expanded. (Refer to “RFI Recommendations for I-Corps™ Expansion.”) The NSF I-Corps™ is organized around nine regional I-Corps™ Nodes designed to support regional needs.²⁰⁸ While these regional nodes are intended to sustain a national ecosystem, the limited geographic reach of I-Corps™ caps its effectiveness in regions that are geographically distant from its nodes. Furthermore, agencies provide I-Corps™ training for the extramural researchers funded under their grants, so agencies without I-Corps™-like programs or agreements with the NSF I-Corps™ program do not have access to the training.

²⁰⁵ Conner Forest, TechRepublic, “Accelerators vs. Incubators: What Startups Need to Know.” June 25, 2018. <https://www.techrepublic.com/article/accelerators-vs-incubators-what-startups-need-to-know/>

²⁰⁶ See SBA Growth Accelerator Fund Competition <https://www.sba.gov/content/sba-growth-accelerator-fund-competition>

²⁰⁷ Cyclotron Road, n.d. “Home.” Accessed Oct 11, 2018. <http://www.cyclotronroad.org/home/>

²⁰⁸ The nine nodes are spread out around the Nation. See a list of the nodes here: https://www.nsf.gov/news/special_reports/I-Corps™/nodes.jsp

RFI Recommendations for I-Corps™ Expansion

“We urge NIST and the administration to continue to support the I-Corps™ program at the NSF and to encourage that other Federal research agencies establish and expand I-Corps™ programs.”

Source: RFI response, AAU, APLU, COGR, AAMC, and ACE

“UC supports the expansion of the successful NSF I-Corps™ program into other agencies. This program helps train academics in entrepreneurship by giving them the tools to effectively commercialize the results of their research.”

Source: RFI response, University of California (UC)

Respondents also indicated that I-Corps™ and I-Corps™-like programs could be improved by targeting populations interested in commercialization. For example, graduate students or postdoctoral researchers may be a target audience to start companies. Entrepreneurial training could also be paired with other training programs to reach groups interested in commercialization—for example, the NASA and NIH I-Corps™-like programs fund groups that have already received Phase I funding from the SBIR/STTR programs.²⁰⁹ Agencies could expand this by pairing entrepreneurial training with SBIR/STTR awards or requiring that SBIR/STTR Phase I awardees participate in an entrepreneurial training or professional development program before becoming eligible to receive a Phase II grant.²¹⁰ Other RFI respondents recommended addressing industry need by establishing training programs relevant to “hot” technologies or specializing I-Corps™ nodes to address specific branches of research. (Refer to “RFI Recommendation to Better Target Training Programs.”)

²⁰⁹ See Chapter on Strategy 2 of this report for an introduction and overview of SBA SBIR/STTR programs.

²¹⁰ Blank, Steve. 2012. “Innovation Corps: A Review of the New National Science Foundation Program to Level Research Investments.”
https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-112-SY21-WState-Sblank-20120716_o.pdf

RFI Recommendation to Better Target Training Programs

“CMU recommends that these programs also include support for establishing regional Lab hubs and I-Core nodes focused on emerging technologies—such as autonomy, AI, quantum computing and critical areas of advanced manufacturing.”

Source: RFI response, Carnegie Mellon University (CMU)

Leveraging regional innovation ecosystems has proven to be a successful approach to increasing economic investment and growth centered on a geographic area. A 2014 economic analysis concluded that the establishment of an accelerator program has an impact on the geographical region where the accelerator was formed. Both startup companies and venture capitalists are often attracted to the region.²¹¹ The establishment of accelerators and incubators can provide an opportunity for Federal Laboratories to pursue partnerships and leverage resources for technology transfer. However, a potential challenge is that there may not be sufficient leadership emphasis and incentives for laboratory researchers to engage with other stakeholders. This support can be indispensable to maximizing the effectiveness of the Federal Laboratory’s technology transfer mission.²¹² (Refer to “RFI Response on Federal Laboratory Leadership Support for Technology Transfer.”)

RFI Response on Federal Laboratory Leadership Support for Technology Transfer

“With some notable exceptions, Federal Laboratory directors do not view tech transfer as central to their core mission. In fact, since some Federal Laboratories support tech transfer through overhead budget lines, tech transfer is in direct competition for funding with operational expenses including security, IT, training, and infrastructure upgrades. Additionally, Federal Laboratories are encouraged and rated on their ability to keep their overhead low, so increasing funding for tech transfer within the overhead budget line is often discouraged. Commercialization performance at Federal Laboratories will continue to lag universities until laboratory leaders are directed, funded, and incentivized to place greater emphasis on commercialization outcomes, including through accountability to meaningful metrics.”

Source: RFI—State University of New York

²¹¹ Daniel C Fehler and Yael V Hochberg; “Accelerators and the Regional Supply of Venture Capital Investment;” September 19, 2014. <http://www.seedrankings.com/pdf/accelerators-and-regional-supply-of-vc-investment.pdf>

²¹² Palminteri, D. 2003. “Partners on a mission: Federal laboratory practices contributing to economic development.” Office of Technology Policy, Technology Administration, U.S. Department of Commerce. Partners on A Mission: Federal Laboratory Practices Contributing to Economic Development [Diane Palminteri, Bruce P. Mehlman]

Most existing entrepreneurial training programs are targeted towards extramural researchers. The primary pathway for admittance in the NSF I-Corps™ program is for participants to have received an NSF award.²¹³ For the NSF I-Corps™, Federal researchers do not typically participate in these programs. Some agencies do host commercialization related training/workshops for Federal researchers. NASA, for example, hosts an annual SBIR Technology Commercialization Workshop for its employees.²¹⁴ However, these training programs are of limited scope due to conflict of interest regulations. For example, I-Corps™ training is developed around the experience of taking a technology to market and understanding its commercial viability—activities that Federal researchers are typically precluded from conducting when they relate to their job functions.²¹⁵ The inability of Federal researchers to participate in I-Corps™ and similar programs limits the reach of current entrepreneurial training programs from a large segment of the Federal R&D portfolio.

In addition to strong entrepreneurship programs externally, it is also important to have trained professionals in technology transfer to promote entrepreneurship. Technology transfer is not clearly recognized as a career choice across Federal agencies. There is a lack of uniformity in the job description, job titles, and described functions for the professionals who carry out the important functions of technology transfer offices. This hinders the ability of the Federal agencies to attract and recruit well qualified candidates, and results in a lack of adequate opportunities for continued growth and development of technology transfer professionals. The basis of technology transfer involves understanding research at the laboratory, and a scientific and technical background is common. However, technology transfer professionals must also be skilled in business applications, negotiation, capital investment, outreach, and management as well as aware of legal contracts and the patent system. Since the Office of Personnel Management (OPM) Occupational Handbook does not currently contain a jobs series for technology transfer,²¹⁶ Federal agencies offer technology transfer positions in a wide variety of occupational series.

²¹³ Another pathway is for teams that have successfully completed regional I-Corps™ training at an I-Corps™ Node or I-Corps™ Site to join the National I-Corps™ program.

²¹⁴ Lal, Bhavya *et al.* 2013. “Expediting the Transfer of Technology from Government Laboratories into the Aeronautics Industry.” IDA Science and Technology Policy Institute.

²¹⁵ See 18 U.S.C. §208 and §209, 5 C.F.R §2935 and §2936, and OGE guidance at <https://www.oge.gov/web/oge.nsf/Use+of+Government+Position+and+Resources>. For more information, see the Conflict of Interest Policies section of this chapter (Section C).

²¹⁶ <https://www.opm.gov/policy-data-oversight/classification-qualifications/classifying-general-schedule-positions/occupationalhandbook.pdf>

3. INTENDED ACTION

Intended Action 11. Establish technology entrepreneurship programs at Federal R&D agencies government-wide.

A. EXPAND TECHNOLOGY ENTREPRENEURSHIP PROGRAMS

Federal R&D agencies should leverage entrepreneurship programs representing best practices, such as NSF's I-Corps™²¹⁷ program for extramural R&D programs, and internal experiential training programs such as DOE's Lab-Embedded Entrepreneurship Program²¹⁸ for intramural R&D programs.

B. GUIDANCE TO IMPLEMENT AND OPERATE TECHNOLOGY ENTREPRENEURSHIP PROGRAMS

Develop, adopt, and use consistent policies and practices government-wide to implement and operate technology entrepreneurship programs at Federal R&D agencies.

C. STRENGTHEN THE I-CORPS™ PROGRAM

A summary of public comments specific to NSF's I-Corps™ Program, DOE's Lab-Embedded Entrepreneurship Program, and others will be provided to the respective agencies for actions. More general comments to strengthen technology entrepreneurship programs will be summarized and provided for consideration and appropriate follow up actions by Federal R&D agencies (Refer to "What We Heard: I-Corps™.")

D. DESIGNATE JOB SERIES FOR TECHNOLOGY TRANSFER PROFESSIONALS

Establish a designated job series to recruit, develop, and retain well qualified professionals to pursue a career in Federal technology transfer and develop needed implementation guidance for government-wide adoption and use. Given the need for individuals with business backgrounds and scientific/technical backgrounds, the job series should be inclusive of both types of professionals required to carry out technology transfer functions.

²¹⁷ National Science Foundation (NSF). "I-Corps™." Website accessed 9/26/2018. https://www.nsf.gov/news/special_reports/I-Corps™/

²¹⁸ Department of Energy (DOE). "Lab-Embedded Entrepreneurship Programs." Website accessed 10/26/2018. <https://www.energy.gov/eere/amo/lab-embedded-entrepreneurship-programs>

What We Heard: I-Corps™

There were numerous suggestions regarding the success of the I-Corps™ Program. Below is a summary of what we heard from the RFI:

- Maintain and expand I-Corps™.
- Customize I-Corps™ to focus on specific areas.
- For large awards, require that the proposal include entrepreneurial training.
- Provide formal programs that are targeted to the tech-based startups needing longer term (>10 years) to reach a product.
- Allow Federal employees to participate in I-Corps™.

C. MANAGING CONFLICTS OF INTEREST

1. BACKGROUND

Technology transfer ultimately happens through the movement of ideas and knowledge. This can be accomplished by enabling personnel mobility. Rotating external technical talent into Federal science and technology projects, or vice versa, serves as a potent vehicle for technology transfer.²¹⁹

Federal laws and regulations present a substantial barrier to the ability of R&D workers to be more entrepreneurial.²²⁰ A conflict of interest can be defined as a situation in which a person's official duties are at conflict with other secondary interests. Conflicts of interest are common among all professions but are especially important for Federal Government interests because workers who administer and use public funds are placed in a unique position of trust.

Federal ethics statutes constrain the actions of Federal employees along with extramural researchers who receive Federal funding. For government employees, the Office of Government

²¹⁹ U.S. Office of Personnel Management. 2018. "Hiring Information: Intergovernmental Personnel Act." Accessed September 21, 2018. <https://www.opm.gov/policy-data-oversight/hiring-information/intergovernment-personnel-act/>

²²⁰ See 18 U.S.C. §208 and §209, 5 C.F.R §2935 and §2936, and OGE guidance at <https://www.oge.gov/web/oge.nsf/Use+of+Government+Position+and+Resources>.

Ethics (OGE) promulgates Federal ethics regulations across the Federal Government. The OGE groups Federal ethics rules into five areas: (1) financial conflicts and impartiality, (2) post-government employment, (3) outside employment and activities, (4) gifts and payments, and (5) use of government position and resources.²²¹ Conflict of interest plays a key role in each of these areas, with the most applicable section to entrepreneurial practices being financial conflict of interest and impartiality.

The basic criminal conflict of interest statute, “prohibits Government employees from participating personally and substantially in official matter where they have a financial interest.”²²² Other important provisions address the ability to represent a third party before the U.S. Government;²²³ and prohibit the supplementation of a Federal employee’s salary.²²⁴ The practical implications of these statutes include the types of business a Federal employee can own and operate, if or for whom they can consult, what royalties they can take from their intellectual property, and what assets they can hold.

The administration of Federal ethics rules is shared among OGE, heads of agencies, designated agency ethics officials, and the Department of Justice (DOJ). The OGE promotes ethical standards and provides overall guidance and accountability. The DOJ is responsible for enforcing the criminal and civil ethics rules. Agencies have primary responsibility for their own internal ethics programs and can supplement ethics regulations to address potential conflicts unique to the agency’s mission.²²⁵ In an effort to avoid conflicts of interest under Title 18, most

²²¹ United States Office of Government Ethics. “Enforcement.” Accessed 10/3/2018.
<https://www.oge.gov/web/oge.nsf/Enforcement>

²²² 18 U.S.C. §208 - Acts affecting a personal financial interest; United States Office of Government Ethics. “Analysis Potential Conflicts of Interest.” Accessed 10/3/2018.
<https://www.oge.gov/web/OGE.nsf/Financial+Conflicts+of+Interest/931A1B0819F5E884852582200075ECC8>

²²³ 18 U.S.C. §203 - Compensation to Members of Congress, officers, and others in matters affecting the Government; 18 U.S.C. §205 - Activities of officers and employees in claims against and other matters affecting the Government

²²⁴ 18 U.S.C. §209 - Salary of Government officials and employees payable only by United States

²²⁵ 5 CFR Part 2635.106—Disciplinary and corrective action.

agencies restrict Federal employees from owning businesses, equity, or consulting with companies related to their Federal work.^{226, 227}

Extramural R&D Programs. Each Federal agency responsible for extramural R&D programs is required to establish conflict of interest policies for awardees.²²⁸ Conflict of interest policies differ across agencies but generally detail requirements for the non-Federal institution to review potential conflicts of interest and for extramural researchers to report both to the institution and award agency. In general, extramural researchers must report conflicts of interest and avoid significant financial conflicts of interest.

Personnel Exchange. Personnel exchange programs have varying degrees of formality²²⁹ and significantly different durations. The DOC promulgated a regulation in 2016 directed at encouraging personnel exchanges.²³⁰

The Intergovernmental Personnel Act (IPA) of 1970²³¹ allows the temporary movement of personnel between the Federal Government and State or local governments, educational institutions, Federally Funded Research and Development Centers (FFRDCs), and nonprofits. IPAs are not available to personnel from private industry, but other mechanisms are, such as the Visiting Scholars Program at the Frederick National Laboratory for Cancer Research.²³²

Entrepreneur-in-residence (EIR) programs represent similar efforts, bringing into the Federal agency outside expertise in the form of academics, software designers, business experts, policymakers, etc. who have demonstrated a significant record of innovative achievement.²³³ RFI

²²⁶ Based on interviews with COI program managers at Federal agencies

²²⁷ The NIST Summary of Ethics Rules 2015 lists principles that apply to entrepreneurship and are consistent with most federal agencies guidelines.

<https://ogc.commerce.gov/file/nist-summary-ethics-rules-2015-updated>

²²⁸ 2 U.S.C. §200.112—Conflict of interest

²²⁹ Ponomariov, B., & Boardman, C. §2012. Organizational behavior and human resources management for public to private knowledge transfer: An Analytic Review of the Literature. Paris: Organisation for Economic Cooperation and Development (OECD).

²³⁰ 15 C.F.R. 17 Personnel Exchanges between Federal Laboratories and Non-Federal Entities.

²³¹ 42 U.S.C. § 4701

²³² Frederick National Laboratory for Cancer Research, “Visiting Scholars Program,” <https://frederick.cancer.gov/workwithus/visitingscholars>

²³³ Reamer, Andrew. 2017. “Federal Efforts in Support of Entrepreneurship: A Reference Guide (Working Draft).” The George Washington University. March 9, 2017.

respondents noted that these entrepreneurs may be posted at an agency (Department of Health and Human Services' IDEA Lab,²³⁴ DOE^{235,236}) to act as opportunity spotters, domain experts, and target industry insiders. Personnel exchange can occur through educational partnership agreements, such as those which exist between the DOD and educational institutions, enabling DOD laboratory directors to make personnel available to teach science courses or assist in developing course materials. There also exist more specific personnel exchanges, such as the Presidential Innovation Fellows²³⁷ and the Information Technology Exchange Program. These programs are supported by the White House and the DOD, respectively.

Developing and commercializing new technologies often happens as a result of the above forms of alliances in which resources, knowledge, and skills are pooled.²³⁸ Formal (or informal) personnel exchange agreements are observable indicators of knowledge transfer and a meaningful gauge for measuring the effectiveness of these relationships.²³⁹ Such alliances have shown impact in Japan, where national universities offer visiting professorships attached to R&D projects.²⁴⁰ Companies can place visiting researchers at universities to serve both as adjunct faculty members and to collaborate on R&D projects. These personnel exchanges, along with technology licensing, proved the most influential factors for generating product innovation and increasing sales.²⁴¹ The movement of university researchers to industrial firms is valuable as well, with scientific breakthroughs often attributed to contributions of the knowledge creators, through either part-

<https://gwipp.gwu.edu/sites/g/files/zaxdzs2181/f/downloads/Reamer%20federal%20entrepreneurship%20reference%20draft%2003-09-17.pdf>

²³⁴ U.S. Department of Health and Human Services. 2018. "Entrepreneurs-in-Residence Program." *IDEA Lab*. Accessed September 21, 2018. <https://www.hhs.gov/idealab/eir-program/>

²³⁵ U.S. Department of Energy (DOE). 2007. "DOE's Entrepreneur in Residence (EIR) Program." *Department of Energy*. Last modified October 24, 2007. <https://www.energy.gov/articles/does-entrepreneur-residence-eir-program>

²³⁶ U.S. Department of Energy (DOE). "Technologist in Residence Program." <https://www.energy.gov/eere/amo/technologist-residence-program>

²³⁷ Presidential Innovation Fellows Program. <https://presidentialinnovationfellows.gov/>

²³⁸ Betz, Frederic. 1996. "Industry-University Partnerships." *Handbook of Technology Management*, Chapter 8. Gayner, G. ed. New York: McGraw-Hill. Pp. 250-259.

²³⁹ Lakpetch, P., & Lorsuwannarat, T. 2012. "Knowledge transfer effectiveness of university-industry alliances." *International Journal of Organizational Analysis*, 20(2), 128-186.

²⁴⁰ Ibid.

²⁴¹ Pittayasophon, S., Intarakumnerd, P., Sumikura, K., Saito, H., & Suzuki, J. 2016. "Firm Characteristics and Modes of University-Industry Collaboration." *STI Policy Review*, 7(1), 17-39.

or full-time assignments.²⁴² Other successful models focus on applied R&D through partnership between representatives of industry, academia, and government.²⁴³ Looking at innovative performance as represented by the number of and citation to firms' patents has supported the idea of a direct link between innovation and the human capital of scientists, provided they are "commercially oriented."²⁴⁴

The various forms of personnel exchange are often described as a triple-win,²⁴⁵ with the home organization, the personnel involved in the exchange, and destination organization all benefiting from the interaction. The destination or host organization may fill a gap in expertise or staff shortage, benefit from fresh ideas and talent, and save money by mitigating the need to hire a full-time employee. The personnel involved in the exchange benefit by being exposed to a different organization's processes and structures, learning new skills, and experiencing professional growth. The home organization develops network ties by participating in this lending process and receives back an employee with greater experience and potentially better job performance.²⁴⁶

Entrepreneurial Leave and Sabbaticals. One specific type of personnel exchange program is entrepreneurial leave and/or sabbaticals. These offer opportunities for workers to take leaves of absence or sabbaticals in which they can pursue the independent commercialization of a product developed in a laboratory. Entrepreneurial leave can be an effective way to leverage the intramural research expertise into business creation. Several Federal Laboratories already make limited use of this practice; for instance:

- Sandia National Laboratories encourages an "entrepreneurial separation to transfer technology," which is a program that allows employees to leave for a time to grow their own business. Reinstatement for employees is guaranteed if the researcher comes back

²⁴² Zucker, L. G., M.R. Darby and M. Torero. 2002. "Labor mobility from academe to commerce." *Journal of Labor Economics*, Vol. 20(3), pp. 629-660.

²⁴³ Fraunhofer-Gesellschaft. <https://www.fraunhofer.de/en.html>

²⁴⁴ Toole, A. A., & Czarnitzki, D. 2009. "Exploring the relationship between scientist human capital and firm performance: The case of biomedical academic entrepreneurs in the SBIR program." *Management Science*, 55(1), 101-114.

²⁴⁵ Wynne, M. 2016. "Lab-to-Market: Commercializing New Technologies by Exchanging Talent." Retrieved from <https://obamawhitehouse.archives.gov/blog/2016/11/22/lab-market-commercializing-new-technologies-exchanging-talent>

²⁴⁶ Howieson, S. V., Yglesias, E., Blazek, S. L., & Tran, E. D. 2013. "Federal Personnel Exchange Mechanisms." Washington, DC: Science and Technology Policy Institute.

within a 2-year window. In 2008, alumni from this program had created 44 companies and expanded another 46.²⁴⁷

- Los Alamos National Laboratory (LANL) has a similar leave program wherein employees can take up to 3 years away from the home organization to participate in a venture based on LANL-developed technologies or expertise. Medical benefits and a comparable job opening are available in the first year, with reduced funding for benefits and hiring preference possible for the year after.²⁴⁸

Sabbaticals for faculty at universities act as similar opportunities to step away and pursue a commercialization venture. However, these opportunities are often only available post-tenure and are not widespread across academia. A survey of more than 50 research universities showed that only half permit this type of temporary leave.²⁴⁹ The use of leave without pay by Federal employees for a sabbatical or entrepreneurship has limited effectiveness, since the full conflict of interest rules apply even during periods of uncompensated leave.

2. CHALLENGES

Definitions of conflict of interest and regulations for managing it vary across agencies and Federal Laboratories, making it difficult for investigators and their institutions to comply with the varying requirements. A 2016 report by The National Academies noted the differing policies across agencies and even in Federal-wide guidance.²⁵⁰ For example, the conflict of interest regulations for the Public Health Service²⁵¹ (PHS) and NSF²⁵² differ significantly even though

²⁴⁷ Sandia National Laboratories. 2008. "Sandia Entrepreneurial Program Is Back," News Release, November 24, 2008.

²⁴⁸ Palmintera, D. 2003. "Partners on a mission: Federal laboratory practices contributing to economic development." Office of Technology Policy, Technology Administration, U.S. Department of Commerce.

²⁴⁹ Blumenstyk, G. 2012. "Recipe for Start-Ups: Sabbaticals, Tenure Credit for Patents, and a Dash of 'Disorder.'" Retrieved from <https://www.chronicle.com/article/Recipe-for-Start-Ups-/130379/>

²⁵⁰ National Academies of Sciences, Engineering, and Medicine. "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century." <https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory>

²⁵¹ See, for example, <https://grants.nih.gov/grants/policy/coi/index.htm>

²⁵² National Science Foundation. 2005. NSF Conflict of Interest Policies, Chapter V, Section 510, NSF Grant Policy Manual, NSF 05-131, July 2005.

they provide funding to many of the same institutions. RFI responses frequently mentioned the increased (and, in their view, extraneous) stringency of the PHS regulations. (Refer to “RFI Response on Aligning PHS COI Policies.”) After pressure from the Office of the Inspector General, PHS revised their regulations, lowering the threshold for disclosing financial interests from \$10,000 to \$5,000, moving the responsibility to analyze potential conflicts of interest from investigators to institutions, and expanding the definition of required disclosures. NSF did not revise their rules to align with the new PHS policies. The differences in policies make it more burdensome for investigators and their institutions to track and comply with Federal policies.²⁵³

RFI Response on Aligning PHS COI Policies

“The government must seek to better align its current PHS conflict of interest policies with its interest in seeing the commercialization of, and ROI on, its NIH research investments.”

Source: AAU, APLU, COGR, AAMC, and ACE

Though conflict of interest policies for Federal employees can vary from agency to agency, the greatest difference is between researchers employed by the Federal Government and by universities. Generally, universities manage the potential for conflict of interest, while most Federal agencies prohibit the potential to exist. In academia and other non-government R&D organizations, employees are granted the ability to remain employees of the institution while starting a company or consulting with an outside organization. This allows inventors to work in an official capacity with a start-up company that has licensed the inventor’s technology. Additionally, academic institutions generally allow faculty members a leave of absence to pursue entrepreneurial opportunities. Federal workers, conversely, may be discouraged from such entrepreneurial participation due to restrictions on receiving external salary while remaining in Federal employment.²⁵⁴ This Federal restriction runs counter to the goal of building a more entrepreneurial R&D workforce.

The lack of a clear policy for leave of absence limits the incentives for Federal researchers to pursue commercialization opportunities, particularly ones that necessitate researchers leaving their positions to begin a start-up or other venture. Other restrictions include limitations on founding a start-up related to the employee’s Federal work, owning equity in a start-up company, or consulting for a start-up. Federal conflict of interest policies negatively affect the proliferation

²⁵³ Ibid.

²⁵⁴ 18 U.S.C. §203 - Compensation to Members of Congress, officers, and others in matters affecting the Government

of network-building activities such as consulting for industry or personnel exchange. Conflict of interest policies can also limit the ability of the government to recruit innovative and highly skilled science, technology, engineering, and mathematics (STEM) employees who may be concerned about conflicts with restriction on partnering with a former employer or divesting financial interests.²⁵⁵

Conflict of interest policies can diminish the effectiveness of the technology transfer process by restricting coordination between the private organization commercializing technology and the Federal researchers by whom it was developed. Several RFI respondents mentioned an example of a start-up company leveraging a technology developed in a Federal Laboratory. In such a situation, the start-up would like to be able to speak or work with the inventors of the technology for technical assistance. However, if the Federal researcher has a patent on the technology, speaking with the company in an official capacity would be considered a financial conflict of interest based on the potential royalties from the patent. These rules prevent scientists from being involved and improving business ventures based from their research, thus limiting the effectiveness of those original partnerships.²⁵⁶ (Refer to “RFI Response on Requiring Federal Employees to Leave Government Service.”)

RFI Response on Requiring Federal Employees to Leave Government Service

“It is unclear to me why this policy was initiated originally, but I can easily understand the rationale for it at the time. This is a complex issue with major perception concerns. I suggest that it is now outdated and can accommodate some flexibility while balancing concerns prudently. Universities (which on this topic are very different organizations) allow carefully crafted “Leave of Absence” or “Sabbaticals” as part of their culture. Some of these have fully paid salaries, some totally unpaid, some partially paid. An ‘Entrepreneurial Leave of Absence’ for 2 years (difficult to accomplish a lot in 12 months), could be offered within Federal Laboratories. At the end, the person can return to the same position without any impact on fringe benefits, pensions, etc., if they wished. This is a non-issue for Agencies with guest researchers on soft money but could work well for full government employees.”

Source: RFI Response, Burnside Development

²⁵⁵ Peña, Vanessa, Michael C. Mineiro, and Ryan M. Whelan. 2014. *Federal Ethics Rules and Their Impacts on Recruiting and Retaining Federal Science, Technology, Engineering, and Mathematics (STEM) Employees*. Washington, DC: IDA Science and Technology Policy Institute.

²⁵⁶ U.S. Government Accountability Office (GAO). 2014. “Federal Laboratory Consortium Should Increase Communication with Potential Customers to Improve Initiatives.” <https://www.gao.gov/products/GAO-15-127>

3. INTENDED ACTION

Intended Action 12. (i) Implement harmonized and consistent government-wide requirements to manage conflicts of interest involving recipients of extramural Federal R&D funding, and (ii) authorize scientists and engineers at Federal Laboratories to engage in entrepreneurial activities that support technology transfer and commercialization.

A. ENTREPRENEURIAL ACTIVITIES BY EXTRAMURAL FEDERAL R&D FUNDING RECIPIENTS

Develop, adopt, and use consistent and streamlined government-wide requirements and practices to manage conflicts of interest involving recipients of extramural Federal R&D funding.²⁵⁷

B. ENTREPRENEURIAL ACTIVITIES BY FEDERAL SCIENTISTS AND ENGINEERS

Legislative change is required to authorize scientists and engineers at Federal Laboratories to engage in entrepreneurial activities²⁵⁸ that support technology transfer and commercialization (notwithstanding 18 U.S.C. § 208-209) if such activities are approved by the agency head, or designee, in consultation with the agency's legal counsel. Implement regulations under the Stevenson-Wydler Act ²⁵⁹ with consistent and streamlined government-wide policies and practices to manage conflicts of interest involving scientists and engineers at Federal Laboratories. Clarification will also be necessary regarding copyright ownership under such programs.

C. ENTREPRENEURIAL LEAVE AND SABBATICALS

Legislative change is required to authorize Federal agencies to grant scientific and technical professionals, including those who are senior executives, at Federal Laboratories entrepreneurial leave and sabbatical absence to engage in compensated or uncompensated entrepreneurial

²⁵⁷ Consider comments received through the RFI process and engage with Nonfederal organizations to identify best practices to manage conflict of interest for extramural Federal R&D recipients.

²⁵⁸ For example, service as an advisor or consultant to companies, service on a scientific advisory board or board of directors of companies, and equity ownership in companies. Companies may be startups, small, or large.

²⁵⁹ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The intended action is discussed under Strategy 1, Section G.

activities²⁶⁰ (notwithstanding 18 U.S.C. § 208-209) that support technology transfer and commercialization for up to 3 years with full reinstatement privileges.²⁶¹, ²⁶² Implement regulations under the Stevenson-Wydler Act²⁶³ with consistent and streamlined government-wide policies and practices to grant scientists and engineers, including senior executives, at Federal Laboratories entrepreneurial leave and sabbatical absence to engage in entrepreneurial activities.

²⁶⁰ To attempt to spin-out a technology or start a business of their own in addition to service as an advisor or consultant to companies, service on a scientific advisory board or board of directors of companies, and equity ownership in companies without fear of losing Federal employment or seniority.

²⁶¹ New language can be added to 15 U.S.C. § 3710 creating the authority for Federal R&D staff to take entrepreneurial leave, provided such language notes the potential conflict with Title 18 (18 U.S.C. 208-209). Such language may want to reflect the intention that the agency will rehire the staff member who elects to take entrepreneurial leave, and that the entrepreneurial leave shall not result in loss of, or reduction in, pay, leave to which the employee is otherwise entitled, credit for time or services, or performance or efficiency rating.

²⁶² For Senior Executive Service career appointees to use sabbatical absence from duty for compensated work experience changes to 5 U.S.C. § 3396(c)(1) may require: (a) extending the term of sabbatical from 11 months to a longer time (i.e., up to 3 years) to reflect the time-consuming nature of commercialization, (b) add permission for appointee to engage in compensated work experience.

²⁶³ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

STRATEGY 4. SUPPORT INNOVATIVE TOOLS AND SERVICES FOR TECHNOLOGY TRANSFER

The fourth of five strategies of the L2M CAP Goal is focused on supporting innovative tools and services for technology transfer. The intended actions are designed to make it easier for potential partners to discover both extramural and intramural Federal R&D results and to access information on Federal R&D programs, facilities, equipment and tools, expertise, services, and other relevant assets. This chapter discusses actions to modernize the Federal IP data reporting system(s) and to provide easy access to Federal R&D assets.

A. INTRODUCTION

Managers and business professionals need timely, accurate, and useful access to Federal R&D, IP, and technology transfer information to identify translational R&D, technology maturation, and commercialization opportunities and engage in collaborative partnerships. Technology managers need accurate information to identify the right private sector contacts to facilitate promising collaborations.

Effective tools and services improve awareness of Federal R&D assets available for commercial opportunities, and avenues for public and private parties to find each other to engage. To facilitate this awareness among relevant stakeholders, tools and services provide access to resources, such as intellectual property, equipment and facilities, and information about mission and capabilities of Federal Laboratories. For extramural inventions, these tools provide a mechanism to report information and for agencies to curate data through standardized reporting requirements. Overall, tools and services assist all stakeholders both within and outside the government with timely, accurate, and potentially impactful data.

In addition, there is a need for timely and accurate information regarding extramural inventions under the Bayh-Dole Act. The requirements to report inventions, elect rights, request extensions of time requirements, request waivers, demonstrate progress, inform the government of their limited use rights, and other interactions are an important part of the obligation of funding recipients to support technology transfer for the American people. Although ease of access to information can help technology transfer, development of these systems can be expensive. The costs to maintain the system and especially the currency of the data can be even higher.

It is essential to modernize the data systems involved in technology transfer. RFI responses overwhelmingly noted the need for simplified and streamlined reporting requirements that keep sensitive data secure and increase timely access to information

and services to support transformational R&D partnerships and technology transfer outcomes for the 21st Century. The cost of reporting and compliance can have a large impact on the government's ability to attract partners.

B. FEDERAL IP DATA REPORTING SYSTEM(S)

1. BACKGROUND

Regulations implementing the Bayh-Dole Act give the extramural funding recipient a period of 2 years to elect rights to a Bayh-Dole Act subject invention, or 60 days before a bar date for patenting under U.S. law.^{264,265} If the funding recipient elects rights, they agree to file for a patent and take steps to achieve practical application of the invention, that is, actively seek a commercial opportunity. Agencies can require additional reporting on progress to ensure that the recipient is continuing to achieve practical application. Invention reporting is also necessary to inform the government of its use right. A major issue with invention reporting is the need to properly secure proprietary information from unauthorized disclosure by the funding agency. Agencies requiring invention reporting must be cognizant of the need to keep information confidential during the patent filing process as well as any specific business plans regarding efforts to commercialize a product.

The Bayh-Dole Act and accompanying regulations require reporting to Federal funding agencies on the utilization of subject inventions. Since the adoption of the legislation, many agencies have used different processes for invention reporting. Most agencies have moved from paper-based reporting to electronic systems. The primary electronic system for invention reporting currently in use is the interagency-Edison (iEdison) system developed and maintained by NIH. The iEdison system is a web-based platform used by all government awardees to report on federally funded inventions.^{266,267} There are currently more than 30 Federal agency offices that have elected to use the

²⁶⁴ See 37 C.F.R. 401

²⁶⁵ See 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act, Public Law 112-29.

²⁶⁶ National Institutes of Health (NIH). n.d. "iEdison.gov." Accessed October 5, 2018.
<https://public.era.nih.gov/iedison>

²⁶⁷ Edison was created in 1995 by the NIH and became iEdison in 1997 when the NSF and USAID joined. <https://public.era.nih.gov/iedison/public/faq.jsp#q2>

iEdison system.²⁶⁸ The iEdison system can track inventions from the reporting phase, starting with funding and invention details, through to commercialization, monitoring utilization, and profit data. Data within the iEdison database is partitioned by agency, allowing individual agencies to view their invention reports. This partitioning does make it more difficult to discover inventions across agencies but enhances the protection of the proprietary information in the system.²⁶⁹

In addition to the iEdison system, agencies may use or design their own tools for this reporting function. For example, NASA developed and uses the New Technology Reporting System (e-NTR). As e-NTR only manages NASA intellectual property data, e-NTR employs one standardized form for intellectual property reporting across all NASA technology transfer offices.²⁷⁰ NASA exploits the standardized and complete data gathered by e-NTR to build metrics and technology transfer reports, as well as collect intellectual property data for public consumption.

The need to report in different systems with unique requirements can be time consuming and difficult for government awardees that work across multiple agencies. While each system is based on the same rules, each has its own commands and operation and requires a separate login.

2. CHALLENGES

Without a single government-wide reporting system, university technology transfer offices and federally funded researchers must devote significant resources to reporting tasks to navigate different agency platforms and reporting requirements. Even within a single agency, individual Federal Laboratories may use unique reporting platforms. RFI respondents noted that this lack of consistent reporting places a burden on technology transfer offices, especially smaller offices or individuals with fewer resources to devote to administrative tasks. Many respondents called for mandated use of a single reporting system by all agencies to meet the Bayh-Dole Act reporting requirements. (Refer to “RFI Response a Unified Federal Invention Reporting System.”)

²⁶⁸ National Institutes of Health (NIH). 2016. “iEdison – Agency Websites.” Accessed October 5, 2018. https://era.nih.gov/iedison/agency_sites.htm

²⁶⁹ Bayh-Dole Act regulations note that the reported information is subject to 35 U.S.C. 202(c)(5). As such, agencies shall not disclose such information to persons outside the government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the agency.

²⁷⁰ National Aeronautics and Space Administration. n.d. “New Technology Reporting System.” Accessed October 5, 2018. <https://invention.nasa.gov/prog/login>.

RFI Response on a Unified Federal Invention Reporting System

“[The University of California (UC)], like many universities, has experienced issues surrounding the process of required invention reporting under iEdison, an outdated system that could be more user-friendly. The fact that not all agencies use the same system is in itself problematic and inefficient. Inconsistencies in reporting requirements from one agency to the next (and even within agencies) lead to confusion and unnecessary time and effort that could better be spent engaged in the substance of technology transfer activities. UC strongly supports a single, consistent government-wide reporting process using a state-of-the-art, easy-to-use portal that is adequately funded and maintained. Agency requirements for invention reporting should be harmonized.”

Source: RFI Response, University of California

Further, agencies do not always have the same reporting requirements, even agencies that use the same platform. RFI respondents echoed this concern, stating that the inconsistent requests for additional information add to the difficulties with reporting. The National Academies recommends developing a standard set of requirements to ensure that reporting requirements do not exceed those stated in Bayh-Dole.²⁷¹ RFI respondents also noted issues related to the quality, timeliness, and transparency of communication between agencies and extramural partners in reporting and called for guidance to be developed in this area (See “RFI Response on Reporting System Experience.”)

RFI Response on Reporting System Experience

“Agencies should ensure that their staff are responsive when issues arise during reporting, especially while the current balky system remains in use. Metrics should be developed for the quality of the reporting system and agency responsiveness and should be disseminated regularly throughout the tech transfer community.”

Source: RFI Response, Massachusetts Institute of Technology and MIT Lincoln Laboratory

ROI Public Forum attendees stated that iEdison is the most widely used reporting system, though users report that it is confusing and difficult to use, sometimes requiring professional assistance. The system has undergone few technical improvements since it was first implemented in 1995. NIH does not have a unique or explicit source of funding to maintain and update the system, and it must therefore compete with other NIH

²⁷¹ National Academies of Sciences, Engineering, and Medicine. 2016. *Optimizing the Nation's Investment in Academic Research*. Washington, DC: The National Academies Press. 175, Recommendation 10.2.

priorities. Inadequate funding rather than technical challenges or lack of capabilities was cited as the primary reason for the shortcomings of the iEdison infrastructure.²⁷² This was noted in the RFI responses, which called for significant reforms to improve current invention reporting platforms. (Refer to “RFI Response on Improved Invention Reporting.”)

Perhaps even more significant than internal reporting requirements for compliance are the multiple benefits for business partners to have a single, consistent, discoverable set of information. Businesses, especially small businesses, do not have the time to discover and use multiple government websites. Making information readily accessible is a key part of the technology transfer mission.

RFI Response on Improved Invention Reporting

“We suggest that the Federal government invests significant resources to modernize and improve the process used to report the status of technology and inventions via its iEdison interface to be improved for clarity and congruency with commercialization, patent prosecution and invention disclosure practices.”

Source: RFI Response, University of California, San Diego

3. INTENDED ACTION

Intended Action 13. Establish a secure and interoperable platform²⁷³ for reporting data on intellectual property²⁷⁴ resulting from extramural and intramural Federal R&D that is easy to access, analyze, and use.

A. SECURE, INTEROPERABLE PLATFORM FOR FEDERAL IP DATA REPORTING

Develop, test, implement, and operate a modern platform government-wide for reporting data on intellectual property (IP) resulting from Federal R&D that is easy to

²⁷² National Academies of Sciences, Engineering, and Medicine. 2016. *Optimizing the Nation's Investment in Academic Research*. Washington, DC: The National Academies Press. 174.

²⁷³ At a minimum, the IP data platform should be interoperable with USPTO's public searchable database, including the assignments data that contains information on government interest licenses: <https://assignment.uspto.gov/patent/index.html#/patent/search>

²⁷⁴ To include inventions, copyrights, and utilization metrics.

access, analyze, and use by extramural and intramural recipients of Federal R&D funding and those responsible for managing that IP data.

B. CONSISTENT FEDERAL IP DATA REPORTING REQUIREMENTS

Implement regulatory change under the Bayh-Dole Act with consistent and streamlined government-wide requirements and practices for timely and transparent reporting of extramural Federal IP data, including inventions, responses from Federal agencies on waiver of invention rights, request for assignment of invention rights, U.S. manufacturing waiver requests, and exceptions to the standard patent rights clauses.²⁷⁵

C. REPORTING FEDERAL IP DATA FROM INTRAMURAL R&D

Legislative change requiring Federal Laboratories to report data on IP resulting from intramural R&D. Implement regulations under the Stevenson-Wydler Act ²⁷⁶ with consistent and streamlined government-wide requirements for Federal Laboratories to report data on IP resulting from intramural R&D.

C. ACCESS TO FEDERAL R&D ASSETS

1. BACKGROUND

Aggregation and curation of Federal technology transfer information, resources, tools, and services is helpful for external stakeholders looking to engage in technology transfer. Harnessing these Federal data on a publicly accessible platform would increase visibility into the Federal innovation ecosystem and aid in opening access to Federal R&D resources, such as Federal Laboratories, expertise, and equipment, among others.

The FLC was formally chartered by the Federal Technology Transfer Act of 1986 (15 U.S.C. § 3710) as a cross-agency organization to foster opportunities for transferring innovative technologies from Federal Laboratories into the marketplace. As stated in FLC’s 2015-2019 strategic plan, its membership represents “virtually the entire extant body of experience and expertise on practical, successful approaches to Federal

²⁷⁵ 37 CFR §§ 401.14

²⁷⁶ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

Laboratory technology transfer, and on its beneficial outcomes.”²⁷⁷ Today, the FLC community is made up of over 300 Federal Laboratories, facilities, and research centers, as well as their parent agencies.

To fulfill its mission, the FLC provides a number of cross-agency tools, services, and educational resources, aimed at making the technology transfer process as accessible as possible for commercialization successes.²⁷⁸ Specifically, the FLC serves as a clearinghouse for Federal technologies by providing the following tools and services:

- FLC Business²⁷⁹: a web-based platform providing a single extensive inventory of Federal Laboratory information, including member laboratories’ missions, capabilities, programs, facilities, equipment, and contacts; technologies available for licensing; funding opportunities; and publications; and
- Technology Locator²⁸⁰: a no-cost, personalized matching service that connects external users with an appropriate laboratory representative to further the user’s R&D goals.

In 2014, a GAO study recommended that the FLC “work collaboratively with agency and laboratory members to increase communication with potential customers and obtain feedback to improve its clearinghouse initiatives.”²⁸¹ This recommendation was considered in FLC’s development of FLC Business.com, which formally launched in April 2014, and has since undergone significant public testing of its user interface and search capabilities. The most recent version of the site, FLC Business 3.0, was released in

²⁷⁷ Federal Laboratory Consortium for Technology Transfer (FLC). 2015. “Strategic Plan 2015-2019.”

https://www.federallabs.org/sites/default/files/FLC_Strategic_Plan.pdf

²⁷⁸ Federal Laboratory Consortium for Technology Transfer (FLC). n.d. “History.” Accessed October 5, 2018. <https://www.federallabs.org/about/history>.

²⁷⁹ Federal Laboratory Consortium for Technology Transfer (FLC). n.d. “FLC Business.” Accessed October 5, 2018. https://www.federallabs.org/FLC_Business.

²⁸⁰ Federal Laboratory Consortium for Technology Transfer (FLC). n.d. “Technology Locator Service.” Accessed October 5, 2018. <https://www.federallabs.org/t2-toolkit/technology-locator-service>.

²⁸¹ U.S. Government Accountability Office (GAO). 2014. *Federal Laboratory Consortium Should Increase Communication with Potential Customers to Improve Initiatives*. Washington, DC. <https://www.gao.gov/assets/670/666361.pdf>

September 2018 and has been updated with additional user capabilities, including refined search categories, advanced filtering options, a tech-locator chat service, upgraded editing capabilities for laboratory profile pages, and integrated success stories and awards with laboratory profiles.²⁸² Still, FLC faces technical challenges in curating agency content, resulting in incomplete or out-of-date data on the platform.

Federal agencies also provide information on agency- or laboratory-specific technology transfer programs, resources, opportunities, and available technologies through their own online platforms. For example, DOE has developed a suite of online applications through its Lab Partnering Service²⁸³ to connect external users with experts, projects, and patents from across the DOE and its National Laboratories. Another example is the DHS Transition to Practice²⁸⁴ program, which identifies the most promising cybersecurity projects across the Federal Government with a demonstrated potential for commercialization and introduces them to potential partners or investors. While these agency-specific sites can provide additional information related to technology transfer that goes beyond what FLC's tools and services curate, they present a challenge for users who are interested in technologies from more than one agency.

2. CHALLENGES

Technology transfer information and opportunities are dispersed on individual agency websites and awareness may not flow out to potential partners. This sentiment was prevalent in the RFI responses, which pointed to lack of awareness and effective knowledge sharing as barriers for external parties engaging in the technology transfer process. RFI respondents recognized the need for a centralized repository of technology transfer information and opportunities across all agencies. Rather than visiting multiple sites to identify a technology or resource, researchers and entrepreneurs could benefit from a more complete inventory in a single source, displayed in a consistent format.

²⁸² Federal Laboratory Consortium for Technology Transfer (FLC). 2018. "FLC Business 3.0 is Here!" September 4, 2018. <https://www.federallabs.org/news/flc-business-30-is-here>.

²⁸³ U.S. Department of Energy (DOE). n.d. "Lab Partnering Service." Accessed October 5, 2018. <https://www.labpartnering.org/home>.

²⁸⁴ U.S. Department of Homeland Security. n.d. "Transition to Practice." Accessed October 5, 2018. <https://www.dhs.gov/science-and-technology/csd-ttp>

To curate content for FLC Business, the FLC depends on information provided voluntarily by agency and laboratory members. To reduce the administrative burden on its members and ensure that information is up-to-date, the FLC automates this information exchange as much as possible. In 2015, the FLC contracted for the development of a web scraper tool²⁸⁵ to aggregate inconsistent, unstructured information with permission from agency and laboratory websites into a consistent schema for searching on FLC Business. The tool uses the visual attributes of the webpage, employing pattern recognition to gather text or downloading documents. Because the level of detail, accuracy, and accessibility of this information varies across agencies, data on FLC Business is sometimes incomplete, out-of-date, or inconsistent. It has also been noted that some information on agency websites is presented using software that is incompatible and inaccessible with this scraping method.

Responses submitted to the RFI call for additional efforts beyond curation of content such as putting available technologies in the context of appropriate collaboration mechanisms and integrating modern capabilities such as semantic search and text analysis (Refer to “RFI Response on a Centralized Platform.”) RFI responses also suggested aligning tools and services with private sector needs, developing mechanisms for confidential interaction between agencies and users, and developing a government- or agency-wide technology transfer communications strategy.

RFI Response on a Centralized Platform

“A renewed attempt to develop a cross-agency platform for searching, identifying, and licensing technologies should be undertaken to take advantage of modern technologies... Rather than building a centralized database of technologies, the Federal Government could create a federated search system where agencies expose their technology inventories to search and provide associated information that can be parsed and processed such that technologies are tagged with a consistent set of taxonomies.”

Source: RFI Response, RTI International

²⁸⁵ Connotate. 2017. “Another Web Data Extraction Use Case: Consolidating Information Spread Across Dozens of Sites to Build a One-Stop Shop for Patent Information.” February 22, 2017. <https://www.connotate.com/another-web-data-extraction-use-case-consolidating-information-spread-across-dozens-of-sites-to-build-a-one-stop-shop-for-patent-information/>.

3. INTENDED ACTION

Intended Action 14. Establish a federated data portal that is easy for the public to access, use, and analyze, which provides information on (i) IP resulting from extramural and intramural Federal R&D programs government-wide, and (ii) Federal R&D programs, facilities, equipment and tools, expertise, services, and other relevant assets.

A. FEDERATED DATA PORTAL FOR FEDERAL R&D ASSETS

Develop, test, implement, and operate a federated data portal that is easy for the public to access, use, and analyze with information on (i) IP resulting from extramural and intramural Federal R&D programs government-wide, and (ii) Federal R&D programs, facilities, equipment and tools, expertise, services, and other relevant assets.

B. REPORTING DATA ON FEDERAL R&D ASSETS

Legislative change requiring Federal Laboratories to report information on their R&D programs, facilities, equipment and tools, expertise, services, and other relevant assets. Implement regulations under the Stevenson-Wydler Act²⁸⁶ with consistent and streamlined government-wide requirements for Federal Laboratories to report up-to-date data on their R&D programs, facilities, equipment and tools, expertise, services, and other relevant assets.

²⁸⁶ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

STRATEGY 5. IMPROVE UNDERSTANDING OF GLOBAL SCIENCE AND TECHNOLOGY TRENDS AND BENCHMARKS

The fifth strategy of the L2M CAP Goal is focused on improving understanding of global science and technology trends and benchmarks. The intended actions are designed to better capture, assess, and improve Federal R&D outcomes, impacts, and operational processes. This chapter discusses actions to determine, adopt, and use appropriate metrics to accelerate technology transfer, strengthen U.S. economic competitiveness and national security, and enable even greater return on investment to the American taxpayer.

In today's global economy, it is no longer enough to demonstrate effectiveness against past performance. Instead, performance must be measured against worldwide competition. It is important to look at the transfer of technology from a broad perspective. Technology transfer is not simply the licensing of patented inventions, but the full range of options available to achieve commercialization and economic development. For example, NIST defines technology transfer as: “the overall process by which NIST *knowledge, facilities, or capabilities* in measurement science, standards and technology promote U.S. innovation and industrial competitiveness to enhance economic security and improve quality of life.”²⁸⁷

A. INTRODUCTION

United States law states that “it is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation’s Federal investment in research and development.”²⁸⁸ Understanding and measuring R&D performance within the global context provides the foundation for informed decision-making and for assessing and improving the return on investment. Metrics, however, must be designed to advance the purpose of the Federal investment in R&D. These measurements are very difficult to make for immediate policy decisions because the actual impacts may take decades to occur

²⁸⁷ Annual Report on Technology Transfer: Approach and Plans, Fiscal Year 2017 Activities and Achievements, U.S. Department of Commerce
https://www.nist.gov/sites/default/files/documents/2018/09/19/fy2017_doc_tech_trans_annual_report.pdf

²⁸⁸ Stevenson–Wylder Technology Innovation Act of 1980 as Amended through P.L. 114–329, Jan. 6, 2017 [15 U.S. Code § 3710].

and be measured. (Refer to “RFI Response on the Length of Time to Realize the Commercial Benefits of Research and Development.”)

RFI Response on the Length of Time to Realize the Commercial Benefits of Research and Development

“Research valuation is difficult because benefits are often unanticipated or unforeseen and may not be realized until the distant future. An example is Albert Einstein’s work on relativity more than a century ago to explain the relationship of space, time, and gravity. The first patented technology from this research came not from the former patent examiner, presumably because he did not envision an immediate commercial application. It was an invention of Ernest Lawrence for the particle accelerator, an instrument now extensively used in research, materials processing, and medicine...The first consumer product based on relativity is the Global Positioning System (GPS), patented in 1970...The particle accelerator and GPS systems are examples of unanticipated and unforeseen benefits of relativity research and have further led to new fields of research unimaginable to Einstein.”

Source: RFI Response, Jefferson Science Associates and Southeastern Universities Research Association

Innovation in science and technology has been a cornerstone of America’s progress since the Nation’s founding.²⁸⁹ The Federal Government invests in basic research, early-stage applied research, and technology transfer efforts that will lead to the breakthroughs of the future. Federal R&D investment adapts to changing National priorities, with the expectation that this investment will strengthen the Nation’s innovation base and position the United States for unparalleled job growth, continued prosperity, and national security. Current R&D priorities include security; artificial intelligence (AI), quantum information sciences, and strategic computing; connectivity and autonomy; manufacturing; space exploration and commercialization; energy; medical innovation; and agriculture.²⁹⁰

The R&D enterprise enables the creation and transfer of knowledge via complex pathways involving discovery, translation, and innovation.²⁹¹ Intellectual property, in its most elemental form, protects the knowledge, innovations, and creations that hold significant strategic value for reasons such as national security, economic competitiveness,

²⁸⁹ See, e.g., Office of Management and Budget, Budget of the United States Government, Fiscal Year 2019, Chapter 18 Research and Development, U.S. Government Publishing Office, Washington 2018.

²⁹⁰ See, e.g., Office of Management and Budget & Office of Science and Technology Policy, FY 2020 Administration R&D Budget Priorities, Memorandum for the Heads of Executive Departments and Agencies, M-18-22, July 31, 2018.

²⁹¹ See, e.g., Furthering America’s Research Enterprise, The National Academies Press, 2014.

commercial innovation, and broad public good (e.g., healthcare, infrastructure). (Refer to “RFI Response on the Many Pathways of Technology Transfer.”)

RFI Response on the Many Pathways of Technology Transfer

“Agency emphasis on, and support for, technology transfer is a significant driver of success at the DOE National Laboratories. We define technology transfer in the broad sense as the process of transferring scientific discoveries, technologies and authored works from our laboratories to other organizations for the purposes of furthering research, development and/or for commercialization to benefit the U.S. The DOE National Laboratories use many pathways to carry out this responsibility, including: (a) publication of our research efforts; (b) hosting scientific users at our cutting-edge user facilities; (c) conducting research and development activities with industry, academia, and others; (d) exchange of personnel via joint appointments with academia or industry exchange; (e) licensing of patents and copyrights secured through our research efforts; (f) creation or support of start-up businesses that help to move our early stage science and technology into commercial applications; and (g) novel commercialization mechanisms sponsored by the DOE that leverage the use of laboratory expertise such as the Small Business Voucher Program, the Lab Embedded Entrepreneurship Program, and the Technology Commercialization Fund.”

Source: RFI Response, National Laboratory Directors Council

The innovations created through Federal R&D investment must be managed in ways that maximize the ROI to the American taxpayer.²⁹² These innovations, knowledge, and creations can be protected through intellectual property such as patents, copyrights, trademarks, and trade secrets. These intellectual property rights can then be leveraged through license agreements to create significant strategic value by controlling the distribution and transfer or release of assets through transaction, operation of law, or passage of time. Though Federal agencies cannot sell intellectual property, non-federal owners can choose to sell or otherwise convey (e.g., license) their protected intellectual property.

Critical and emerging technologies also hold significant strategic value for the Nation. While the contribution of international collaborations to the scientific and technological strength of the United States is widely acknowledged, the Federal Government has established various programs to identify critical technologies and the way in which they should be protected to ensure that they are provided to foreign entities only when doing so is consistent with U.S. interests. Export control laws and regulations, for example, are designed specifically to protect the national security, economic, and foreign

²⁹² See, e.g., Managing University Intellectual Property in the Public Interest, The National Academies Press, 2011.

policy interests of the United States. The R&D enterprise is responsible for carefully balancing the need for openness with the need to adhere to export laws and regulations, including deemed exports, that protect critical technologies—which hold significant strategic value—from unauthorized transfer, such as theft, espionage, reverse engineering, or illegal export.

B. BENCHMARKING AND METRICS

1. BACKGROUND

Metrics. Measuring the success of technology transfer and commercialization is not a new topic, and it has been widely studied.²⁹³ “Metrics” are employed as a figure of merit and are often proxies for outputs or outcomes to better understand the performance of a system. Metrics should not become the goal itself but, rather, used to understand aspects of a system.

Technology transfer metrics may be collected for multiple purposes. They can be motivated by a need to better manage activities internal to an organization or to better understand certain phenomena such as interactions between stakeholders. They can also be used to answer external stakeholder questions—ranging from industry to universities to Congress. Still another motivation to collect metrics is for larger studies, such as econometrics analyses, that showcase impacts. Table 1 shows different potential purposes with hypothetical examples.²⁹⁴

Ultimately, metrics can be an important source of information used by organizations to make decisions to improve effectiveness and efficiency. They can enable better management of the transfer of federally funded technologies for commercial and government applications. Metrics could be collected and analyzed for many aspects of Strategies 1 through 4.

To effectively manage technology transfer, it is also necessary to evaluate the technology transfer process, outputs, outcomes, and impacts. One goal of substantiating technology transfer value is to ensure that it is based on measuring ROI as well as other qualitative benefits of federally funded R&D.

²⁹³ See e.g. Hill, C. and J. Roessner. New directions in Federal laboratory partnerships with industry. *Science and Public Policy* 25: 297-304. 1998; Barry Bozeman. 2013. “Technology Transfer Research and Evaluation Implications for Federal Laboratory Practice,” April 4, 2013

²⁹⁴ Hughes, Mary E., Susannah V. Howieson, Gina Walejko, Nayanee Gupta, Seth Jonas et al. 2011. *Technology Transfer and Commercialization Landscape of Federal Laboratories*, Washington, DC: IDA Science and Technology Policy Institute.

Table 1. Motivations for Technology Transfer

Purpose	Example
For internal management	Identify specific activities that are contributing to the laboratory's goals and identify those that are not
To understand specific phenomena	Assess the factors that affect laboratory-industry interactions
To answer stakeholder questions	Identify how many small businesses worked with the laboratories over the past year
To meet official requirements	Report on the indicators required in the annual report on technology transfer activities
To promote interest and support	Highlight the effect that laboratories have on local economic development

Source: Hughes, M. et al. 2011

Framework for Metrics. Many Federal agencies have developed metrics and associated reporting requirements to assess the effectiveness and efficiency of Federal R&D to assist both those who fund and those who conduct R&D. There is general agreement that reporting requirements are inherently burdensome but are critically important in characterizing the outcomes, impacts, and operations of technology transfer and commercialization.

A unifying framework is needed for assessing and improving the effectiveness and efficiency of the technology transfer system in a holistic manner that is aligned with the overall purpose of Federal R&D. The system should include three broad types of metrics: (1) operational processes, (2) R&D outcomes, and (3) R&D impacts. Examples of these three types of metrics are discussed below.

I. OPERATIONAL PROCESS METRICS

Operational metrics are needed to assess and improve the efficiency of the technology transfer process. Such metrics must be customer-focused and designed to develop and implement uniform processes and best practices,²⁹⁵ consistent interpretation and application of authorities, timely government-university-industry partnerships, and a culture that values and incentivizes technology transfer through leadership, entrepreneurship, professional development, training, and marketing. Operational

²⁹⁵ Including consistent and universal definitions as well as appropriately standardized and simplified processes.

metrics may also be used to track and assess the progress of the intended actions discussed in this document.

Operational efficiency metrics encompass transaction times (e.g., for CRADAs, licenses, and other partnership agreements), resource utilization (e.g., financial, labor, and ancillary costs), performance expectations (e.g., for R&D staff and managers as well as technology transfer professionals), and unified reporting requirements (e.g., ease of access, use, and search). The right set of operational metrics will help streamline and accelerate technology transfer processes and better align them with the speed of today's market transforming innovations.

II. R&D OUTCOME METRICS

The R&D enterprise uses a variety of mechanisms to disseminate intellectual property. R&D outcome metrics are needed to assess and improve R&D effectiveness over the near term (e.g., within 3 years) to medium term (e.g., 3 to 8 years). The applicable time horizon will vary with the types of technologies and industries (e.g., mature versus emerging).

Classically-focused outcome metrics encompass patents (e.g., disclosures, applications, issued), copyright and trademark registrations and disputes, trade secret assertions, licenses (e.g., fees, royalties, equity), start-ups (e.g., formation, financing, buyouts), and partnerships (e.g., CRADAs and other agreements). Additionally, measures such as the ratio of patents filed to patents issued, and the ratio of patents issued to patents licensed may give a better sense of the effectiveness of patenting than counting the numbers of patents. Likewise, it might be useful to consider the percentage of start-ups that survive (e.g., beyond 5 years).

Broader outcome metrics that may be used to more accurately and appropriately capture the full range of Federal R&D contributions to the Nation encompass publications (e.g., peer-reviewed journal articles, citations, impact factor of journals), placement of highly skilled students and postdoctoral associates (e.g., via employment in the private and public sectors), use of shared facilities, new and improved standards (e.g., testing, measurements, materials, products, process, interoperability), as well as new and improved technology services (e.g., reference materials and data, calibrations, accreditations).

III. R&D IMPACT METRICS

R&D impact metrics are needed to assess and improve R&D effectiveness over the medium (e.g., 3 to 8 years) to long term (e.g., beyond 8 years) to assess the impacts of federally funded R&D on national security, economic competitiveness, job creation, commercial innovation, and other areas of broad societal benefit (e.g., healthcare,

infrastructure). Such metrics can be used retrospectively or prospectively to focus efforts on approaches proven to work.

Utilization metrics encompass new and/or improved products and services on the market that use intellectual property resulting from Federal R&D, their uses, consumer base, sales activity, time to market, and jobs created, including information related to whether the intellectual property used was protected (e.g., via patents and copyrights) or not (but still had commercial value). They represent an excellent measure of impact since they are fully aligned with the purpose of Federal R&D and technology transfer laws. Such metrics can also be tailored to measure the impact of Federal R&D on agency missions (e.g., national security, human health, agriculture, and infrastructure).

Broader R&D impact metrics may be tied to the reputation and stature of scientists and engineers performing Federal R&D through prestigious awards such as the Nobel Prize, Fields Medal, National Medal of Science, and National Medal of Technology and Innovation.

Examples of Data Collection. An overview and select examples of how U.S. and global S&T metrics are applied in analyses are provided below. There is a broad community of stakeholders assessing domestic metrics, including agencies, NSF-funded researchers within the Science of Science Policy community, and other universities technology transfer offices, and local/regional economic development authorities. A number of these organizations provided feedback via the RFI on how to improve data collection for metrics.

I. U.S. DOMESTIC TECHNOLOGY TRANSFER METRICS

NIST prepares an annual summary report to the President and the Congress on Federal Laboratory technology transfer.²⁹⁶ Several metrics are used in that report including new inventions disclosed, patent applications filed, start-ups, and patents issued. The patents issued by the USPTO are broken down by technology area. The report contains data on total active licenses, total active invention licenses, total active income-bearing licenses, new licenses, new invention licenses, income-bearing licenses, total income from all active licenses, licenses granted to small business, and total earned royalty

²⁹⁶ National Institute of Standards and Technology (NIST) and U.S. Department of Commerce. 2017. *Federal Laboratory Technology Transfer, Fiscal Year 2015*. Washington, DC: U.S. Department of Commerce.

income. In addition, metrics are shown for total active CRADAs, total active traditional CRADAs, new CRADAs, small business involvement in CRADAs, and other collaborative R&D relationships. Finally, the summary includes science and engineering articles and citations thereof by field.

The Association of University Technology Managers (AUTM) conducts similar analyses for university research.²⁹⁷ AUTM conducts a voluntary licensing activity survey that includes information on research funding, patent activity, innovation impacts, licensing income, and other indicators. They also fund research in harnessing the input-output “I-O” approach to estimate the economic impact of academic licensing and summing that impact over 20 years of available data.²⁹⁸ Estimates of the total number of person-years of employment supported by licensed-product sales of U.S. universities, hospitals, and research institutes are also developed. They also report AUTM-associated contributions to Gross Domestic Product (GDP), calculated using the I-O approach, are compared with U.S. GDP as a whole, and to selected industry, as defined by North American Industry Classification System codes, contributions to GDP.

The use of the I-O approach for R&D performed by Federal Laboratories provides some interesting results. NIST funded a study using the same author and a similar approach to the AUTM analysis.²⁹⁹ When viewed in isolation, the results look promising showing a range of economic impact up to \$83.6 billion over the study period. These estimates, however, are lower than those from university research in the AUTM report. There are a variety of potential reasons for the difference, but one of the biggest drivers is license income, which typically has not been a priority for Federal Laboratories. Federal Laboratories tend to place greater emphasis on the agency’s R&D mission over technology transfer, including license income. While the results for Federal Laboratories may be explained in this context, there is considerable opportunity for improvement in economic impact, given the critical need to strengthen American innovation, economic competitiveness, and national security.

²⁹⁷ AUTM 2018. “What is Tech Transfer, Anyways? <https://autm.net/about-tech-transfer/what-is-tech-transfer>

²⁹⁸ Pressman, Lori Mark Planting, Robert Yuskavage, Sumiye Okubo, Carol Moylan, and Jennifer Bond. 2017. The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2015. https://autm.net/AUTM/media/About-AUTM/Documents/AUTM_BIO_Economic_Impact_Report_2017.pdf

²⁹⁹ A Preliminary Application of an I-O Economic Impact Model to US Federal Laboratory Inventions: 2008-2015. <https://www.nist.gov/sites/default/files/documents/2018/09/20/prelimappioeconimpactmofedlabinventions2008-2015.pdf>

II. GLOBAL S&T METRICS

International S&T comparisons offer policymakers the opportunity to compare a country's competitiveness, particularly in terms of R&D and S&T activities. Any changes made to how the U.S. measures technology transfer and the corresponding health of the Nation's technology transfer system needs to be comparable with how other nations are performing. Indicators that measure economic growth and competitiveness in the broadest sense capture aspects of technology transfer, but often do not offer direct measures of a nation's technology transfer activities and downstream impacts.

Investment in R&D is often cited as an input measure for international comparison of R&D capacity, both total R&D spending, and also R&D intensity, which is R&D as a percent of GDP. R&D indicators serve as a measure of "innovation infrastructure" or inputs to a country's capacity to innovate. RFI respondents described how countries seek to increase their R&D efficiency by using existing funding for scientific research to incentivize universities to focus more on technology commercialization.

Another set of metrics that capture the input of knowledge capacity of a country are human capital metrics—the number of first university degrees in STEM fields or the number of researchers in a country. The number of patents filed or granted are captured internationally, both using USPTO data and triadic patent families, which are a special class of patents reflecting a series of corresponding patents filed at the European Patent Office, USPTO, and the Japan Patent Office, for the same invention, by the same applicant or inventor.³⁰⁰ Similar to metrics collected for the Annual Federal Laboratory Technology Transfer Report in the U.S., the international metrics for innovation and competitiveness and loosely technology transfer, are counting inputs to the technology transfer system.³⁰¹

Economic Impact Studies. Economic impact studies that focus on institutions or regions is another approach to measuring ROI. In contrast to metrics, economic impact studies identify and use indicators to assess the collective impact of a set of investments made by a group of stakeholders, which can be Federal Government, State and local

³⁰⁰ National Science Board. 2018. Science and Engineering Indicators 2018. NSB-2018-1. Alexandria, VA: National Science Foundation. Available at <https://www.nsf.gov/statistics/indicators/>.

³⁰¹ Caroline S. Wagner, Irene Brahmakulam, Brian Jackson, Amy Wong, Tatsuro Yoda; "Science and Technology Collaboration: Building Capacity in Developing Countries?" RAND Corporation, MR-1357.0-WB, March 2001.

governments, and corporations or private investment on a local economy. For example, the Mid-Region Council of Governments recently completed a study assessing the economic impact of Sandia Science and Technology Park in the local economy including the increase in tax revenue and the increase in wages.³⁰² Other impact studies focus on the economic contributions of investments at Federal Laboratories.

Economic impact metrics may be used to assess and improve the net benefits to society through transfer of technology resulting from Federal R&D. Measures of net benefits include net present value, social rate of return, and benefits to cost ratio. Using these measures correctly, however, depends on a choice of conceptual methods and the requirement for quality data.³⁰³ The methods involve significant time and effort but serve as useful estimates of the financial ROI. Three basic alternatives are available:

- Measures to guide public R&D policies such as allocation of resources, including those that influence investment decisions by firms and businesses;
- Measures to guide private industry investments in R&D, such as net present value, return on investment, and benefit-cost ratio; or
- Measures with which to evaluate the research and innovation systems, such as productivity growth, employment growth, and other economic and societal impacts.

2. CHALLENGES

Each stakeholder in the technology transfer process may have a different metric by which to gauge value given and received. For example, government metrics that include a monetary return on investment in the form of royalties for patents licensed are used to understand the more valuable metrics for government performance in job creation, economic competitiveness, and national security capabilities. University metrics may include licensing fees, recruitment success, academic stature, and endowments. Private sector metrics typically include a return on investment commensurate with risk, in addition to growth, market position, and liquidity.

The RFI responses and literature note that the current ways to collect technology transfer data and report and analyze metrics are problematic. There are inconsistent

³⁰² Sams, Rachel. “The impact Sandia Science and Technology Park has had over 20 years.” <https://www.bizjournals.com/albuquerque/news/2018/08/24/the-impact-sandia-science-and-technology-park-has.html>; <https://sstp.org/about-sstp/economic-impact> (accessed October 10, 2018)

³⁰³ See, e.g., *Furthering America’s Research Enterprise*, The National Academies Press, 2014.

approaches among agencies, due to the differences in agency missions, technologies, and technology transfer activities. For example, the DOD may provide incentives and track metrics for transitioning technology back into the national security industrial base through procurement actions. In contrast, research at NSF, NIH, and DOE could lead to transitions into the private sector and public consumption. A report by the Institute for Defense Analyses found that the Annual Summary Report on Technology Transfer is not consistently interpreted by the agencies and laboratory-level analysis of technology transfer and commercialization are not feasible because the measures lack standardization.³⁰⁴

RFI respondents indicated that metrics requirements are inconsistent across Federal agencies and do not align with metrics used for evaluating university R&D. For example, the reporting requirement for the Stevenson-Wydler Act is not equivalent to the Bayh-Dole Act requirement. This misalignment creates metrics that are not comparable and do not provide a full characterization of the outcomes of Federal R&D. The creation of a broad framework to assess effectiveness and efficiency would ideally provide a holistic approach that aligns with the overall purpose of R&D and the need for prudent management of resulting intellectual property. It is important to note, however, that there is a difference in opinion about consistency. Because different organizations have different missions, it may be worthwhile to allow some variations in the metrics collected. (Refer to “RFI Response on Differences in Metrics Across Sectors and Activities.”

RFI Response on Differences in Metrics Across Sectors and Activities

“Universities and medical schools have themselves worked to develop metrics for success of technology transfer and for proper contextualization of tech transfer in broader knowledge transfer and socio-economic development. As university-level efforts continue, we find that different and complimentary sets of measures emerge for technology commercialization, industry/entrepreneur engagement and partnerships, and economic development. Because all these activities and resulting outcomes measures are highly sensitive to individual universities’ missions, size, resources, geography, and a variety of other factors, it is most appropriate for further development of appropriate measures to happen at the individual university level.”

Source: RFI Response, Higher Education Associations

³⁰⁴ Hughes, Mary E., Susannah V. Howieson, Gina Walejko, Nayanee Gupta, Seth Jonas et al. 2011. *Technology Transfer and Commercialization Landscape of Federal Laboratories*, Washington, DC: IDA Science and Technology Policy Institute.

Meaningful effectiveness and efficiency metrics have the potential to assess and improve the ROI that accrues to the American taxpayer. However, current measures that are tracked and reported do not accurately reflect the impact or effectiveness of technology because they are counts of outputs, not measures resulting from analyses of the technology transfer system.³⁰⁵ RFI responses noted that there is not a set of consistent and universal definitions of success in technology transfer to guide metrics development. At the same time, agencies have been tasked with developing goals and metrics for measuring the needs of technology transfer and commercialization. Traditional metrics for success in technology transfer often focus on economic benefits, such as job creation or sales. Agencies with R&D missions that do not provide impacts in these traditional metrics often struggle to communicate their effectiveness. Developing broad definitions of success that recognize the diversity of agency R&D missions would enable technology transfer offices to craft metrics that more accurately describe the efficiency and effectiveness of their efforts at the cost of making cross-governmental comparisons impossible. (Refer to “RFI Response on Developing New Metrics and Measures.”)

RFI Response on Developing New Metrics and Measures

“Agencies have received numerous presidential and departmental directives on increasing the rate of technology transfer and economic and societal impact from Federal R&D investments. Each time the directives came with a goal of improving the results of technology transfer and commercialization activities. While agencies were tasked to develop goals and metrics, consistent and universal definitions have not been developed. Success should not be measured primarily by revenue, but by contributions to broader economic prosperity and societal impact. New methods and metrics with universal definitions should be developed to effectively capture impacts and improve measurements of effectiveness across the various recipients of Federal funding.”

Source: RFI Response, Association of University Technology Managers

A 2011 GAO report found that metrics focused on counting and reporting on the number of patents, licenses, and startups means academic officials will emphasize those activities in their own activities, and may not see the bigger picture of technology

³⁰⁵ U.S. Government Accountability Office (GAO), “Entrepreneurial Assistance: Efficiency and Effectiveness of Fragmented Programs are Unclear” 2012

transfer.³⁰⁶ It has been suggested that university reporting about technology transfer and commercialization needs to provide more detailed financial and performance information and to think about the incentives its metrics provide to university administrators and faculty researchers.³⁰⁷ It has also been suggested that universities should publicize information on “money in versus money out” and citations to patents as a way to measure promulgation.³⁰⁸ Many technology licensing offices do not provide adequate information to gauge their performance, and this makes it impossible to judge their initiatives.³⁰⁹

Metrics can be helpful to both those who fund R&D and those who conduct R&D, but come with a set of challenges and tradeoffs. RFI respondents indicated that metrics should not distort behavior that lead to unintended consequences, but to transition new technologies into the marketplace as quickly and efficiently as possible to benefit society. Another challenge with developing and implementing metrics is they require stability and should not be altered frequently given the need to make comparisons over time. (Refer to “RFI Response on Measuring and Reporting on Effectiveness.”) Having stability as an absolute requirement, however, may not be best under all circumstances. Measurement error, bias, and variability are also important considerations. Furthermore, single metrics often do not portray the complete perspective; interrelating metrics may lead to improved insights.

RFI Response on Measuring and Reporting on Effectiveness

“There is no single, obvious way to measure the success of tech transfer that everyone has somehow been missing. Metrics themselves should be seen as experimental, and their impact needs to be monitored. At the same time, metrics should not be altered lightly because stability is needed to make comparisons over time.”

Source: RFI Response, Massachusetts Institute of Technology

³⁰⁶ U.S. Government Accountability Office (GAO), “Mechanisms for Collaboration and Technology Transfer Could Be Enhanced to More Fully Leverage Partner Agency and Industry Resources” 2011

³⁰⁷ West, Darrell. 2012. “Improving University Technology Transfer and Commercialization.” Issues in Technology Innovation, Num 20.

³⁰⁸ *Ibid*

³⁰⁹ U.S. Government Accountability Office (GAO), “Mechanisms for Collaboration and Technology Transfer Could Be Enhanced to More Fully Leverage Partner Agency and Industry Resources” 2011

RFI respondents also indicated that data collection for metrics could be burdensome despite their value as important indicators of the success of Federal technology transfer. Accordingly, metrics-related reporting requirements and mandates should be kept to the minimum needed to provide the necessary information. Metrics, however, must be a good representation of the phenomena they measure, otherwise they drive sub-optimal behaviors. To minimize the burden, RFI respondents indicated that reporting requirements should be limited to only the information critical to evaluate technology transfer and commercialization.

Spam et. al (1993) discussed how developers could improve their rate of technology transfer and adoption by using more measures of performance, particularly those oriented to commercial success and adopter benefits.³¹⁰ A recent forum involved discussion of how agencies and laboratory members could work collaboratively to develop performance goals and measures for FLC's clearinghouse initiatives and use the results to evaluate progress toward meeting FLC's goals on outreach and networking.³¹¹

RFI respondents suggested new metrics in terms of both measured parameters and timespans that more accurately reflect the range of benefits from federally funded R&D. RFI respondents noted that current metrics, such as number of licenses and start-ups created, do not fully reflect the range of socioeconomic benefits of federally funded R&D. Potential new metrics include a broader set of economic measurements and additional social measurements that more fully describe the outcomes, impacts, and operations of technology transfer and commercialization.

Technology transfer varies across sectors in terms of the time required to execute licenses and move technology to market. Agencies often struggle to demonstrate return on investment when various stages of the technology transfer process delay outcomes. Furthermore, short timeframes for demonstrating ROI may deter experimentation in technologies that require more time to develop or drive similar disincentives.

³¹⁰ Spam, Adams and Souder, "Improving Federal Technology Commercialization: Some Recommendations from a Field Study" T2 Journal, 1993

³¹¹ U.S. Government Accountability Office (GAO). 2014. *Federal Laboratory Consortium Should Increase Communication with Potential Customers to Improve Initiatives*. Washington, DC. <https://www.gao.gov/assets/670/666361.pdf>

3. INTENDED ACTION

Intended Action 15. Establish metrics to better capture, assess, and improve Federal R&D outcomes and impacts as well as operational processes underpinning technology transfer within the context of benchmarking with global science and technology trends and metrics. ³¹²

A. MEANINGFUL OUTCOME AND IMPACT METRICS FOR FEDERAL R&D

Complete an authoritative analysis to provide a meaningful view of metrics for federally funded R&D that can be used to capture, assess, and improve R&D outcomes and impacts across the broad spectrum of applications and the time required to realize R&D impacts. Determine outcome and impact metrics beyond current practice and reporting requirements that can also be customized to better align with (i) the mission of Federal R&D agencies and laboratories, and (ii) global measures to better benchmark performance.

B. REPORTING METRICS FOR FEDERAL LABORATORIES

Develop, adopt, and use government-wide guidance for reporting broad-based R&D outcome and impact metrics at the Federal Laboratory level³¹³ to facilitate comparison with universities.

C. REPORTING EXTRAMURAL AND INTRAMURAL R&D METRICS

Legislative change requiring reporting of broad-based R&D outcome and impact metrics for extramural and intramural Federal R&D programs government-wide by amending the Bayh-Dole Act and Stevenson-Wydler Act statutes.

D. STANDARD PROTOCOL FOR ECONOMIC IMPACT STUDIES

Develop, adopt, and use a standard protocol government-wide for economic impact studies, including a standard data collection instrument (e.g., survey, questionnaire) pre-approved by the Office of Management and Budget (OMB).

³¹² (a) Outcome metrics: consider current outcome metrics as well as broader outcome metrics to capture full range of Federal R&D contributions, (b) Impact metrics: consider utilization, economic impact, and broader R&D impact metrics, and (c) Operational process metrics: consider transaction times, resource utilization, performance expectations (e.g., for R&D staff and managers as well as technology transfer professionals), and unified reporting requirements (e.g., ease of access, use, and analysis).

³¹³ Federal R&D agencies generally report aggregated metrics for multiple Federal Laboratories (e.g., at the department level).

SUMMARY AND CONCLUSIONS

This ROI Green Paper outlines actions intended to streamline and accelerate the transfer and commercialization of technology resulting from federally funded research and development. The purpose of this green paper is to summarize stakeholder input, agency feedback, and literature related to advancing the President's Management Agenda Lab-to-Market Cross Agency Priority Goal.

This green paper highlights challenges and intended actions in the context of each of the five strategies inspired by the PMA L2M CAP Goal:

- Strategy 1: Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices;
- Strategy 2: Increase engagement with private sector technology development experts and investors;
- Strategy 3: Build a more entrepreneurial R&D workforce;
- Strategy 4: Support innovative tools and services for technology transfer; and
- Strategy 5: Improve understanding of global science and technology trends and benchmarks.

The intended actions outlined in this green paper are designed to overcome systemic challenges raised by technology transfer stakeholders that will unleash American innovation and even greater return on investment to the American taxpayer. Table 2 provides a summary of intended actions.

Table 2. Summary of Intended Actions for Return on Investment (ROI) Initiative to Advance the President’s Management Agenda and Unleash American Innovation

PMA Lab-to-Market Strategy	Intended Action	Action Type		
		Regulation ^b	Legislation ^b	Other ^c
Strategy 1. Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices. The Intended Actions are designed to make it easier for industry to work with Federal Laboratories and access federally funded R&D by removing real and/or perceived regulatory and administrative barriers.	Intended Action 1 – Government Use License. Define the scope of the “government use license” for use directly by the government—or a government contractor in the performance of an agreement with government—for a government purpose only, including continued use in research and development. The scope of the government use license should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with government—does not directly use or consume those goods and services.	BD SW ^a		
	Intended Action 2 – March-In Rights. Define the circumstances under which the government may exercise march-in rights consistent with the uses of march-in specified in statute and not as a regulatory mechanism for the Federal Government to control the market price of goods and services. Reserve march-in for a compelling national issue or declared national emergency when other remedies have failed. Clarify definition of “reasonable terms” consistent with original statutory intent.	BD		
	Intended Action 3 – Preference for U.S. Manufacturing. Protect and strengthen the statutory requirement that products embodying or using federally funded inventions be manufactured substantially in the United States. Streamline and implement a uniform waiver process government-wide in accordance with statutory requirements. Identify the pathway for expanding the preference for U.S. manufacturing to (i) all licenses rather than limiting this preference to exclusive licenses as it is in current statute and (ii) all contractors at any tier in addition to licensees.	BD SW ^a		P
	Intended Action 4 – Software Copyright. Establish copyright protection for software products of Federal Government R&D. This narrowly tailored change is consistent with original statutory intent to transfer IP created from R&D to the private sector to develop marketable goods and services. This will not affect most Government Works since they are not R&D inventions as defined in statute.		BD	
	Intended Action 5 – Trade Secrets. Establish clear and consistent definition as well as authorities required to protect the trade secrets of companies involved in R&D collaborations with Federal Laboratories. Extend potential CRADA information protection period to 10 years (from 5 years specified in current statute) in cases where there is a demonstrable need for a business collaborator to achieve	SW ^a	SW	

	practical application of products that result from CRADA work.			
	Intended Action 6 – Strengthen Technology Transfer at Federal Laboratories. Authorize the Secretary of Commerce to issue regulations implementing consistent and streamlined policies and practices government-wide under the Stevenson-Wydler Act. Confirm the mission requirement of contributing to U.S. innovation for all government entities engaged in research and development. Develop and implement consistent policies for appropriate use of international intellectual property protections in support of U.S. innovation, manufacturing, and export. Legislative change is required to authorize royalty payments to Federal employees for non-invention forms of licensed intellectual property and to extend to Federal employees at all agencies the increase in royalty cap of up to \$500,000 per year authorized in the FY 2018 National Defense Authorization Act (P.L. 115-91).	SW ^a	SW	
	Intended Action 7 – Presumption of Government Rights to Employee Inventions. Provide for a present assignment of invention rights by Federal employees to the Federal Government and provide for streamlined rights determination processes for Federal employee inventions. Implement regulatory change under Executive Order 10096; Legislative change is required to codify the Federal employee's requirement to report inventions and assign all right, title, and interest in work related inventions to the Federal Government.	EO SW ^a	SW	
Strategy 2. Increase engagement with private sector technology development experts and investors. The Intended Actions are designed to make it easier for the private sector to partner with Federal agencies and to attract private sector investment for translation R&D, technology maturation, and commercialization.	Intended Action 8 – Streamline Partnership Mechanisms. Establish consistency in legislative interpretation and use of best practices government-wide and implement streamlined, transparent partnership agreements, including licensing and indemnification terms. Develop, adopt, and use speed-of-business-based best practices and tools that deliver modern, streamlined, and responsive customer-experience government-wide. Consistent, transparent licensing policies and practices for federally funded inventions will maintain flexibility to tailor specific financial terms of each license, consistent with the statutory goal to promote commercial use of inventions. Consistent indemnification terms for Federal R&D contractors, grantees, and collaborators government-wide will consider the use of alternative terms, including disclaiming liability to the extent of the Federal Tort Claims Act. Use of license royalties will be clarified to primarily promote compliance to the terms of development and achieve practical application of technology. Statutory change is required to fix conflicting language in CRADA authority regarding who can be a CRADA partner.	SW ^a BD	SW	P
	Intended Action 9 – New/Expanded Partnership Mechanisms. Authorize new and expanded mechanisms to establish partnership agreements at the speed of business and to attract private sector investment for translational R&D, technology maturation, and commercialization. Expand use of Agreements for Commercializing Technology (ACT) authority—which enables partnerships with terms more compatible with industry practices—to all GOCO Laboratories. Extend use of ACT authority by GOGO Laboratories through partnership intermediaries authorized by statute.	SW ^a	SW	P

	- Establish Research Transaction Authority (RTA) to support translational R&D collaborations by simplifying, accelerating, tailoring, and executing partnership agreements at the speed of business. Modeled after <i>Other Transaction Authority</i>, uniform government-wide implementing regulations will (i) limit the use of RTA to R&D but not for use in procurement or financial assistance actions, and (ii) ensure that the RTA appropriately conveys intellectual property rights consistent with the Bayh-Dole Act. - Authorize all Federal R&D agencies to establish Non-Profit Foundations that will advance their missions by attracting private sector investment to accelerate technology maturation, transfer, and commercialization. Develop, adopt, and use consistent policies and practices to establish and operate such nonprofit foundations. - Expand Enhanced Use Lease Authority (EULA) to all Federal Laboratories for leasing unused real property to the private sector for use to support technology transfer and commercialization activities.			
	Intended Action 10 – Technology Maturation Funding. Allow the limited use of R&D funds awarded through government grants, contracts, and cooperative agreements for technology transfer, specifically to secure the government’s right and interest to a patented invention. Provide a summary of public comments on SBIR/STTR technology maturation funding and related improvements to the U.S. Small Business Administration (SBA) for consideration, to develop follow up actions.	BD		F
Strategy 3. Build a more entrepreneurial R&D workforce. The Intended Actions are designed to promote start-ups, job creation, and economic growth by facilitating technology transfer activities through an R&D workforce more knowledgeable about the needs of industry and with the flexibility to support industry’s needs.	Intended Action 11 – Technology Entrepreneurship Programs. Establish technology entrepreneurship programs at Federal R&D agencies government-wide. Federal R&D agencies will leverage entrepreneurship programs representing best practices, such as NSF’s I-Corps™ program for extramural R&D programs and experiential training programs such as DOE’s Lab-Embedded Entrepreneurship Program for intramural R&D programs. Develop, adopt, and use consistent policies and practices government-wide to implement and operate technology entrepreneurship programs at Federal R&D agencies. A summary of public comments specific to NSF’s I-Corps™ Program, DOE’s Lab-Embedded Entrepreneurship Program, and others will be provided to the respective agencies for appropriate actions. Establish a designated job series to recruit, develop, and retain well qualified professionals—with both business and scientific/technical backgrounds—to pursue a career in Federal technology transfer.			P F
	Intended Action 12 – Managing Conflicts of Interest. (i) Implement harmonized and consistent government-wide requirements to manage conflicts of interest involving recipients of extramural Federal R&D funding, and (ii) authorize scientists and engineers at Federal Laboratories to engage in entrepreneurial activities that support technology transfer and commercialization subject to harmonized and consistent requirements for managing conflicts of interest, including any financial interests, approved by the agency head in consultation with the agency’s legal counsel. Authorize Federal agencies to grant scientific and technical professionals, including those who are senior executives, at Federal Laboratories entrepreneurial leave and sabbatical	SW ^a	SW	P

	absence to engage in compensated or uncompensated entrepreneurial activities that support technology transfer and commercialization for up to 3 years with full reinstatement privileges.			
Strategy 4. Support innovative tools and services for technology transfer. The Intended Actions are designed to make it easier to report intellectual property resulting from both extramural and intramural Federal R&D and for the public to access information on Federal R&D assets.	Intended Action 13 – Federal IP Data Reporting System(s). Establish a modern, secure, interoperable platform for reporting data on intellectual property (inventions, copyrights, and utilization metrics) resulting from Federal R&D government-wide that is easy to access, analyze, and use by extramural and intramural recipients of Federal R&D funding and those responsible for managing the IP data. Consistent and streamlined government-wide regulatory requirements and practices for timely and transparent reporting of extramural Federal IP data. Address statutory requirements and provide consistent, streamlined implementing regulations for Federal Laboratories to report data on IP resulting from intramural R&D.	SW ^a	BD SW	T
	Intended Action 14 – Access to Federal R&D Assets. Establish federated data portal that is easy for the public to access, use, and analyze which provides information on (i) IP resulting from extramural and intramural Federal R&D programs government-wide, and (ii) Federal R&D programs, facilities, equipment and tools, expertise, services, and other relevant assets. Address statutory requirements and provide consistent, streamlined implementing regulations for Federal Laboratories to report up-to-date data on their R&D assets.	SW ^a	SW	T
Strategy 5. Improve understanding of global science and technology trends and benchmarks. The Intended Actions are designed to better capture, assess, and improve Federal R&D outcomes, impacts, and technology transfer operational processes.	Intended Action 15 – Benchmarking and Metrics. Establish metrics to better capture, assess, and improve Federal R&D outcomes and impacts as well as operational processes underpinning technology transfer within the context of benchmarking with global science and technology trends and metrics. • Complete an authoritative analysis to provide a meaningful view of metrics for federally funded R&D that can be used to capture, assess, and improve R&D outcomes and impacts across the broad spectrum of applications and the time required to realize R&D impacts. Determine outcome and impact metrics beyond current practice and reporting requirements that can also be customized to better align with the mission of Federal R&D agencies. • Develop, adopt, and use government-wide guidance for reporting broad-based R&D outcome and impact metrics at the Federal Laboratory level to facilitate comparison with universities. • Address statutory requirements for reporting broad-based R&D outcome and impact metrics for extramural and intramural Federal R&D programs government-wide. • Develop, adopt, and use standard protocol government-wide for economic impact studies, including a standard, pre-approved data collection survey questionnaire.		BD SW	A P T

- a. Statutory authority is required to implement consistent and streamlined regulations under the Stevenson-Wydler Act (see Intended Action 6).
- b. BD=Bayh-Dole Act, SW=Stevenson-Wydler Act, EO=Executive Order.
- c. Other Actions: P=Policy and Guidance, T=Tool Development, A=Analysis, and F=Forward Summary of Agency-Specific Comments.

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ABBREVIATIONS

ACT	Agreements for Commercializing Technology
AI	Artificial Intelligence
API	Application Programming Interface
ARL	Army Research Lab
AURP	Association of University Research Parks
AUTM	Association of University Technology Managers
CAP	Cross Agency Priority
COI	Conflict of Interest
CRADA	Cooperative Research and Development Agreement
CTSA	Clinical and Translational Science Awards
DHS	Department of Homeland Security
DOC	Department of Commerce
DOD	Department of Defense
DOE	Department of Energy
DOJ	Department of Justice
DTSA	Defend Trade Secrets Act
e-NTR	New Technology Reporting System
EIR	Entrepreneur-in-residence
ERC	Engineering Research Centers
FFMI	Fast Forward Medical Innovation
FFRDC	Federally Funded Research and Development Center
FLC	Federal Laboratory Consortium for Technology Transfer
FNIH	Foundation for the National Institutes of Health
FOIA	Freedom of Information Act
FTE	Full-time Employee
GAO	Government Accountability Office
GDP	Gross Domestic Product
GOCO	Government-Owned, Contractor-Operated
GOGO	Government-Owned, Government-Operated
IAWGBD	Interagency Working Group on Bayh-Dole
IAWGTT	Interagency Working Group on Technology Transfer
I-Corps™	Innovation Corps™
IP	Intellectual Property

IPA	Intergovernmental Personnel Act
IUCRC	Industry-University Cooperative Research Centers
ManTech	Manufacturing Technology
MBDA	Minority Business Development Agency
MEP	Manufacturing Extension Partnership
L2M	Lab-to-Market
L2M SC	Lab-to-Market Subcommittee
LANL	Los Alamos National Laboratory
LWOP	Leave Without Pay
NASA	National Aeronautics and Space Administration
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NSA	National Security Administration
NSF	National Science Foundation
NSTC	National Science and Technology Council
OECD	Organisation for Economic Cooperation and Development
OGE	Office of Government Ethics
OMB	Office of Management and Budget
OPM	Office of Personnel Management
ORTA	Office of Research and Technology Applications
OSTP	Office of Science and Technology Policy
OTA	Other Transaction Authority
PFI	Partnerships for Innovation
PHS	Public Health Service
PIs	principal investigators
PIA	partnership intermediary agreement
PMA	President's Management Agenda
PRA	Paperwork Reduction Act
R&D	Research and Development
RFI	Request for Information
ROI	Return on Investment
RTA	Research Transaction Authority
S&T	Science and Technology
SBA	Small Business Administration

SBIR	Small Business Innovation Research
SPP	Strategic Partnership Project
STEM	Science, Technology, Engineering, and Math
STPI	Science and Technology Policy Institute
STTR	Small Business Technology Transfer
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UC	University of California
USAID	United States Agency for International Development
USDA	Department of Agriculture
USPTO	United States Patent and Trademark Office

Appendix 1. Select Technology Transfer Mechanisms in Use by Federal Agencies

Mechanisms in Use by Agency		DHS	DOC	DOD	DOE	DOT	EPA	NASA	HHS	USDA	USGS	VA
Invention Protection	Invention Disclosures	X	X	X	X	X	X	X	X	X	X	X
	Patents	X	X	X	X	X	X	X	X	X	X	X
	Copyrights		X*		X			X*				
Property Transfers	Patent Licenses	X	X	X	X	X	X	X	X	X	X	X
	Material Transfer Agreements (MTA)		X	X					X	X		X
	Email MTAs								X			
Research Partnership Agreements	CRADAs	X	X	X	X	X	X	X	X	X	X	X
	Other Transaction Authority			X					X			
	Space Act Agreements							X				
Resource Use Agreements	Commercial Test Agreement			X								
	Facility Use Agreement		X	X								
	Test Service Agreements			X								
	User Facilities Agreement		X*	X	X							
	Work-For-Other Agreements			X	X							
Educational Agreements	Educational Partnership Agreements			X								
	Intramural Research Training Award								X			
Personnel Exchange Agreements	Guest Researcher Agreement		X									
	Industrial Staff Member, Assignment, or Fellow Agreement				X							
	Intergovernmental Personnel Act	X	X	X	X	X	X	X	X	X	X	X
Agreements with Intermediaries	Partnership Intermediary Agreements			X				X		X		
	Other Types of Agreements with Partnership Intermediaries		X	X					X			

*Represents a partial capacity limited to certain parts of an agency or fairly restricted areas of use.

Original Source: Hughes, Mary E., Susannah V. Howieson, Gina Walejko, Nayanee Gupta, Seth Jonas et al. 2011. *Technology Transfer and Commercialization Landscape of Federal Laboratories*, Washington, DC: IDA Science and Technology Policy Institute. Updated based on more current information.

Appendix 2. Comparison of SPP, CRADA, and ACT Attributes

Attribute	Non-Federal SPP	CRADA	ACT
Parties	Laboratory* and sponsor**	Laboratory* and sponsor**	M&O contractor* and sponsor
Approval	DOE approves each SPP agreement, including SOW and contract terms***	DOE approves each CRADA, including SOW and contract terms	DOE approves each statement of work, plan to mitigate organizational conflicts of interest, if applicable, and SPP-like “checklist” but does not approve ACT agreement with sponsor
Performance guarantee	None	None	M&O contractor can commit to negotiated schedule or performance guarantee. Removes uncertainty for sponsor and adds risk for M&O contractor.
Advance payment	Sponsor provides 60-day advance payment, with some DOE-approved exceptions****	Sponsor provides 60-day advance payment, with some DOE-approved exceptions****	Negotiable; M&O contractor ensures funds are available before work is performed, can begin work before company transfers funds.
Indemnification	Sponsor indemnifies both M&O contractor and government	Sponsor indemnifies both M&O contractor and government	M&O contractor indemnifies government; sponsor indemnification is negotiable. Reduces government risk, enables sponsor risk sharing.
Intellectual property	Sponsor may elect title to inventions with certain restrictions	Sponsor owns its inventions; laboratory owns its inventions Undivided rights in joint patents; sponsor has option to license laboratory rights	Rights waived to “IP lead” designated in deal negotiation (either sponsor or M&O contractor); in some cases, M&O contractor can retain rights to some or all IP on M&O contract termination
Government use license	Negotiable; government may retain only a research license to intellectual property	Government always retains a use license to intellectual property	Negotiable; government may retain only a research license to intellectual property
3-Percent Federal Administrative Fee	Waived for state and local governments, nonprofit organizations, and small businesses	Waived for state and local governments, nonprofit organizations, and small businesses	Never waived

Source: Adapted from K. Edmonds, “Energy Department Answering President’s Call on Commercialization,” Energy.Gov News, October 28, 2011, <http://energy.gov/articles/energy-department-answering-presidents-call-commercialization>, and M. Paulus “Agreement to Commercialize Technology (ACT): A New Technology Transfer Mechanism,” Oak Ridge, Tennessee: Oak Ridge National Laboratory, 2011.

* *Laboratory* refers to the organization that DOE shares an interest and risk with; *M&O contractor* is the organization that operates the laboratory.

** *Sponsor* funds work performed by the laboratory; also referred to as *partner*.

*** DOE sometimes pre-approves certain model terms, which then allows the submission of a statement of work (SOW) without repeating an approval of the terms.

****DOE reduced the previous requirement for payment 90 days in advance to 60 days in 2011