

# Unleashing American Innovation Next Steps

# NIST and Tech Transfer

- Policy coordination, technology transfer regulation
- Lead for Interagency Workgroup for Technology Transfer (11 agencies)
- Interagency Workgroup for Bayh-Dole
- Annual reports for the President, the Congress, and OMB on technology transfer across federal agencies
- Lead in Lab-to-Market NSTC Subcommittee
- Host Agency for the Federal Laboratory Consortium for Technology Transfer (FLC)



Credit: Peter Cutts

**Unleashing American Innovation Symposium, April 19, 2018**

NIST has a unique role in promoting and reporting on the overall strength of federal technology transfer efforts

# President's Management Agenda

## Lab-to-Market Cross Agency Priority Goal: *Improve Transfer of Federally-Funded Technologies from Lab-to-Market*

### CAP Goal Leads

**NIST**



**Walter Copan**

Under Secretary of Commerce for Standards and Technology  
Director, National Institute of Standards and Technology



**Michael Kratsios**

Deputy Assistant to the President for Technology Policy  
White House Office of Science and Technology Policy

### Participating Agencies



### Interagency Partnering & Coordination

National Science and Technology Council Lab-to-Market Subcommittee

Interagency Working Group for Technology Transfer

Interagency Working Group for Bayh-Dole

Small Business Innovation Research (SBIR) Program Managers Working Group

Interagency I-Corps Community of Practice

Federal Laboratory Consortium for Technology Transfer

# Lab-to-Market CAP Goal Strategies



Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices



Increase engagement with private sector technology development experts and investors



Build a more entrepreneurial R&D workforce



Support innovative tools and services for technology transfer



Improve understanding of global science and technology trends and benchmarks.

# Return on Investment (ROI) Initiative

To advance the *President's Management Agenda*, the U.S. seeks to enable even greater return on the Federal government's \$150 B/year R&D investment



**Open, inclusive, and collaborative outreach** to Federal R&D, IP, and technology transfer stakeholders

- **Extensive inputs** from 100s of experts and organizations representing 1000s of companies, universities, and institutions
- Four main **Public Forums** totaled 341 registered attendees
- 104 written comments in response to **Request for Information**; plus feedback on **Draft Green Paper** released December 2018
- Other information sources:
  - **Unleashing American Innovation Symposium** (D.C. – ROI Launch April 19, 2018)
  - Multiple **stakeholder engagement sessions nationwide**
  - Extensive review of **prior reports and studies**

# ROI Final Green Paper



RETURN ON  
INVESTMENT  
INITIATIVE

TO ADVANCE  
THE PRESIDENT'S  
MANAGEMENT  
AGENDA

FINAL GREEN PAPER  
APRIL 2019



UNLEASHING  
AMERICAN  
INNOVATION

NIST Special Publication 1234



- **Green Paper** published **April 24, 2019** as **NIST Special Publication 1234**
- Based on extensive stakeholder inputs via open, inclusive process—and closely coordinated with interagency working groups
- 15 key findings to inform actions that will help remove unwarranted impediments to innovation at the public private sector interface, and streamline and accelerate transfer of technology from Lab-to-Market

## Next Steps:

1. Develop and submit draft Legislative and Regulatory Reform Packages for interagency review and clearance.
2. Share stakeholder inputs outside NIST purview with relevant agencies for action.
3. Develop interagency Lab-to-Market action and deployment plan.
4. Conduct further analysis on issues where more input is necessary.

# ROI Findings Address CAP Goal Strategies

## Regulatory & Administrative Barriers

- Scope of **Government Use License** and circumstances under which **March-In Rights** may be appropriately exercised are not well defined
- The **Preference for U.S. Manufacturing** process for requesting waivers is confusing to stakeholders
- “Government works” exception to **Copyright Protection for Software Products** of Federal R&D at GOGO laboratories constrains commercialization



## Private Sector Engagement

- Improved clarity and use of best practices would streamline **Partnership Agreements** with Federal Labs
- Private sector collaborations and investment for translational R&D/technology maturation could be increased via **Expanded Partnership Agreements** (i.e., ACT, OTA, Foundations, Outleasing)
- Recipients of Federal funding could benefit from a **Limited Use of R&D Awards** to enable IP protection



## Entrepreneurial R&D Workforce

- Expanding **Technology Entrepreneurship Programs** at Federal R&D agencies government-wide will help build a more entrepreneurial R&D workforce (e.g., leverage best practices)
- Current requirements for **Managing Conflicts of Interest** pose challenges to build a more entrepreneurial R&D workforce (note: finding applies to both extramural and intramural R&D programs)



## Innovative Tools & Services

- A secure, modern platform is not available for **Reporting Data on IP** resulting from Federal R&D
- A federated data portal is not available to easily access, use, and analyze information on **Federally Funded Technologies, Knowledge, and Capabilities** that are available to the public



## Benchmarking & Metrics

- Current metrics to capture, assess, and improve broad **Technology Transfer Outcomes & Impacts** of federally funded R&D and underpinning operational processes are inadequate



# March-In Rights

According to stakeholders, the circumstances under which the government may exercise march-in rights are not well-defined.

Market uncertainty is created by the lack of a clear definition of the use of march-in rights that is consistent with statute, rather than as a regulatory mechanism for the Federal Government to control the market price of goods and services.

- Congress noted that the **goal of the Bayh-Dole Act was to use IP to help make research results ultimately available to consumers in the marketplace** – the so-called “practical application” of inventions
- Authors of the Bayh-Dole Act, Senators Bayh and Dole made have stated that **government march-in rights are not to be used as a price control mechanism**
- ***Some parties would like to change this situation so that march in rights will be more broadly interpreted, for example, to set the market price of drugs***
- The **Administration’s blueprint to lower drug prices does not envision use of march in rights as a price control mechanism**
- Bayh-Dole Act **implementing regulations include a rigorous process for agencies to exercise march-in rights** in accordance with conditions specified in statute
- **Transitioning research discoveries to actual products requires significant private investment**, particularly in new drug development; investors need certainty in IP rights and confidence in the opportunity to create value from their investment
- The **Federal Government has never exercised march-in rights since 1980, spanning now seven Administrations; Clarification of the statutory terms and conditions for exercising march-in rights is within the scope of the Bayh-Dole Act implementing regulations**



# Copyright of Government Software

According to stakeholders, the “Government Works” exception to copyright protection for software products of R&D at Government-Owned, Government-Operated Laboratories constrains commercialization.

- The **digital economy** accounted for 6.9 percent of the U.S. GDP or \$1.35 trillion in 2019 and showed a 9.9 percent annual growth rate from 1998 to 2017, compared to 2.3 percent growth in the overall economy.
- The digital economy is significantly larger since this estimate does not include contributions from the digital portion of goods and services with both digital and non-digital components, e.g., advanced manufacturing and IoT
- **IP protection for software components of goods and services derived from Federal R&D via copyright is critical to U.S. economic competitiveness and national security** due to intense global competition in software-based industries such as AI/ML, next-gen communications (5G), and advanced manufacturing
- **Universities and GOCO Laboratories are already able to assert copyright for any works, including computer programs derived from Federal R&D**
- ***Copyright protection is not available to GOGO Laboratories for computer programs derived from R&D***; Not all computer programs that represent products of R&D at GOGO Laboratories would be appropriate for copyright
- **A narrowly tailored change allowing GOGOs to secure copyright for computer programs derived from R&D could help ensure U.S. companies and taxpayers reap the economic benefits from the Federal R&D investment**

Review NIST's current technology transfer policies and practices, and provide their individual technical assessments on the principles that should drive these policies and practices for effectively engaging the business community and communicating with stakeholders;

Assess NIST's performance in the development and dissemination of work products and knowledge, and recommend improvements. Specific areas that the visiting technical experts should address include the development and use of intellectual property and collaborative research.

# Additional Inputs

The members of the Subcommittee and its contributing experts are requested to provide guidance to NIST's proposed approach by comparing and contrasting the strategies your organization would utilize or recommend for NIST consideration in the development, protection, and commercialization of intellectual properties. Specifically, we are interested in:

- Intellectual Property (IP) Strategy
- Marketing of IP for License and Further Commercial Development
- Portfolio Management

Furthermore, NIST looks forward to your critical assessment and recommendations about NIST's technology transfer approaches and organization, with the goal that NIST must be positioned to repeatably achieve positive, measurable impacts for U.S. innovation.

# Thank you!



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