Opportunities to Substantially Increase Technology Transfer in Response to the October 28, 2011 Presidential Memorandum:

Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses[1]

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I. Introduction

On October 28, 2011, the President issued the Presidential Memorandum (PM) -- *Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses.* This PM recognized the importance of Federal laboratory technology transfer and instructed agencies "*to increase the successful outcomes of these activities significantly over the next 5 years, while simultaneously achieving excellence in our basic and mission focused research activities.*"

The PM directed that "*The Interagency Workgroup on Technology Transfer [(IAWGTT)]…shall recommend…opportunities for improving technology transfer from Federal laboratories, including: (i) current technology transfer programs and standards for assessing the effectiveness of these programs; (ii) new or creative approaches to technology transfer that might serve as model programs for Federal laboratories; (iii) criteria to assess the effectiveness and impact on the Nation's economy of planned or future technology transfer efforts; and (iv) an assessment of cooperative research and development venture programs.*" In addition, individual agencies prepared agency-specific plans to examine their technology transfer operations, describing existing technology transfer programs and describing how each agency would improve and streamline its technology transfer and Small Business Innovative Research (SBIR) programs.

This report consolidates the recommendations from the IAWGTT for innovative approaches to technology transfer and summarizes innovative approaches proposed by agencies in their individual agency plans. The individual agency plans describe the current state of technology transfer within each agency and are considered baseline documents for this report.[3]

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

[2] For further information contact the Technology Partnerships Office, National Institute of Standards and Technology, U.S. Department of Commerce, www.nist.gov/tpo.

[3] The Presidential Memorandum also directed the IAWGTT to provide an assessment of "cooperative research and development venture programs." The IAWGTT is not aware of such programs.

Pursuant to the PM, the National Institute of Standards and Technology (NIST) (in accordance with functions delegated by the Secretary of Commerce) in conjunction with the Office of Science and Technology Policy and the Office of Management and Budget, worked with Federal agencies through the IAWGTT to develop this report. The interagency effort began in November 2011 and continued via a series of meetings and discussions through September of 2012 in time to implement agency responses in fiscal year 2013. The IAWGTT formed several internal workgroups chaired by IAWGTT agency members. These workgroups focused on the key issues in the PM and served to coordinate activities across agencies. Each workgroup was tasked to develop findings and recommendations in a specific area. The areas addressed included:

- Opportunities – developing and communicating new initiatives within agencies to serve as models to increase commercialization and collaboration.
- Regional partnerships – working with stakeholders, such as regional, state, and local economic development organizations, to look for areas of cooperation.
- Metrics – examining goals, objectives, and data requirements to develop a suite of metrics that better track technology transfer efforts as compared to the current metrics used in annual reporting.
- Communications – using communication tools to increase the pool of potential investment partners interested in available technologies for commercialization, as well as developing improved outreach efforts to communicate available technologies to potential partners.
- Legislative considerations –examining the impact of the Smith-Leahy America Invents Act (AIA) to identify how recent changes to patent law and policy impact Federal technology commercialization.
- Administrative considerations –examining how administrative roadblocks slow technology transfer implementation.

II. Background

Technology transfer involves the transition of research from the laboratory into products and services in the economy. Federal legislation[4] provides a variety of vehicles through which technology developed with U.S. Government funds can be transferred to non-government entities in ways that benefit the Nation. These vehicles facilitate the potential commercialization of inventions produced from Federal funds, enable the use of Federal laboratory facilities by non-Federal entities, and allow for the establishment of research partnerships between Federal

4 The primary legislation addressing Federal technology transfer includes the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480), Patent and Trademark Act Amendments of 1980 (P.L. 96-517) (Bayh-Dole Act), Small Business Innovation Development Act of 1982 (P.L. 97-219), Federal Technology Transfer Act of 1986 (P.L. 99-502), Omnibus Trade and Competitiveness Act of 1988 (P.L. 100-418), National Competitiveness Technology Transfer Act of 1989 (P.L. 101-189), American Technology Preeminence Act of 1991 (P.L. 102-245), Small Business Research and Development Enhancement Act of 1992 (P.L. 102-564), National Department of Defense Authorization Act for 1994 (P.L. 103-160), National Technology Transfer and Advancement Act of 1995 (P.L. 104-113), Technology Transfer Commercialization Act of 2000 (P.L. 106-404), Energy Policy Act of 2005 (P.L. 109-58), and the America COMPETES Act of 2007 (P.L. 110-69). Numerous other acts indirectly affect Federal technology transfer activities.

Government laboratories and other entities. Federal legislation provides Federal agencies with the authorization to apply for patents or other forms of protection on inventions in which the Federal Government owns a right, title, or interest. Federal agencies are also authorized to grant nonexclusive, exclusive, or partially exclusive licenses of patented, federally owned inventions. Agencies make the decisions to exercise these authorities within the context of their missions. In addition to these statutory authorities, Federal laboratories utilize many other mechanisms for transferring the results of Federal research to potential users. Federal laboratories disseminate basic and applied research results in archival, peer-reviewed literature; create publicly accessible software and databases; and provide advanced educational opportunities for Science, Technology, Engineering, and Mathematics (STEM) disciplines.

Successful commercialization of an invention depends on a number of variables. Inventions, as described within a patent or other publication, are rarely at a state from which they can be pushed into an existing market. Additional development and investment are usually required before a new innovation can be made market-ready. This development and investment are part of an overall progression in time from idea, to laboratory prototype, to patent, to license, to development, to robust commercial product. Different Federal technology transfer activities can assist entities at various pre-commercial stages in this progression from idea to product. Successful commercialization of a product, especially a high-technology product, typically requires more than one technology. Technology pathways from basic research to highly complex, commercial technologies that required multiple technological advances can be illustrated for medical imaging technologies, information technologies, nuclear power generation, and a host of other technologies that are critical to the Nation's economy and well-being. Accrued benefits might not be determinable for many years after the development of any particular research accomplishment. In many cases, the benefit of one technology advance might not occur until other technologies are developed much later. Measures of short-term outputs, e.g., patents and licenses, are therefore not directly interpretable as quantified benefits to the Nation's long-term economy. Thus, economic impact studies of research results will often fail to assess the true benefit that will accrue from the subsequent technology advance, if the studies are conducted too early in the technology's development timeline.

Increasingly, new inventions incorporate software to control some aspect of the invention. Robotics, medical-diagnostic devices, advanced control systems, and other new technology devices require software for the functionality of the device or system. In some cases, the software is device/system dependent (e.g., a medical-diagnostic device or system) and in others the software may form a platform that can be used across many devices (e.g., robotics). Inventions incorporating software could require the same intellectual property protections afforded to other inventions created from Federal funds to make their commercialization attractive. Outside of government operated Federal laboratories, protection for software is typically through copyright, although software can also be patented. In the case of a Federal invention that includes both hardware and software developments, the software produced by a Federal employee (and consequently a work of the Federal government) cannot be copyright protected, although software produced by a government owned/contractor operated laboratory can receive a copyright, and the Federal government may also receive and hold copyrights transferred to it by assignment, bequest, or otherwise.[5] The ability to protect part of a device or

[5] 17 U.S.C. § 105.

system (e.g. protecting the hardware by patent), but not the other part of that device or system (the device's software not protected by copyright) could be an impediment to the willingness of a potential licensee to make the investment necessary for commercialization.

Small businesses can find it difficult to navigate through various agencies' technology inventories to find potential solutions to the problems they seek to solve. This is especially true when a solution to a complex problem requires multiple innovations – and would also require license negotiations with multiple agencies. Reduction in the time required to process contracts and agreements with Federal Laboratories could have significant benefits for all Federal partners, and particularly for small companies.

The PM has provided a greater visibility of technology transfer operations within the agencies affected. In response, several agencies have reviewed existing technology transfer policies and operations, and, in some cases, have strengthened their Offices of Research and Technology Applications. Agencies have reviewed existing policies and agreements seeking ways to streamline processes where possible.

III. New and Creative Approaches to Technology Transfer

A. New Technology and Scientific Work Products

A major focus for technology transfer activities has been leveraging the Nation's investment in its mission-focused research and development programs to assist and expand economic development and the commercialization of new products and services. This focus includes the traditional concept of patents and licensing, as well as other ways to convey knowledge to the private sector. New trends, such as open source models, require new approaches and new tools for transferring technology. Increasingly shorter product lifecycles in key areas may not readily lend themselves to the traditional patent/license model. In response to these trends, Federal agencies have developed a number of new and creative approaches to technology transfer that could serve as model programs for Federal laboratories.

Improving Outreach for Technology Transfer
A major component of technology transfer is communicating with potential partners. There are many new plans described by various agencies that will strengthen outreach to potential partners. Outreach is particularly important for small businesses that may not have the infrastructure to efficiently gather and track information across multiple agencies.

In addition to improvements in individual agency websites and other outreach, the Federal Laboratory Consortium for Technology Transfer (FLC) has updated its "Available Technologies" page (see: http://www.federallabs.org/available_technologies/) and "Technology Locator Service" page (see: http://www.federallabs.org/locator/) to provide an easy way to link all Federal technology data to a single web-based source.

Some of the initiatives highlighted in the agency plans are:

- The Centers for Disease Control (CDC) will explore new outreach activities (e.g., trade meetings, social media, and targeted marketing) and the use of social media.
- DHS will update its website to include a list of technologies available for licensing to attract and promote the commercialization of DHS technologies. DHS will work toward linking the data from the DHS website to provide a feed into the planned interagency-developed database for advertising Federal agency technologies to the inquiring public.
- DOD will consolidate access to technologies available for commercialization from all DOD Laboratories through the Defense Innovation Marketplace website. DOD will also ensure that all publicly available, federally owned inventions are listed on a public database, such as data.gov.
- DOT will improve technology marketing efforts by increasing the number of marketing events attended in order to collaborate with stakeholders in support of technology deployment efforts. DOT will also evaluate agency research content on the agency's website and identify ways to improve content.
- FDA will explore collaboration with local and regional biomedical companies, universities, and non-profit research organizations in areas where FDA laboratories exist. FDA will engage in new outreach activities (e.g., trade meetings and workshops) and will update its outreach materials (e.g., consolidated information on a FDA website and updated marketing materials).
- NIH has developed electronic and social media tools to promote its inventions available for licensing and collaboration. These include websites, RSS feeds, iPhone® and iPad® apps, e-mail subscriptions, Twitter®, and Facebook®. NIH also participates in CTSAIP.com, a website that aggregates technologies from across the NIH-supported Clinical and Translational Science Award consortium of medical research institutions.
- NASA has several plans under way to encourage licensing of its patented inventions, including development of an agency-wide website for its diverse intellectual property portfolio, and cross-center industry outreach events.
- DOE has developed a new search feature using a novel web crawling technology to allow users to search technology transfer terms across the DOE complex. The Energy Innovation Portal has also been developed to provide users with access to DOE Energy Efficiency and Renewable Energy Technologies (EERE) that are available for licensing.

Use of Intermediaries

Intermediaries and other similar arrangements can expand the reach of Federal laboratories to provide a variety of different services to potential partners. Intermediaries typically have an interest in local, regional, or general technology-based economies and are particularly useful for small and developing businesses by providing additional business assistance that leverages the resources offered by the Federal government.

The formal term "Partnership Intermediary" means an agency of a state or local government, or a nonprofit entity owned in whole or in part by, chartered by, funded in whole or in part by, or operated in whole or in part by or on behalf of a state or local government, that assists, counsels, advises, evaluates, or otherwise cooperates with small business firms, institutions of higher education or educational institutions that need or can make demonstrably productive use of technology-related assistance from a Federal laboratory. Federal agencies can pay the Federal

costs of a Partnership Intermediary Agreement (PIA) (15 U.S.C. § 3715). However, agencies today are employing their Partnerships Intermediary authority in new and creative ways to provide additional support, especially to support new businesses and to promote U.S. manufacture of products.

The DOD (see: http://www.ottpin.com/PIN/Index.aspx) and USDA (see: https://www.ars.usda.gov/sp2UserFiles/Place/01090000/USDA%20Technology%20Transfer%20and%20the%20Agricultural%20Technology%20Innovation%20Partnership%20program.pdf) have well-established intermediary networks. These networks continue to serve as an example for other agencies. In addition, within the DOC, NIST's Hollings Manufacturing Extension Partnership (MEP) (see: http://www.nist.gov/mep/) is available to assist businesses that utilize technology transfer. Businesses can use the support services of local and regional MEP centers to grow their business, while agencies may take advantage of the network to promote U.S. manufacturing of technologies.

Some of the initiatives highlighted in the agency plans are:

- DOD, USDA, and others have begun coordinating intermediaries between agencies.
- CDC will expand their collaborations with GeorgiaBIO™ (a nonprofit, membership-based organization that promotes the interests and growth of the life-sciences industry), Georgia Research Alliance (an independent not-for-profit entity governed by leaders from industry and academia), CDC Foundation, and local chambers of commerce.
- FDA will explore partnerships with innovation intermediaries and economic development organizations.
- DHS will develop additional PIAs with various economic development organizations for outreach throughout the Nation. Through these PIAs, the DHS Technology Transfer Office will have the ability to reach small businesses and leverage their skills, knowledge, and capabilities.

Place-Based Technology Focus

Technologies are often found in particular geographic areas because of the local infrastructure, including a pool of qualified employees. Many agency plans take advantage of the place-based aspect of technology to try to leverage growth through collaborations with Regional Technology Development Organizations (RTDOs). RTDOs know the technology businesses in their respective regions and can facilitate partnership arrangements between small, high-growth businesses and Federal laboratories. RTDOs may also be able to assist small businesses in securing state or regional funding to help in commercialization of newly transferred technologies. Several agencies have long-standing, formal and informal relationships with various RTDOs.

Some of the initiatives highlighted in the agency plans are:

- The USDA Agricultural Research Service (ARS) partnered with Maryland's Technology Development Corporation (TEDCO) to host a series of Innovation Forums to address specific regional issues. The structure of ARS's program is to first conduct "listening sessions" in which public audiences describe local/regional agriculture issues that could potentially be addressed with technology solutions. Following the listening sessions, ARS and TEDCO host forums that present USDA technologies or research capabilities

to address specific regional issues. ARS plans to incorporate NIST's MEP into its Maryland Forums. USDA also plans to roll out this program across the U.S. through the 10 members of the Agricultural Technology Innovation Partnership (ATIP) program. USDA/ATIP is seeking future involvement from other agencies with common technology interests, e.g., the Bureau of Reclamation on water-use issues, the DOE on bio-energy feedstocks, and local manufacturing extension programs.

- The Environmental Protection Agency's (EPA) National Risk Management Research Laboratory in Cincinnati provides support to the Water Technology Innovation Cluster (WTIC) in the Cincinnati area. WTIC is a regional innovation cluster with key stakeholders from economic development organizations; large and small businesses; universities; and federal, state and local governments. WTIC seeks to be the world's source for practical and affordable water solutions. EPA will facilitate other joint efforts with other agencies to work on regional outreach to small businesses that could benefit from collaborative research projects with EPA or that may have an interest in licensing EPA patented technologies for their business portfolios.
- A number of opportunities have emerged for the DOE to support the cluster development efforts that have been funded by the DOC, such as the i6 Green Challenge. This program focuses on creating proof-of-concept centers, which support all aspects of the entrepreneurship process, from assisting with technology feasibility and business plan development to providing access to early-stage capital and mentors to offer critical guidance to innovators. DOE is partially funding three of the six recipients of the i6 Green Challenge award to support the development of clean energy technologies.
- CDC will explore collaborations with local and regional biotechnology, pharmaceutical, and occupational safety-focused companies located in parts of the United States where CDC offices are located.
- DOD will enhance commercialization ecosystems by fostering additional DOD lab engagement with economic development entities and state and local governments.
- DOD will provide greater access to unique or underutilized R&D assets through Enhanced Use Lease authority and other facility use agreements.

Complementary Technologies

Some agencies have laboratories that research different aspects of a larger, national problem. These agencies may have complementary technologies that work together. Some agencies suggested creating collaborative websites or e-catalogs that span either: 1) particular research areas; or 2) the entirety of Federal laboratories. EPA and USDA proposed the idea of working across agencies to investigate options for coordinating complementary agency patents and outreach opportunities with other government agency technology transfer programs. Such complementary technology programs can be useful to small and new businesses by presenting a more complete picture of the problem and proposed solutions rather than relying on a business with limited resources to piece together that information from multiple agencies and sources.

Examples of national problems with multiple agency interests are:

- Water management issues, both quantity and quality of water – Bureau of Reclamation, U.S. Department of Agriculture, Environmental Protection Agency, U.S. Geological Survey.

- Biopesticide Development – U.S. Department of Agriculture, Environmental Protection Agency.
- Detection and vaccine development for zoonotic diseases (e.g., avian and swine influenzas) – Centers for Disease Control, U.S. Department of Agriculture, National Institutes of Health.
- Bioenergy feedstocks and refining – Department of Energy, U.S. Department of Agriculture.

Licensing Incentive Programs

Licenses form a key vehicle by which the rights required to advance nascent technologies to commercial use are secured, facilitating the necessary financing for development. However, approaching the Federal laboratory system to obtain one or more licenses can be a daunting challenge, especially to a small business. Several pilot programs have been proposed to facilitate better access for new and small businesses through lower rates and established and known costs.

Some of the initiatives highlighted in the agency plans are:

- DOE initiated a new program, "America's Next Top Energy Innovator," that lowers the cost for option agreements for start-up companies. An option is a precursor to a license agreement in which specified terms are outlined as a condition for license execution. The option program provides the start-up company with critical time to evaluate a new technology and to assemble resources required to commercialize the technology. The option duration is typically 12 months, with the possibility of an extension.
- The USDA Licensing Section is currently reviewing several proposals for establishing standard pre-commercialization license terms for all Cooperative Research and Development Agreements (CRADA) inventions.
- NIH created a Start-Up License to expedite the process for start-up companies to license technologies for drugs, vaccines, and therapeutics. The new license reduces both the costs and paperwork requirements for start-up companies. NIH has developed a similar license for non-profit institutions, such as non-government organizations (NGOs) and product development partnerships (PDPs) that are playing an increasing role in developing new products to diagnose, treat, or prevent diseases in low income regions of the world.
- DOC/NIST has developed new licensing programs to assist start-ups and small businesses.

B. Collaborations – Public/Private Partnerships for Research and Development

Collaboration is another key area of technology transfer. Many Federal inventions are possible due to the ability of Federal laboratories to partner effectively with the private sector. Partnerships allow the direct transfer of knowledge and ideas. Partnerships also facilitate the development of commercial applications for the mission-focused research and development of Federal laboratories. The statutorily-defined CRADA[6] is used by many agencies as a formal collaboration tool. Other agency-specific authorities are also used, such as NASA's Space Act

[6] 15 U.S.C. § 3710a.

Agreements, Material Transfer Agreements, or Facility Use Agreements. These agreements allow businesses, particularly small businesses by statutory preference, to access the power and capabilities of the U.S. laboratories to enhance business opportunities and growth.

Many of the outreach activities discussed above also benefit collaborations, particularly by opening the Federal laboratories to small businesses. One of the outcomes of gathering people together by technical and geographic areas is the ability to form partnerships for on-going research and development. By highlighting new technologies, new ideas and shared interests may emerge.

Software

Software presents a challenge for Federal technology transfer because, as discussed above, Federal work products cannot be copyright protected. Although software is also patentable, the fast-moving field of software development most typically relies on copyright protection. It has been found that even collaborating in an open source environment requires some level of control of the subject matter to make such collaboration effective and productive. Collaborating partners and Government Owned/Contractor Operated laboratories, however, may copyright works. This disparity in the availability of copyright protection can inhibit the willingness of the private sector to collaborate with a Federal agency to develop software because of the uncertainty that the private sector collaborator would have the necessary intellectual property protection to commercialize the resulting software. One example of an agency that is attempting to deal with software issues follows.

- FDA's Technology Transfer Program will establish strong intellectual property policies for software developed under CRADA collaborations. The policies will maintain appropriate Agency rights and access to the software with recognition of the CRADA partner's interest in commercialization of software inventions. FDA's Technology Transfer Program will establish a model software development CRADA with terms that are relevant and fair to the parties and that will align with the software intellectual property policies that will be developed.

New Tools

The PM challenged agencies to look at new approaches using existing authorities. Several agencies are revisiting and expanding the use of their authorities to increase successful technology transfer outcomes.

Some of the initiatives highlighted in the agency plans are:

- USDA will explore expanded use of Enhanced Use Lease (EUL) authority as a technology transfer tool to promote longer-term relationships with key customer groups. ARS currently has pilot authority for EULs only for its Beltsville, Maryland facility.
- USDA will develop a Material Transfer Research Agreement (MTRA) as a new instrument to promote development and commercialization of materials from USDA. USDA scientists create new materials that may have value in further research and development with the private sector. Current Material Transfer Agreements (MTAs), widely used by USDA, allow only the transfer of materials, and do not allow engagement in joint research between the provider and the recipient of the materials.

The new MTRA will serve as an authorization to conduct some joint research on the materials transferred. Because this instrument would not convey rights to negotiate exclusive licenses to any intellectual property arising from the research, it is intended to be an early-stage opportunity for proof of concept that may lead to more extensive research that would be conducted under a CRADA.

- NASA's primary collaboration mechanism is the Space Act Agreement.[7] However, Space Act Agreements do not provide NASA with the authority to grant a first option to license under the Space Act Agreement process. CRADAs directly support the transfer of technology to a non-Federal party, because the CRADA authority authorizes a Federal agency to grant the non-Federal party a first option to license Federally-owned inventions made under a CRADA or made in anticipation of a CRADA. NASA will develop an Agency-wide policy delegating CRADA authority to NASA Center Directors, facilitating wider use of that collaboration vehicle.
- NASA's Office of Strategy Formulation will establish a multi-center NASA team to develop recommendations on ways to initiate and implement cost and risk-sharing partnerships to enable development of U.S. capabilities for increased commercial use of space.
- NIH has proposed to develop an Entrepreneurship Sabbatical Program. An Entrepreneurship Sabbatical would be a leave of absence for a Federal technical professional to develop inventions in a small business incubator or other non-Federal venue. The patenting of an invention is only the first step towards commercialization. Significant amounts of additional research and development are required to move the originally patented invention closer to something that can be commercialized. The most efficient agent for conducting this further research is often the inventor, as the inventor has the key insight that led to the invention in the first place. However, conflict of interest regulations and rules can restrict Federal inventors from co-operating with a business that might license and further develop the invention towards commercialization. This severance of the intellectual link between the inventor and the commercialization entity adds additional risk to the development of the invention, to the point that a small business may be unwilling to pursue the necessary development. The Entrepreneurship Sabbatical would allow a Federal inventor to pursue additional development towards commercialization.
- Congress recently passed legislation that authorizes the use of prizes and challenges across the Federal government to spur innovation, solve tough problems, and advance core missions through processes like open innovation.[8] EPA's Open Innovation Challenges tap into the vast expertise that exists beyond the boundaries of a single organization. Over the next year, EPA will use the prize and challenge authority to attract innovative solutions, from both the public and its own employees, to high-priority environmental protection needs. These challenges will be posted online so that solutions may be developed by external parties.
- USDA encourages Small Business Innovation Research (SBIR) awardees to enter into CRADAs with the Agricultural Research Service, the Forest Service, or other USDA agencies. These CRADAs help small business grantees by providing them access to

[7] 42 U.S.C. § 2473 (c)(5)
[8] The America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358), section 105.

USDA scientists and facilities to help move an invention or new technology closer to a competitive stage. Linking SBIR proposers and Federal scientists within CRADAs is a new concept in the Federal laboratory arena. To facilitate the adoption of this model, USDA's Office of Technology Transfer and SBIR Office are creating a jointly produced webinar for USDA's scientists. This webinar will cover the basics of CRADAs, SBIR grants, and the proposed connection of the two.

C. Technology Transfer Efficiency

One of the most common general complaints about Federal programs is their bureaucracy, and Federal technology transfer programs are no exception. The PM specifically addressed the need to streamline operations to address the needs of business. Small businesses are especially vulnerable to a slow-moving system. Although there have been many improvements over the years, the President's challenge has led agencies to review their operations and propose ways to improve the overall customer experience. Some of these changes are internal to the agencies, by which the agencies seek to improve understanding and capabilities throughout their research and development programs to open doors to more efficient technology transfer. Other improvements target the way customers interact with the Federal system.

Streamlining Operations

Many agencies' plans directly propose measures to tackle red tape and improve the customer interface.

Some of the initiatives highlighted in the agency plans are:

- CDC will create internal working groups that will examine its policies, identify areas needing improvement, implement identified improvements, and identify processes to increase the effectiveness of patent prosecution and to reduce costs.
- CDC will improve and simplify model agreements, including MTAs, CRADAs, Proprietary Technology License Agreements (PTLAs), Patent License Agreements (PLAs), and other collaboration agreements to reduce resources and time spent on negotiation, and to identify internal bottlenecks and devise approaches to eliminate or reduce them.
- CDC will explore the use of automated workflow systems for routine transfer agreements and royalty distribution.
- DHS plans to add an evaluation form to all of its CRADAs, to be completed by each collaborating party. The evaluation form will capture relevant information, including whether the CRADA moved the technology to a greater Technology Readiness Level, whether new intellectual property was created, and whether any new licensing agreements were generated.
- DOC/NIST is reviewing and simplifying its model CRADA document in an effort to expedite the CRADA process. NIST will conduct a detailed review of its standard CRADA with a view toward eliminating unnecessary restrictions and hindrances to acceptance by U.S. industry.
- DOC/NIST is committed to achieving a 10% reduction in the time to review and approve CRADAs.

- DOC/NIST will provide a website for outside parties to express interest in developing partnerships with NIST.
- DOD will review patent licensing and collaboration practices to reduce the time required to license DOD Laboratory technologies.
- DOD will standardize CRADA usage throughout its numerous laboratories.
- DOE undertook a "Speed of Business Study" to identify bottlenecks in its current CRADA approval process. DOE then convened a best practices meeting for DOE facilities. The facilities have been able to reduce processing and approval cycle times significantly - one laboratory achieved a 45-day cycle, down from 150 days. In addition to improving the process as a whole, DOE has begun to streamline the CRADA contract itself. DOE is revising its DOE Order governing CRADAs and updating its model CRADA to eliminate outdated clauses, consolidate clauses where appropriate, and eliminate redundancy.
- DOE has updated its policies to substantially reduce the number of days required for advance payment by sponsors for work to be performed at the facilities. The requirement for advance payment assures that the facility has the funds to commence and continue performing work for the sponsor company. The original 90-day requirement has proven onerous for both large and small companies. It has been reduced to 60-days, and can be reduced even further when the cognizant DOE field office's financial officer makes a determination that an individual facility has adequate procedures to allow for a shorter period for advance payment.
- DOI has started the use of partnership intermediaries to facilitate patenting, licensing, and research partnerships with industry via an intermediary agreement and interagency agreements with USDA.
- DOI will develop a unified website that will present information on DOI inventions and other intellectual property.
- EPA is establishing an improved database, currently in development, that will allow for improved tracking of CRADA and license funding, and an improved status tracking system for pending and active FTTA agreements. An improved database will make the internal review process for CRADAs, licenses, and non-disclosure agreements more efficient, thereby reducing the average time it takes to execute agreements.
- FDA will streamline implementation of technology transfer agreements to facilitate collaboration between FDA and potential partners, including external scientists, industry, academia, and non-profit organizations.
- FDA will facilitate appropriate exchange of proprietary research materials and information needed to carry out regulatory science and biomedical research. FDA will evaluate use of tools, such as the NIH electronic Transfer Agreement Dashboard, to streamline processes regarding MTAs.
- FDA will collaborate with the NIH Office of Technology Transfer to streamline licensing and to more effectively market FDA technologies - under an FDA-NIH interagency agreement through which FDA technologies are available under NIH's new Start-Up License Program.
- FDA will publish standard operating procedures for FDA's technology transfer processes on a common website to make them easily available throughout the Agency, thereby enhancing the transparency of FDA's technology transfer processes. FDA will

improve processes to centrally track pending and finalized technology transfer agreements.

- NIH is reviewing its CRADA practices with the goal of reducing the time required to establish CRADAs. NIH is designing a new process and procedure for CRADAs that should greatly reduce the negotiation time, as well the internal approval time.
- NIH is reviewing all model license agreements to simplify and expedite the licensing process. NIH will implement automated workflow systems for routine activities where applicable and practical, e.g., Transfer Agreement Dashboard (TAD) and the electronic Research Materials Catalog (eRMa).
- To simplify and expedite royalty payments, NIH has implemented Pay.gov, a web-based application that allows licensees to make payments by debit from a checking or savings account. NIH continues to market this option to companies in order to broaden its use. This process speeds licensing, particularly when an initial payment is required prior to shipping biological materials obtained pursuant to a license.
- VA will conduct an analysis of its operations by identifying and analyzing the Strengths, Weaknesses, Opportunities and Threats (SWOT) involved in the invention disclosure and licensing process. The SWOT analysis will allow VA to draft a successful strategy to meet its goals for the current year and foreseeable future. VA expects to revise its standard operating procedures in all areas of technology transfer.
- The existing software used by VA imposes unacceptable operational difficulties, often forcing difficult work-arounds. VA recently conducted a thorough search for a new database to meet its needs and has identified a suitable software solution. New software will enable its Technology Transfer Program to automate many current processes and allow for the on-line submission of invention disclosures.
- VA will streamline its "Determination of Rights" process for inventions made by VA employees.
- Further efficiencies can be obtained by taking advantage of other agencies' process improvements. Specifically, patent applicants can also take advantage of a recently established program by the U.S. Patent and Trademark Office to accelerate the examination of patent applications under the "Track 1" program, which allows final disposition to be completed in less than one year. More details can be found at http://www.uspto.gov/patents/init_events/Track_One.jsp.

Training

A key element of successful technology transfer is ensuring that scientists and engineers understand their responsibilities and obligations to identify potential inventions. Technical professionals must be aware of their statutory responsibilities in technology transfer, as well as their agency's procedures for disclosing inventions. For many scientists, publication in the open literature is familiar and easy, but that familiar route may sacrifice the government's ability to obtain timely intellectual property protection necessary for subsequent commercialization. Proper training is essential to make the invention disclosure route a known and viable pathway. Agencies find that invention disclosures often increase following training. The initial contact of a non-Federal entity with a Federal laboratory is often through individual researchers and a well-trained staff can help a company form a partnership with its laboratory. Successful collaboration activities also require periodic training for science and engineering professionals in Federal laboratories.

Some of the initiatives highlighted in the agency plans are:

- CDC will develop a training plan including development of a training module with tracking and reporting capability.
- CDC will develop plans to reduce or manage impediments to effective training.
- CDC will identify external experts to present training seminars.
- CDC will develop a plan to better market Technology Transfer Office services to CDC scientists and staff.
- DHS will review research activities to find inventions/discoveries made within the agency's laboratories, but not previously reported to the Department's Technology Transfer Program. A previous evaluation of one DHS laboratory resulted in a 300% increase in invention disclosures for the agency.
- DHS will conduct training on introductory topic areas, such as how to enter into a CRADA, how to complete an invention disclosure, and the value of licensing inventions. The new, advanced topic areas of training will be geared toward those laboratories that have already received the formal presentation "Overview of Technology Transfer and Intellectual Property Training."
- FDA will develop a training plan, including recurring training for FDA scientists. FDA will develop and implement a training module with tracking and reporting capability.
- FDA will conduct training of technology transfer staff, scientists, and engineers to understand business practices within the biotechnology and pharmaceutical sectors and to understand marketing research that informs as to the commercialization potential of inventions.
- DOI will train R&D personnel in technology transfer activities. DOI will encourage bureaus and laboratories to include, where appropriate, technology transfer as a criterion in the evaluation of such personnel.
- DOT will invite technology transfer coordinators to inter-agency meetings. The Department's Technology Transfer Office will coordinate with technology transfer professionals to deliver training sessions to researchers and to the Department's technology transfer personnel.
- EPA will increase training programs to inform a greater percentage of EPA staff about technology transfer opportunities and responsibilities associated with protecting intellectual property, which is expected to lead to an increase in the number of CRADA projects and employee reports of inventions.
- The USDA ARS will develop a series of training events organized by ARS National Program area, rather than conducting general training by geographic area. The objective is to achieve more robust technology transfer approaches tailored to the agricultural industry sector served by the scope of the national program.
- A "one USDA" approach will be adopted for technology transfer policies and procedures. Consequently, USDA should be able to provide more uniform nurtured relationships for common customers and stakeholders of USDA agencies. Policy and Procedure (P&P) guides will be developed for each participating agency for subsequent in-depth training of scientists, engineers, and managers.
- Personnel from the VA's Technology Transfer Program have begun to make site visits to VA Medical Centers and academic affiliates to raise awareness of the technology transfer program, and of the procedures and regulations that inventors are required to

follow regarding disclosing inventions to VA. This outreach has resulted in significant increases in both invention disclosure rates and royalty revenues. Training includes: an introduction to technology transfer for all personnel, explaining the duty to disclose, aspects of quality disclosures, and the technology transfer process; a discussion of technology transfer operations, targeting those involved in the preparation and processing of disclosures; and the basics of patenting, allowing interested researchers to gain a deeper understanding of the patenting process.

D. Small Business Innovation Research

The PM directed agencies that participate in the SBIR/Small Business Technology Transfer (STTR) program to streamline operations. SBIR programs are valuable tools to reach out to the small business research community to develop new businesses and products.

Linking SBIR/STTR to Technology Transfer

In addition to streamlining, many agencies have introduced direct steps to combine SBIR/STTR programs with technology transfer opportunities as an additional means to engage the small business community.

Some of the initiatives highlighted in the agency plans are:

- The CDC Technology Transfer Program coordinates with the SBIR Program to bring CDC inventions to the attention of small businesses. Working together, the Technology Transfer Program and the SBIR Program will facilitate more partnerships that can potentially result in the commercialization of more CDC technologies, ultimately leading to improved health and disease prevention. Strengthening this partnership is a key focus of CDC's 5-year plan.
- DOC/NIST will continue to offer SBIR opportunities for small businesses to develop and commercialize NIST technologies. The intent of the program will be to have awardees move commercially viable technologies to the marketplace. Award recipients are granted a royalty-free, non-exclusive, internal, research-use license to develop technology into a commercial product, thereby providing benefit to the public.
- The DOT SBIR Program established a SBIR Technology Transfer Pilot Program. The pilot program will use the SBIR Program to complete intramural research that requires further research and development for DOT inventions to move successfully to the marketplace. Aligning DOT's SBIR Program mission with DOT's technology transfer activities encourages small businesses to engage in research and development that has the potential for commercialization and meets Federal objectives.
- EPA will explore inclusion of EPA patented technologies in its SBIR solicitations.
- EPA will work to identify potential internal partnerships with the EPA SBIR Program possible inclusion of EPA patents into SBIR solicitations.
- FDA will work to establish a program to support the transfer and development of FDA technologies, while concurrently providing support to small business initiatives. The proposed program will exist within FDA's currently established SBIR Program and will not require new funding.

- In 2011, NASA devoted a SBIR subtopic to licensing NASA's internally developed technologies that would benefit either NASA projects or commercialization (technology transfer) with further research and development. Subtopics addressed the objective of increasing commercial applications or the infusion of innovations derived from NASA intellectual property.
- In 2010, the NIH's National Cancer Institute (NCI) linked its patents and SBIR programs to facilitate the development of NIH inventions under SBIR contract awards. Other institutes at NIH are now exploring similar programs for their technologies.

New Initiatives to Assist Small Businesses

Some of the initiatives highlighted in the agency plans are:

- DOC/NIST will allow non-awardees to opt-in to a referral to other programs, including NIST's MEP, for additional assistance.
- DOD/Navy has developed a referral system that seeks to introduce non-awardees to Offices of Research and Technology Applications as resources to identify complementary government technologies that might be advanced through collaboration of small businesses with the Navy's laboratories.
- DOE will implement a Fast Track application process in FY13 that will allow applicants to eliminate the Phase I to Phase II funding gap, a program feature of particular interest to startup companies. Also in FY13, DOE will introduce a Phase II follow-on program that will require private sector cost-sharing to continue product R&D and commercialization beyond Phase II.
- DOT continues to strengthen its SBIR Program as it establishes several program enhancements, including a Phase IIB Bridge Financing Program. The Bridge Financing Program provides select DOT Phase II awardees a one-time financial bridge award to accelerate the commercialization of the innovation to the marketplace. DOT Phase II awardees seeking Phase IIB SBIR funding are encouraged to also seek private sector matching funds and/or in-kind investment.
- The NIH leverages its investments by helping small businesses become market-ready through a suite of Technical Assistance Programs: the Niche Assessment Program (NAP) offered to Phase I SBIR awardees provides in-depth market opportunity analysis information, and the Commercialization Assistance Program (CAP) is a customized mentoring and training program to help Phase II SBIR awardees develop actionable business strategies through addressing challenges in intellectual property, reimbursement, market penetration, financing, and other areas unique to each selected company. The recent NIH re-authorization increases the amount of funding NIH can spend on technical assistance programs and expands the technical assistance to include STTR awardees. NIH will implement changes to these programs in the next year.
- NIH Fast-Track Awards: Per regulations, all small businesses must progress through the SBIR program first by competing, receiving, and completing Phase I funding and then competing and receiving Phase II funding. This basic program structure, albeit necessary to ensure proper vetting of promising ideas, has presented unanticipated challenges for some small businesses that had the momentum and quality of work to complete the two phases quickly. The NIH Fast-Track program was created to address the limitation of a Phase II funding gap, the time after Phase I where a company applies and may wait seven to nine months before a Phase II award is granted. The Fast-Track

process requires only one application for both Phase I and Phase II, effectively eliminating the funding gap between Phase I and Phase II and thus allowing the research to move forward without delay or interruption.

- The U.S. Patent and Trademark Office offers under the Smith-Leahy America Invents Act significant fee reductions to micro entities. The fee setting provision in the AIA sets the micro entity discount at 75% of the fees set or adjusted for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents. This authority is codified in 35 U.S.C. § 123. With this significant fee reduction, qualifying patent applicants will enjoy greater access to the patent system.

Streamlining SBIR/STTR

The PM specifically directed streamlining of SBIR/STTR programs. Agencies' plans have included commitments that address this challenge. Agencies have, for example, proposed developing or expanding SBIR outreach, training, and websites to assist small businesses in both spin-in and spin-out technology transfer activities. Coupled to agencies' efforts to streamline their SBIR programs, several agencies have proposed opportunities to assist SBIR recipients of awards as well as those small businesses that were not selected for an award (more detail is provided in the IAWGTT report entitled "Revised Technology Transfer Metrics in Response to the Presidential Memorandum – Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses").

Some of the initiatives highlighted in the agency plans are:

- CDC will increase the number of topics included in the annual SBIR grant and contract omnibus announcement.
- CDC is initiating targeted SBIR funding announcements throughout the year with varying due dates.
- CDC is developing SBIR outreach and training materials targeted to small businesses and associated organizations, and developing SBIR collaborations with state-level economic and business development centers.
- DOC/NIST will streamline administrative practices to reduce the administrative burden on small businesses and reduce the time needed to process and issue awards by reducing the number of topics and subtopics to balance the work required to obtain proposals and the selection rate for worthwhile proposals. The goal is to bring NIST's Phase 1 SBIR award rate up to the national average of 17%.
- DOC/NIST will reduce by 10% the time from close of solicitation to award issuance.
- DOD will conduct an internal policy review to reduce or eliminate award constraints, simplify paperwork, and reduce the time from application submission to award date. DOD will encourage an increased use of private sector reviewers in grant proposal reviews.
- DOE's award process for applicants to the SBIR program is undergoing a major streamlining assessment. The DOE SBIR program has made significant improvements over the past year in reducing the award cycle to be more supportive of the small businesses it supports.
- DOE will engage in efforts to reduce the time from close of solicitation to notification of award from 5.5 to 3.5 months beginning in FY12.

- In FY11, DOE established an “other” subtopic to each topic that allowed applicants to submit ideas that might fall outside of the technology areas in focused topics.
- DOE will implement a Fast Track Program in FY13 to eliminate the Phase I to Phase II funding gap.
- DOT is creating a plan to further streamline processes and accelerate awards to small businesses.
- FDA will develop presentations and an SBIR intranet site to help disseminate information about the SBIR program within the agency.
- NIH will work to identify steps in the overall process from receipt of application to award that could be eliminated to reduce the time from receipt to award. While NIH is statutorily obligated to make final award decisions within 12 months, the agency will continue to explore ways in which the timeline can be further reduced.