**Testimony on Behalf of the Maryland Life Science Advisory Board (LSAB) Task Force on Federal Laboratory Commercialization Opportunities to the National Institute for Standards and Technology (NIST) Return on Investment Initiative (ROI)**

**June 14. 2018**

The Maryland Life Sciences Advisory Board was created by the Maryland General Assembly to assist in maintaining Maryland's preeminence in the life sciences industry. The board includes the Secretary of the Maryland Department of Commerce, a representative designated by the Maryland Technology Development Corporation (TEDCO) and 16 members appointed by the Governor.

The Federal Laboratory Commercialization Task Force consists of state, federal, academic and private sector stakeholders and was created by the LSAB to consider ways to deepen and improve scientific and economic development connections among federal laboratories and the state and region. We are pleased to submit this testimony on behalf of the LSAB.

Although the LSAB is focused on life sciences, our policy recommendations are intended to apply to all federal laboratories.

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# For the Competitiveness of the Nation and the Prosperity of the Region:

## Improving Technology Commercialization and Localizing the Impact of Federal Laboratories in the Greater Washington Region

National Institutes of Health, Bethesda, Maryland.

Maryland ranks as the No. 1 state in the nation in research and development spending, and a major reason for this is the presence of federal research laboratories—such as the National Institutes of Health—along with major research universities such as Johns Hopkins University and the University of Maryland.

Federal laboratories in the Greater Washington region are incredible scientific resources, hosting supremely talented researchers, including Nobel Prize winners, and housing some of the nation's most advanced laboratory equipment. In fact, Maryland ranks No. 1, Virginia is No. 2 and the District of Columbia No. 3 in total internal federal laboratory research and development spending, according to the National Science Foundation.

But due to federal laws, policies, practices, and management structures, federal labs underperform in terms of economic engagement and technology commercialization.

As U.S. Commerce Secretary Wilbur Ross noted recently, federal laboratories lag greatly behind universities in royalty generation and economic engagement with local communities.

We are submitting recommendations how the federal government might better leverage the considerable human, physical and technological resources resident in our local federal laboratories, allowing them to become greater economic players in the region, and how federal laws, policies and tools can be reformed so these laboratories can delivermore technologies to make our nation more competitive.

The federal government investment in federal labs in the region is extraordinary: over $15 billion is spent in DC, Maryland and Virginia annually, much more than research budgets of Harvard University, Stanford University, Massachusetts Institute of Technology, University of California, Berkeley, University of Virginia, JHU and UMD combined.

However, the DC region in particular has higher barriers to unlock the enormous potential of its resident federal laboratories because most federal labs in the DC area are managed by the federal government itself(government owned, government operated or "Go-Gos"), instead of being managed by the private or academic sector (government owned, contractor operated or "Go-Cos"), as many federal labs in other parts of the country are organized, providing more flexibility in their operations.

At its core, technology commercialization is a business. Accordingly, as Secretary Ross has signaled, a new approach for the business of commercialization of technologies from federal laboratories is needed. Many of the lessons learned from public research universities and states since passage of the Bayh-Dole Act can be used as models for improving the economic engagement of federal labs managed by the federal government.

Our recommendations include examining ways to improve the work of federal lab researchers with spin-out companies, the use of federal lab facilities and property, and the transfer of federal technologies to the private sector.

**Human capital:**

Congress should reform federal conflict of interest (COI) statutes, policies and agency practices to increase agency-wide consistency and accommodate the need for involvement of federal researchers in technology commercialization, while requiring transparent policies, continuing management of conflicts, and approval at the local agency level. The federal government should create new entrepreneurial leave tools and partnership activities for federal researchers, including using Intergovernmental Personnel Act (IPA) authority to recognize and support entrepreneurial federal researchers. The COI policies at NIH, in particular, seem to discourage industry, NGOs and investors from taking better advantage of the great research being performed in world's largest biomedical institution and producing new health technologies that would advance the health of the public.

These reforms can be modeled on public university conflict of interest models that states adopted after the Bayh-Dole Act, including the state of Maryland and University of Maryland, and which affect university researchers and technology transfer programs.

Many other states across the nation adopted similar reforms to their state conflict-of-interest statutes to accommodate the fact that university researchers now had financial interest in federally supported research and development grants.

**Physical capital:**

Use land adjacent to federal laboratories to create communities of innovation by academic and private users by extending Enhanced Use Lease Authority (EUL) to all federal laboratories. Locate new federal lab resources near universities and centers of innovation, and make federal labs and fed lab equipment more welcoming for use by private and academic users by expanding Facility Use Agreements (FUA) to all federal labs.

The proposed science campus adjacent to the U.S. Food and Drug Administration in White Oak, Maryland, the autonomous vehicles research facilities adjacent to Navan Air Station Patuxent River in St. Mary's county and the open lab campus concept of Army Research Lab are some of the projects that need to be made systematic across the lab system for government owned, government operated labs in the region.

For example, the Stevenson-Wydler Act, applicable to all federal labs, allows federal lab managers to declare surplus lab equipment for transfer to nonprofits does not generally authorize across the board access by the private sector to unique federal equipment.

In many ways the federal government's cumbersome approach to licensing its intellectual property to the private sector parallels the inefficiencies in selling its excess real property: some excessive delays, procedural roadblocks, and varying abilities among federal agencies. Fortunately, both Congress and the federal government are interested in reforms in both areas.

**Technology capital:**

Create a Federal Laboratory Commercialization Authority (FLCA), as an adjunct to the existing Federal Lab Consortium, to take on the business of improving federal technology commercialization as a congressionally chartered nonprofit corporation.

Technology commercialization is a business, and the federal government needs business-like tools to accomplish this task. When Congress wanted to rebuild Pennsylvania Avenue it charted the Pennsylvania Avenue Redevelopment Corporation to take on the business of redeveloping that area of the District of Columbia.

The FLCA would be modeled on federal authorities, such as the congressionally chartered Henry M. Jackson Foundation for the Advancement of Military Medicine, which has a strong record of research and technology commercialization for the US Uniformed Health Services University across the street from NIH in Bethesda Maryland. But because the Jackson Foundation charter is broad and flexible, it now partners with federal laboratories across the US to improve military medicine, and is one of Maryland's largest nonprofit entities with nearly half a billion dollars in annual revenue.

The famous Wisconsin Alumni Research Foundation (WARF) is an example of such an organization that operates at the state level. When University of Wisconsin researchers synthesized Vitamin D, they created an independent, nonprofit corporation to manage the university's Vitamin D patents and invest the resulting revenue to support future research.

Since its inception 90 years ago, WARF has provided $2.3 billion in cumulative direct grants to the university.

States have chartered independent technology intermediaries, such as the Maryland Technology Corporation (TEDCO) that have successful records in improving the technology commercialization performance of their states.

An FLCA that would be authorized to work with all federal laboratories, hold patent rights as an agent for federal labs and hire experienced staff with strong backgrounds in technology commercialization from private sector venture and angel groups is needed to systematically improve the technology performance of the federal laboratory system.

We also need to ensure the continued funding and sustainment of the Small Business Innovation Research (SBIR) program and the STTR (Small Business Technology Transfer) programs. These initiatives are rightfully referred to as 'America's Seed Fund' and they are important links between federal laboratories and the private and academic sectors.

**Conclusion:**

Over the years, groups including the National Governors Association, the Brookings Institution and the Association of University Research Parks have called on Congress and the Executive Branch to find ways to improve economic engagement of federal laboratories similar to the economic engagement mission of research universities across the United States.

We greatly appreciate NIST's leadership role in organizing the opportunity to suggest new ways to improve the technology engagement of federal labs with the private sector. The density of federal laboratories in the Greater Washington region makes these recommendations all the more imperative to economic success of our area. But improving technology commercialization of federal laboratories will also improve the international competitiveness of the United States.

In our July submission, we will expand on these recommendations and propose draft legislation and policy recommendations for your consideration.

# For the Competitiveness of the Nation and the Prosperity of the Region:

## Improving Technology Commercialization and Localizing the Impact of Federal Laboratories in the Greater Washington Region

**A report from the Maryland Life Sciences Advisory Board Task Force on Federal Commercialization Opportunities**

**The National Institutes of Health, Bethesda, Maryland.**

The Federal Commercialization Opportunities Task Force consists of state, federal, academic and private sector stakeholders and was created by the Maryland Life Sciences Advisory Board (LSAB) to consider ways to deepen and improve scientific and economic development connections among federal laboratories and the state and region.

Although the LSAB is focused on life sciences, our policy recommendations are intended to apply to all federal laboratories.

A summary of this report was presented at the National Institute of Science and Technology (NIST) Return on Investment hearing on June 14, 2018 at NIST headquarters in Gaithersburg, Maryland.

**EXECUTIVE SUMMARY:**

Federal laboratories in the Greater Washington region are incredible scientific resources, hosting supremely talented researchers, including Nobel Prize winners, and housing some of the nation's most advanced laboratory equipment. In fact, Maryland ranks No. 1, Virginia is No. 2 and the District of Columbia No. 3 in total internal federal laboratory research and development spending, according to the National Science Foundation.

This is a big number. Collectively, over $15 billion in internal federal lab research and development spending takes place in Maryland, Virginia and the District of Columbia, more than the research budgets of Harvard, Stanford, Massachusetts Institute of Technology, UC Berkeley, University of Virginia, Johns Hopkins and University of Maryland combined.

But due to federal laws, policies, practices, and management structures, federal labs underperform in technology commercialization and in many ways are sealed off from economically engaging with the communities where they are located.

The impact of federal labs often goes unnoticed. For example, *Genetic Engineering News* publishes national ranking of biotechnology clusters each tear, looking at a region's biotech related VC funding, growth in National Institutes of Health grants, and amount of wet lab space. However, the $3 billion in annual internal research spending at NIH in Bethesda isn't counted, nor is the tens of thousands of square feet of its wet lab space. The Biohealth Capital Region, consisting of Maryland, Virginia and the District of Columbia, currently ranks #5 nationally in the GEN ranking, but likely would rank higher were there an appropriate evaluation of NIH's local contribution to the biotech ecosystem.

The DC region in particular has higher barriers to unlock the enormous potential of its resident federal laboratories because most federal labs in the DC area are managed by the federal government itself (government owned, government operated or "Go-Gos"), instead of being managed by the private or academic sector (government owned, contractor operated or "Go-Cos"), as many federal labs in other parts of the country are organized, providing more flexibility in their operations.

At its core, technology commercialization is a business. But as U.S. Secretary of Commerce Wilbur Ross noted recently, federal laboratories lag greatly behind universities in royalty generation and economic engagement with local communities. Therefore, a new approach for the business of commercialization of technologies from federal laboratories is needed.

Public research universities and state government have launched new economic engagement programs over the past 20 years when universities gained the right to manage federally funded intellectual property. These are useful models for the federal government to consider for its own laboratories.

Our recommendations include examining ways to improve the work of federal lab researchers with spin out companies, the use of federal lab facilities and property, and the transfer of federal technologies to the private sector.

A new approach for the business of commercialization of technologies from federal laboratories is needed.

We also believe that given the unique opportunity for suggesting new ways of engaging with federal laboratories is so important to the welfare of Maryland, a standing advisory committee made up of local experts should be established by the Governor to monitor these and other policy recommendations as they are considered by NIST, the Congress and other stakeholders in the upcoming year. Because these discussions involve a number of federal laboratories, not just life science laboratories, we suggest this engagement task be undertaken by a separate authority established by the Governor. *(See* Attachment 1, draft Maryland Governor Executive Order)

**Human capital:**

Reform federal conflict of interest (COI) statutes, policies and agency practices to increase agency-wide consistency and accommodate the need for involvement of federal researchers in technology commercialization, while requiring transparent policies, continuing management of conflicts, and approval at the local agency level.

Create new entrepreneurial leave tools and partnership activities for federal researchers, including using Intergovernmental Personnel Act (IPA) authority.

Recognize and support entrepreneurial federal researchers. The COI policies at NIH, in particular, seem to discourage industry, NGOs and investors from taking better advantage of the great research being performed in world's largest biomedical institution and producing new health technologies.

These reforms can be modeled on public university conflict of interest models that states adopted after the Bayh-Dole Act, including the state of Maryland and University of Maryland, and which affect university researchers and technology transfer programs.

These improvements must also be implemented in a manner designed to ensure the benefits of more flexible technology transfer provisions are also matched with the

appropriate guardrails – oversight, monitoring and action to address potential conflicts of interest. Fortunately, multiple state and private universities' experience shows that these conflicts can be addressed and managed in a manner that is balanced and ensures that promising technologies ultimately reach the market to the benefit of our nation.

**Physical capital:**

Use land adjacent to federal laboratories to create communities of innovation by academic and private users by extending Enhanced Use Lease Authority (EUL) to all federal laboratories.

Locate new federal lab resources near universities and centers of innovation, and make federal labs and fed lab equipment more welcoming for use by private and academic users by expanding Facility Use Agreements (FUA) to all federal labs.

The proposed science campus adjacent to the U.S. Food and Drug Administration in White Oak, Maryland, the autonomous vehicles research facilities adjacent to Naval Air Station Patuxent River in St. Mary's county and the open lab campus concept of Army Research Lab are some of the projects that need to be made systematic across the lab system for government-owned, government-operated labs in the region.

The Stevenson-Wydler Act, applicable to all federal labs, allows federal lab managers to declare surplus lab equipment for transfer to nonprofits but does not generally authorize across the board access by the private sector to unique federal equipment.
A federal laboratory-wide inventory of equipment accessible to the private sector is needed, and policies to create avenues to access the equipment. Some agencies have adopted vouchers for use by small businesses to access equipment but these policies are not uniform.

Some agencies have land and other property in excess of their needs. In many ways, the federal government's cumbersome approach to licensing its intellectual property to the private sector parallels the inefficiencies in selling its excess real property: excessive delays, procedural roadblocks, and varying abilities among federal agencies. Fortunately, both Congress and the federal government are interested in reforms in both areas.

**Technology capital:**

Create a Federal Laboratory Commercialization Authority (FLCA) as an adjunct to the existing Federal Lab Consortium to take on the business of improving federal technology commercialization as a congressionally chartered nonprofit corporation.

Technology commercialization is a business, and the federal government needs business-like tools to accomplish this task. When Congress wanted to rebuild Pennsylvania Avenue it charted the Pennsylvania Avenue Redevelopment Corporation to take on the business of redeveloping that area of the District of Columbia.

The FLCA would be modeled on federal authorities, such as the congressionally chartered Henry M. Jackson Foundation for the Advancement of Military Medicine, which has a strong record of research and technology commercialization for the US Uniformed Health Services University across the street from NIH in Bethesda Maryland. But because the Jackson Foundation charter is broad and flexible, it now partners with federal laboratories across the US to improve military medicine, and is one of Maryland's largest nonprofit entities with nearly half a billion dollars in annual revenue.

The famous Wisconsin Alumni Research Foundation (WARF) is an example of such an organization that operates at the state level. When University of Wisconsin researchers synthesized Vitamin D, they created an independent, nonprofit corporation to manage the university's Vitamin D patents and invest the resulting revenue to support future research. Since its inception 90 years ago, WARF has provided $2.3 billion in cumulative direct grants to the university.

States have chartered independent technology intermediaries, such as the Maryland Technology Corporation (TEDCO) that have successful records in improving the technology commercialization performance of their states.

An FLCA that would be authorized to work with all federal laboratories, hold patent rights as an agent for federal labs and hire experienced staff with strong backgrounds in technology commercialization from private sector venture and angel groups is needed to systematically improve the technology performance of the federal laboratory system.

The FLCA might also take on other tasks, such as maintaining a list of specialized equipment or facilities in federal laboratories available to the private sector or academia.

We also need to ensure the continued funding and sustainment of the Small Business Innovation Research (SBIR) program and the STTR (Small Business Technology Transfer) programs. These initiatives are rightfully referred to as 'America's Seed Fund' and they are important links between federal laboratories and the private and academic sectors.

By accelerating and improving the transfer of new technologies from federal laboratories to the commercial marketplace by focusing on human, physical and technology capital, we believe we can accelerate the technology competitiveness of the nation, while increasing the local impact of federal laboratories in the region.

## REPORT OF THE FEDERAL LABORATORY COMMERCIALIZATION OPPORTUNITIES TASK FORCE

Federal laboratories funded and managed by the federal government are enormous engines for research and technology in the Greater Washington region. These labs employ tens of thousands of scientists and engineers, produce Nobel Prize winners, and generate world class research results. In Maryland, there are 74 federal laboratories, at least twice as many as any other state, and include National Security Administration, NASA Goddard, Army Research Lab, NIH, Pax River, Indian Head and many others. These labs represent the best in fundamental research, applied research, and test and evaluation projects, and attract quality researchers.

To cite one example, the NIH counts more than 20 intramural researchers who have won Nobel Prizes who were nurtured at NIH—doing the bulk of their research in NIH labs or training in an NIH lab—a record any research university in the world would envy.

Moreover, federal labs in the region are major drivers of the economy in terms of scale of investment. According to the National Science Foundation (NSF), *over $10 billion of research and development was performed internally by federal researchers in research laboratories* in Maryland in 2015. Adding in DC and Virginia laboratories, the amount spent in the region internally on research and development by federal agencies each year *exceeds $15.5 billion*, far more than the amount of federal research and development spending for any region in the country. The amount of internal federal research in the region exceeds the combined research budgets of Harvard, MIT, Stanford, Michigan, UVA, UMD and JHU.

This enormous cluster of internal federal research activity, though, is largely invisible outside of federal labs. And our federal labs are often overlooked as sources of research, technology and talent.

For example, *Genetic Engineering and Biotechnology News (*GEN) annually ranks the nation's top biopharma clusters, looking at VC funding for biotech companies, NIH awards in a region, and amount of life science lab space. (The Greater Washington region was ranked #5 in the most recent evaluation).

However, the billions of dollars of biotechnology research performed internally at NIH ($6.2 B of internal R&D spending by HHS was performed in Maryland in 2015 according to NSF), its hundreds of thousands of square feet of life science lab space and the NobelPrize-winning quality of its researchers doesn't count in the GEN rankings since GEN ignores research performed in federally owned research facilities

In fact, outside of the NIH campus in Bethesda, Maryland, you don't find many physical

manifestations of the presence of the world's largest medical research facility, such as spin-out companies or technology incubators, as you might next to a university campus. (The recent announcement of a $100M privately funded bio lab to be constructed in downtown Bethesda is a hopeful example of the largely untapped potential of NIH and Walter Reed National Medical Center to spur local physical economic development.)

This is primarily a result of stringent federal and NIH conflict-of-interest rules and policies that appear to place the NIH at a disadvantage in federal researcher involvement with spin-outs. Furthermore, NIH COI policies prohibit its researchers from providing consulting to companies in various areas of biomedical expertise.

To ensure that federal government laboratories continue to attract and retain excellent researchers and compete with academic institutions and private sector laboratories, they need to have policies that will accommodate entrepreneurial interests of young researchers.

**Maryland and Government Owned, Government Operated (GO-GOs) Federal Laboratories**

Both Go-Gos and Go-Cos are funded with federal tax dollars, but the flexibility in personnel management and use of physical assets and resources that are implicit in the management of Go-Cos allow them to create more collaboration-friendly and entrepreneurially oriented federal research campuses.

For example, outside the Department of Energy Sandia National Laboratories campus in Albuquerque, an affiliated science and technology park hosts over two thousand private sector employees working on technologies of interest to the Department of Energy and Sandia and the US Air Force Research Lab. A related technology ventures fund is also associated with the park. *(See,* Attachment 2, Sandia Science and Technology Park.)

There are many other examples of federal labs that are managed as Go-Cos being extensively involved with sponsoring entities and communities. For example, the famous NASA Jet Propulsion Laboratory (NASA-JPL) is managed as a Go-Co by the California Institute of Technology.

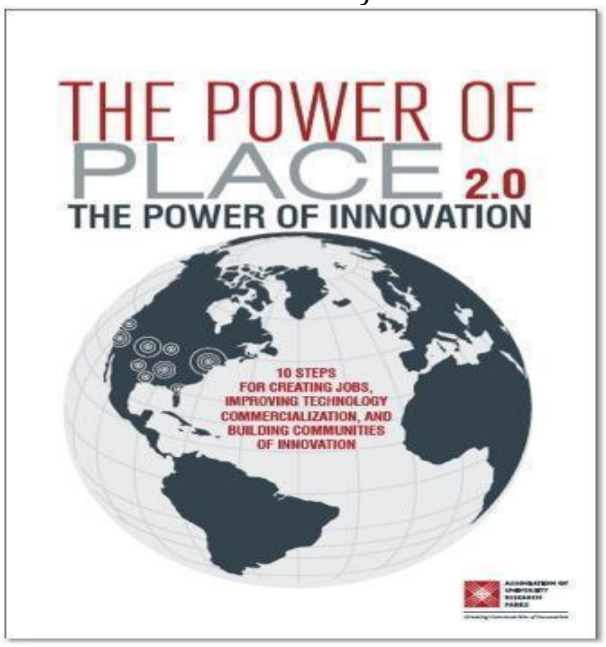
But there is growing national interest in seeing how all federal labs can be greater players in their region's economy and greater resources for national competitiveness.

As the U.S. Secretary of Commerce Wilbur Ross recently noted at the April 16, 2018 **Unleashing American Innovation Symposium**, federal labs underperform in terms of tech transfer and economic engagement with the local community. The lack of robust federal policies that reward commercialization of technologies by federal civil servant researchers undercuts the economic presence of federal labs in the region.

The Brookings Institution and the Information Technology and Innovation Foundation (ITIF) issued a similar call in 2016 calling on federal labs to be tasked with a local economic development mission. (*See* Attachment 3: *Localizing the Economic Impact of*

*Research and Development,* December 2016).

The Association of University Research Parks issued a report in 2010 calling on more flexibility for federal research labs in building communities of innovation. (*See* Attachment 4: *The Power of Place 2.0: The Power of Innovation)*




Under the Obama Administration, an executive order was issued and a 'Lab to Market' initiative launched by the White House Office of Science and Technology Policy (OSTP) that suggested reforms to technology commercialization. Among the reforms was a call for establishment of clear ethical policies and guidelines that encouraged federal researchers to work for limited periods on industrial and entrepreneurial detail. (*See*, Attachment 5: *OSTP 'Lab to Market' Initiative.)*


Nevertheless, the many physical and life science technologies embedded in the billions of dollars of internal federal research that could improve the lives of Americans still have a difficult time being transferred to industry as there are not robust pathways for

relationships with the private sector and academia.

After the Bayh-Dole Act passed, public research universities and state governments had similar barriers. Initially, it was assumed by university presidents and state governors that by giving universities title to federally funded research, the technology ecosystem would grow on its own.

Technology transfer is very hard work. But over the past 30 years, public universities and their state governments have experimented with a number of different models and funding streams to create more risk tolerance and more robust innovation eco-systems once universities were allowed to take intellectual property title to federally sponsored research.

The record is impressive. The Association of University Technology Managers (AUTM) estimate that university technology transfer contributed $1.3 trillion to US gross industrial output and supported 4.3 million jobs from 1996 to 2015. Eighty thousand patents have been issued to US universities in the past 25 years.

To do this, universities and states have partnered to reform their conflict of interest laws and policies affecting university researchers. Additionally, states and universities have launched research parks, innovation districts, accelerators and incubators adjacent to universities, provided gap funding and other financial tools and created research foundations and state technology intermediaries as 'work around' entities to reduce friction in public/private partnerships. In some cases, states had to amend their state constitutions to allow faculty to hold equity interests in public university startup companies.

All of this contributed new technologies to the nation and supported local and regional economies through technology-based economic development strategies.

States and research universities continue to refine their approaches to technology transfer by experimenting with new ways to develop partnerships with the private sector and small businesses, such as standardizing licensing agreements, being flexible on license terms and otherwise trying to reduce the barriers between technology commercialization and the private sector. The State Science and Technology Institute (SSTI) documents and provides information nationally on many of these state legislative approaches and university policy reforms.

By contrast, the federal government's legislative approach to encouraging technology transfer from its federal laboratories has been much more modest, and it hasn't had a major rewrite of its fundamental laws in over 30 years.

The federal government passed the Stevenson-Wydler Technology Innovation Act of 1980 to support federal research labs' technology transfer and the Technology Transfer Act of 1986, which created the Federal Lab Consortium (FLC). But, with the exception of modifications in cooperative research and development acts (CRADAs), there has not been a comprehensive reform since that time. *(See*, Attachment 6: *Summary of Federal Tech Transfer Laws*)

We are encouraged that a number of actors are now calling on Congress and executive branch to consider new approaches to improve technology commercialization from federal laboratories.

**SUGGESTIONS**

**1)Developing Human Capital:**
*Reform federal conflict of Interest laws, regulations and procedures for federal civil servant researchers using conflict of interest models used by state public university faculty; Encourage use of existing federal tools for entrepreneurial initiatives by federal lab researchers by expanding their use across the entire federal lab landscape*

**Federal Conflict of Interest Law and Intramural Federal Researchers:**

Generally speaking, a federal government employee is prohibited under federal law from directly participating in a matter in which she or he as a financial interest. This law was passed in 1962. *See*, generally, 18 U.S.C. section 208.

These conflict of interest laws in many cases preclude a federal researcher from participating in a company using a technology that he/she developed while in the intramural lab. This is a major impediment to the involvement of federal researchers in federal lab spin-out companies. Additionally, federal labs as part of larger federal agencies have their own internal administrative regulations on conflicts of interest, which can add layers of complexity and that may inhibit entrepreneurial endeavors.

There are federal post-employment restrictions that add to the complexity of working with federal researchers as entrepreneurs, which many university researchers are not subject to. For example, a federal employee cannot represent himself back to the

government on a matter they worked on in their official capacity. However, not all federal labs are created equal, as there are a few federal agencies that have managed to successfully implement entrepreneurial leave policies within their agencies. In these instances, federal researchers can take sabbatical leave to work at companies and return to the agency should they wish to do so. Additionally, NIH COI rules prohibit federal lab researchers from providing scientific expertise and consulting to companies.

While federal tech transfer law has a number of provisions regarding the ability of a federal researcher to take title to inventions or share in royalties, there is no specific provision relieving them from general federal conflict of interest rules that prohibit and stifle collaboration and entrepreneurship.

The federal Technology Transfer Act of 1986 simply provides that federal researchers may be involved in technology transfer activities to the extent 'there is no conflict of interest.'

By contrast, many public university researchers were under similar prohibitions under their own state conflict of interest statutes. But states across the nation took it upon themselves to resolve this issue by explicitly amending their conflict of interest laws covering public university researchers.

Among the first to address this issue was the state of Maryland.

When the Maryland state ethics law was created in the 1970s, the idea that university employees might benefit from state contacts was not recognized because the federal Bayh-Dole Act, which mandated university researchers share in royalties and potentially in equity of spin out companies, had not yet passed.

At the University of Maryland College Park in the late 1980s, shortly after the university created a technology incubator and faculty led startups began to acquire space, the conflict was recognized and the university developed draft legislation to address this issue and directly reform the state ethics law in light of the federal Bayh Dole Act that required faculty share in royalties.

After some debate, a reform emerged.

Section 15-533, et seq. of the *Maryland State Government Article* provides a general exemption for university researchers from many of the provisions prohibiting state employees from participating in a state contract, provided their involvement is:

i. Disclosed;

ii. Approved by the university administration; and

iii. A transparent management plan is in place to guide the development of the technology over the course of the project.

The state law required each university to develop internal regulations that had to be approved by the Maryland Ethics Commission. Research universities in Maryland

accordingly have standing conflict of interest committees to disclose, explore and manage conflicts of interest in exploiting intellectual property owned by the university and shared by the faculty member.

The importance of the reform can be seen in the creation of Harpoon Medical, Inc., which manufactures a device that assists in minimally invasive heart surgeries developed by a researcher at University of Maryland, Baltimore. The company was acquired for $100M last year. The UMD researcher remained involved with the project because the investors wanted the faculty inventor to work with professionals from the university's tech commercialization office, successfully create the company, and improve health internationally while benefiting the local economy.

Many other states across the country had to modify their own state ethics laws or, in some cases, amend state constitutions to allow royalty sharing or allow a university to hold equity in a startup company. In some states, such as Virginia, the University of Virginia created a standalone affiliated entity called UVA Patents Foundation to handle technology licensing.

(Because private universities are not subject to state conflict of interest laws, this issue was not a concern to private universities, but they adopted internal conflict of interest mechanisms to manage conflict of interest)

The importance of reforming conflict of interest policies for researchers is illustrated by the example of example: the Mayo Clinic in Minnesota.

A change in policy at the Mayo Clinic has "single-handedly sprouted a startup ecosystem in Rochester, as med-tech startups, accelerators, co-working spaces and a venture capital ecosystem have flourished in the area over the last half decade," according to new research by Maddy Kennedy of the *Minneapolis/St. Paul Business Journal*.

Prior to 2013, Mayo researchers were able to form companies and receive a portion of royalties, but they were not allowed to hold leadership positions. This offered little incentive for faculty and researchers to venture outside their labs.

Upon changing that policy, Mayo implemented new employee entrepreneurship programs and collaborated with the City of Rochester and the Rochester Area Economic Development Initiative (RAEDI) to develop the Mayo Clinic Business Accelerator. About 20 startups are currently tenants in the space, which offers access to offices, mentorship, legal services and connections to capital. Nearly 60 companies have participated in the accelerator since it opened five years ago, creating 75 new jobs and attracting approximately $40 million in capital

Since the time the Bayh-Dole Act was enacted in the early 1980s, university presidents, governors, technology trade associations, medical institutes and others lobbied state governments across the country to reform their respective laws or find other work-around organizations because they had an incentive to leverage the research being

performed in their state.

The federal government needs to take a similar approach to reform conflict-of-interest laws affecting federal civil servant researchers while ensuring adequate management of conflicts of interest.


Dr. Christopher Austin, Director, NIH National Center for Advancing Translational Sciences Director at Unleashing American Innovation Symposium, commenting on conflict of interest regulations at NIH.

Other ways to help develop entrepreneurial talent within federal labs include the following other suggestions:

**Entrepreneurial Leave:** Ensure that entrepreneurial leave programs for federal researchers to explore interest in startup activities are available across all federal laboratories. Most public research universities have some variation on this theme and appropriate versions of this policy should be applied to all federal laboratories.

**Technology Commercialization IPA**: Use the federal Interagency Personnel Act (IPA) coupled with a Cooperative Research and Development Agreement (CRADA) to allow federal lab entrepreneurs experience with a nearby research university in a shared technology commercialization experience working with a start up firm. Current IPA laws allow part time or full time assignment of federal lab researchers to a university, and this program might be utilized as a method to more effectively develop federal technology in partnership with an existing research university.

**Expand I-Corps program to federal lab researchers**: The NSF-funded I-Corps program trains university scientists and engineers to extend their focus beyond the university laboratory and accelerates the economic and societal benefits of research to projects that are ready to move toward commercialization through a rigorous customer discovery process. There is a local I-Corps node in the mid-Atlantic region, with UMD, George Washington University, Virginia Tech and JHU participating.

There have been several I-Corps pilot projects involving federal lab researchers and they should be expanded across the federal lab system.


**Recognize the accomplishments of federal researchers involved in successful federal lab commercialization activities:** Celebrate the accomplishments of federal researchers in federal labs by creating agency recognition programs and a Presidential level program to recognize federal laboratories researchers who have contributed to technologies that have been successfully transferred to the private sector

**Train PhD scientists in product development:**. Creating collaborative "externships" with pharmaceutical, medical device, materials and other industry leaders will enable fellows and graduate students to experience product development in the real world and making connections in industry without impacting their training and tenure in their academic laboratories. This expertise will provide invaluable confidence and connections to spin out their own (or others') technologies from federal labs.

**2) Using Physical Capital:**
*Federal labs can be used to create clusters of technology. Federal leasing and construction of federal research and related facilities near universities and other centers of innovation are best practices nationally:*

Sandia Science and Technology Park, adjacent to the US Department of Energy Sandia National Laboratory, New Mexico

To the maximum extent possible, the Government Services Administration (GSA) and Army Corps of Engineers (for DOD construction) should support facilities to be constructed or leased adjacent or near existing communities of innovation, including research universities, community colleges or other centers of innovation.

For existing federal labs, the GSA and Army Corps should support the construction of adjacent research parks, accelerators and co-working spaces by providing all federal agencies Enhanced Use Lease Authority(EUL).

Access to federal equipment at federal labs by the private sector and academia is important. The authority to enter Facility Use Agreements (FUA) should be expanded across the federal lab system. Allowing federal lab managers flexibility in leasing out underutilized space is critical.

The National Institute of Standards and Technology (NIST) has been a leader in allowing the private and academic sector to utilize its specialized labs and equipment, and has been a leader in co-locating its facilities on or near universities. (The NIST JILA facility at University of Colorado Boulder, and the NIST Joint Quantum Institute at UMD are just two examples).

The Department of Energy has a research park adjacent to its Sandia Lab in New Mexico. This park provides a meeting point for researchers from the private sector and federal sector and the park won a national award from the Association of University

Research Parks for its work in technology commercialization.

The Department of Energy (DOE) Berkeley Lawrence Livermore Lab in California, a GO-CO managed by the University of California, has a program to allow entrepreneurs from across the country access to the lab's resources to spur development of technologies around the lab. A program to import entrepreneurs to the DOE lab, since 2015, Cyclotron Road has awarded more than $10 million to 28 innovators who have gone one to generate more than $48 million in early stage funding to support their projects

Some federal labs offer voucher programs that allow small businesses to access state of the art technologies, instrumentation and expertise in their labs, and this program should be expanded to help the small business community, possibly in conjunction with SBIR/STTR funding.

Some agencies have land and other property in excess of their needs. In many ways the federal government's cumbersome approach to licensing its intellectual property to the private sector parallels the inefficiencies in selling its excess real property: excessive delays, procedural roadblocks, and varying abilities among federal agencies. Fortunately, both Congress and the federal government are interested in reforms in both areas.

Planned Global Innovation Hub in White Oak, Maryland adjacent to the FDA headquarters and research campus

### 3: Technology Capital:

*Ensure federal lab technology transfer offices are appropriately staffed and funded; create a congressionally chartered technology intermediary, such as a Federal Laboratory Commercialization Authority (FLCA); and other policy tools to attract to more efficiently*

*commercialize technologies emanating from federal laboratories:*

Ensure that federal tech transfer offices are adequately funded and staffed with experienced professionals with experience in financing, licensing and other areas of business development. University technology transfer offices used to be organized as passive patent agents, but that model has been supplanted with more robust innovation commercialization models that federal labs should emulate.

Many universities and many states have launched university or state affiliated entities to act as public/private technology intermediaries to help as a conduit or agent to commercialize technology, hold equity or do other projects.

The Maryland Technology Development Corporation (TEDCO) is a nationally recognized public corporation chartered by the state of Maryland that works with research universities, counties, and other stakeholders in the state. The Utah Science Technology and Research Initiative (USTAR) and the Georgia Research Alliance (GRA) are two examples of state-chartered, agile intermediary organizations that promote technology-based economic development in the state using state, private, university and federal resources for technology based economic development.

In 1920 the Wisconsin Alumni Research Foundation (WARF) was created as an independent nonprofit affiliated with the University of Wisconsin, Madison. It has an unparalleled record of providing support to the university, but also delivering new technologies to the public, such as synthesized Vitamin D and the lifesaving blood thinner, Warfarin. The University of Virginia Patent Foundation is another example of one of the many public research university affiliated organizations that take on the work of technology commercialization on behalf of parent organizations.

A national study, A New Direction for Technology Based Economic Development, published in the *Journal of Industry and Higher Education,* demonstrates the value of these technology-flexible, agile intermediaries in aligning university, business and state resources to create local clusters of economic growth.

http://www.innovationamerica.us/about-us/publications-and-presentations/white-papers/90-a-new-direction-for-technology-based-economic-development

The existing Federal Lab Consortium (FLC), established at 15 USC Section 3710, operates as a reporting and facilitator entity for federal laboratories across the US. The FLC, with additional congressionally chartered powers and modest funding, might be augmented into a Federal Lab Commercialization Authority *(*FLCA*)* to take on operational aspects and best practices from universities and states to apply them to federal laboratories, especially those organized as government-owned, government operated laboratories that predominate in the Greater Washington region.

A properly authorized and funded Federal Lab Commercialization Authority, or other Congressionally chartered organization, would be a 'work around' tool that existing fed labs could use to help use to meet technology commercialization goals. Because federal labs are created by Congress, a congressionally-chartered intermediary organization is

needed to create an agile, flexible organization that could operate on behalf of all federal laboratories. (Congress has experimented with single-use technology commercialization entities, but not one that can operate across all sectors of the federal lab ecosystem on an operational basis)

This new organization could accept federal appropriations, act as a trusted agent for federal technology transfer organizations, hold equity and perform other actions to benefit federal laboratories, similar to what university research foundations or state-chartered technology intermediaries do for their respective clientele. This nonprofit congressionally chartered intermediary could more easily attract funding and other resources that currently aren't easily available to federal labs pursuing technology commercialization partnerships.

A federally affiliated research entity model to consider is the approach used by Congress in giving VA medical centers more tools to meet their mission. In 1988 Congress authorized the Secretary of the Department of Veteran Affairs to establish nonprofit research and education foundations for the purpose of providing VA medical center with flexible funding mechanism to accept and administer private sector and non-VA appropriated funds. Under this statute, in Maryland, the Baltimore Research and Education Foundation (BREF) was incorporated as a nonprofit foundation to promote, conduct, facilitate and coordinate medical research and related education within the VA Maryland Health Care System. Similar VA-related research foundations were created across the US by VA hospital systems and have proven to be useful organizations in helping the federal government meet its mission in health care delivery, and a similar approach could be used in technology commercialization.

The FLCA could be modeled on, among other federal authorities, such as the congressionally chartered Henry M. Jackson Foundation for the Advancement of Military Medicine, which has a strong record of research and technology commercialization for the US Uniformed Health Services University, located across the street from NIH in Bethesda, Maryland. But because the Jackson Foundation charter is broad and flexible, it now partners with federal laboratories across the US in improving military medicine, and is one of Maryland's largest nonprofit entities with nearly half a billion dollars in annual revenue. (*See* Attachment 7 for draft federal legislation creating a FLCA.)

University experience shows that scaling a startup, especially a life science startup, requires social and capital networks, mentorships, and access to scientific and managerial talent. Marshalling all these disparate parts is very difficult for a stand-alone federal lab technology transfer office. A properly funded and scaled federal authority could take on some of these challenges.

**4) Other recommendations:**

**Create more entrepreneur-in-residence programs at federal labs**: For example, Bio Health Innovation (BHI), a nonprofit technology intermediary in Maryland, has developed an innovative and nationally recognized entrepreneur -in-residence (EIR)

program at some of the NIH Institutes to help identify technologies of interest to the private sector. This program should be expanded to more federal laboratories.

The EIRs also advise both the NIH and the entrepreneurs they through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, the leading source of non-dilutive funding in the world ($980 million per year funding approximately 1,300 companies ). BHI EIRs are also working in the NIH central office to further develop the EIR program throughout the agency. These types of programs bring commercial expertise to federal labs and facilitate the out licensing and commercial development of federally-funded innovation

**Federal Lab Performance and Evaluation Plan (PEMP:)** The Brookings/ITIF report suggests that the OMB Performance Evaluation and Management Plan (PEMP) for federal labs include a technology impact metric to evaluate the incentive for lab managers to engage and support technology commercialization.

**Expert Panel**: Convene a working group of AUTM, COGR, AAU, APLU, SSTI, AURP, Angel Capital Association, venture capital representatives, BHI and other organizations to work with the Office of Science and Technology Policy (OSTP), OMB, Cabinet secretaries, federal laboratory technology offices and others to provide ongoing guidance for improving technology commercialization practices of federal laboratories. Have this group work with the proposed state federal laboratory commission created by Executive Order, as outlined in Attachment 1.

**Conclusion:**

Since the Bayh-Dole Act passed in 1980, public research universities and states have experimented with many new laws, models and pilot projects to better connect their research and development resources to technology-based economic development in their communities using federally funded research dollars.

Because it takes considerable effort to pass a federal law, and due to the complexity the federal lab system, parallel efforts at the federal level for the federal government's own federal lab ecosystem have lagged, especially for the laboratories it manages directly.

The NIST Request for Information provides a great opportunity to take a fresh look at changing federal laws, policies and practices to reimagine and align the incredible human, physical and technology resources of the federal government's federal laboratory system for greater technology impact nationally and locally.

We hope these suggested reforms and changes in laws, policies and practices will help better achieve the federal government's goal in leveraging the investment in the federal lab system for continued research outcomes and increased engagement with commercialization and impact in their local communities.

Over the years, groups including the National Governors Association, the Brookings Institution and the Association of University Research Parks have called on Congress and the Executive Branch to find ways to improve economic engagement of federal

laboratories similar to the economic engagement mission of research universities across the United States.

We greatly appreciate NIST's leadership role in organizing the opportunity to suggest new ways to improve the technology engagement of federal labs with the private sector. The density of federal laboratories in the Greater Washington region makes these recommendations all the more imperative to economic success of our area. But improving technology commercialization of federal laboratories will also improve the international competitiveness of the United States.

## Members of the Task Force

Rich Bendis - Chair, President & CEO, BioHealth Innovation

Ken Carter - Chairman, Noble Life Sciences

Brian Darmody - Associate Vice President for Corporate Engagement, UMD

Harold Modrow- Senior Scientist Life Sciences Operation, Leidos

Sara Morningstar - Federal Relations Coordinator and Legislative Analyst, Montgomery County Government

Ted Olsen - President, PathSensors, Inc.

Eric Victory - Vice President, Partnering and Strategy, MedImmune

Brad Fackler - Facilitator; Director, Office of BioHealth and Life Sciences

Bret Schreiber - Senior Director, Office of BioHealth and Life Sciences

**ATTACHMENTS**

### Attachment 1: Draft Executive Order

DRAFT

EXECUTIVE ORDER
01.01.2018.—

ENHANCING THE ROLE OF FEDERAL LABS IN MARYLAND AND REGION FOR LOCAL ECONOMIC IMPACT

WHEREAS, The State of Maryland is also home to a unique network of federal labs that bring high quality jobs to Maryland;

WHEREAS, the federal executive and legislative bodies are exploring ways to more effectively take advantage of federally funded research for economic development and technology commercialization;

WHEREAS, The Brookings Institution has called on federal labs to have a local economic development mission in states where they reside;

WHEREAS, according to the National Science Foundation, over $10 billion of internal research and development spending was performed by federal labs in Maryland in 2015, the highest amount of any state in the nation;

WHEREAS, tens of thousands of high quality researchers work in federal labs in Maryland and can be a source of innovation and technology for the state;

WHEREAS, federal laboratories in Maryland are an important cluster of economic importance to Maryland;

WHEREAS, proposals to build private sector research and technology development spaces adjacent to federal laboratories are being proposed in various parts of the state, including adjacent to the FDA, NIST, Pax River, DOD, Ft. Detrick and elsewhere, designed on the successful university research park model;

WHEREAS, these projects would be enhanced if we maximize federal lab flexibility in partnering with universities, the private sector and foundations;

WHEREAS, Science and technology is important to the state and nation;

WHEREAS, other states have developed programs to take better advantage of local federal laboratories in their regions;

WHEREAS, Congress and the federal administration, including NIST, are exploring ways to make federal labs sources of innovation and technology for the nation through the encouragement of technology transfer, and local partnerships

NOW, THEREFORE, I, LAWRENCE J. HOGAN, JR., GOVERNOR OF THE STATE OF MARYLAND, BY VIRTUE OF THE POWER INVESTED IN ME BY THE CONSTITUTION AND LAWS OF MARYLAND, DECLARE THE FOLLOWING EXECUTIVE ORDER, EFFECTIVE IMMEDIATELY:

A. Commission. There is a Commission on Enhancing the Role of Federal Labs in Maryland and Region for Local Economic Impact (the 'Commission').

B. Membership. The Commission membership shall consist of the following:

1) The Governor shall appoint a chair of the Commission.

2) Membership will include:
A) One member from the Maryland Technology Development Corporation
B) One member from the Governor's Washington Office
C) One member from the Maryland Technology Council
D) One member from Bio Health Innovation, Inc.
E) One member from the Maryland Life Science Advisory Board
F) One member from the Fort Meade Alliance
G) One member from the Army Alliance, Aberdeen
H) Two members from the Maryland Department of Commerce
I) One member from the University System of Maryland
J) One member from the Federal Laboratory Consortium
K) Three additional members appointed by the Governor representing national venture, small business, and angel investing groups

3) Five members of the Commission shall constitute a quorum for the transaction of any business.

4) To the extent practicable, the members of the Commission shall reflect the diversity of the population of the State

C. Duties.

A. Consult with stakeholders, including the Federal Lab Consortium (FLC), on best practices nationally and other initiatives to create local economic development missions for federal laboratories

B. Work with the Maryland Congressional delegation and other state delegations with large federal lab presence on reforms to allow federal researchers more interaction with technology transfer, similar to what is allowed for university researchers, and other initiatives

C. Work with federal lab leadership on new approaches to federal lab 'open' campus concepts to improve science and innovation for the benefit of the nation nationally, and the state of Maryland locally

D. The Commission shall hold publicly announced meetings at such times and such places as it deems necessary. The meetings shall be open and accessible to the general public in accordance with the State Open Meetings Act or other applicable law.

E. The Commission shall forward its recommendations to be presented to the Governor no later than December 15, 2019.

D. Disbandment. The Commission shall automatically be disbanded on December, 15, 2019, unless its term is extended by executive order.

**Attachment 2: Sandia Labs Science and Technology Park, New Mexico**

**Sandia Science and Technology Park, adjacent to DOE Sandia National Lab**

Internationally recognized, master-planned, and strategically located, Albuquerque's Sandia Science & Technology Park (SS&TP) is home to companies, engineers, and researchers involved in advancing new technologies. Currently 42 companies and organizations and more than 2,000 employees reside in SS&TP's more than 300-acre high-tech campus.

Adjacent to the multibillion-dollar engineering and science facilities of Sandia National Laboratories and the Air Force Research Laboratory (AFRL), the SS&TP's mature companies and startups collaborate with these top laboratories on a broad assortment of technologies, products, and services.

**History**

The SS&TP Program Office was formed in 1998 to assist in the development of the Park and provision of services to its residents. It is funded by Sandia National Laboratories. The Sandia Science & Technology Park Development Corporation (SSTPDC) was formed in 1998 to assist in the development of the SS&TP and its high-speed telecommunications infrastructure. It is a non-profit 501(c)(3) charitable foundation.

Over the years, the Park has steadily grown in international stature and was recognized by the Association of University of Research Parks as the 2008 Outstanding Research Park of the Year.

**Location**

The SS&TP is in the high desert Manzano Mountain foothills of Albuquerque, New Mexico. The Park is strategically located east of Kirtland Air Force Base. It extends along the south end of Eubank Boulevard, adjacent to Sandia National Laboratories.

Sandia Science & Technology Park is where technology works.

The Sandia Science & Technology Park (SS&TP) is a 300+ acre master-planned technology community. Affiliated with Sandia National Laboratories and adjacent to Kirtland Air Force Base, companies have easy access to world-class facilities, technologies, scientists, and engineers. From startups to Fortune 500 companies, the SS&TP is *where technology works*. **MORE INFO**»

**Attachment 3. Excerpts from Brookings/ITIF Report on federal laboratory engagement with local community**

*"Localizing the economic impact of research and development: Fifty policy proposals for the Trump administration and Congress." Stephen Ezell and Scott Andes. Wednesday, December 7, 2016.*

**2. Task federal laboratories with a local economic development mission**

Federal agencies such as DoD, DoE, DHHS, and the NSF that own and fund federal laboratories and FFRDCs should adopt an explicit mission to support the regional economies in which they are located. Many lab managers and agencies approach regional economic development as mutually exclusive from their core missions; this is especially true for weapons labs located within the Departments of Defense and Energy. But defense and weapons labs like Sandia and Los Alamos in New Mexico have successfully integrated regional economic development programs within their broader research objectives.

For example, both labs have partnered with the state of New Mexico on the New Mexico Small Business Assistance Program, which connects small businesses seeking technical assistance with lab researchers.[17] Every federal agency and federal lab should view regional economic development as part of its overarching mission. Moreover, increasing the technical capacity of the regions in which labs are located is mutually beneficial for the labs and the local economy. Moreover, given the mobility of the scientific workforce, creating homegrown talent helps labs address attrition.

**6. Allow labs to repurpose a small portion of existing funds for timely local collaboration**

Increasing collaboration between regional universities and tech-based entrepreneurs and corporate partners requires greater flexibility in funding contracts. The next administration should allow federal labs to set aside a small amount—perhaps 5 percent—of fiscal year funding for unexpected research partnerships that may emerge throughout the year and that clearly align with lab mission and research goals. Labs would not be required to reserve these funds, nor be required to invest in regional partnerships, but interested labs would have the option. Similar repurposing rules should be encouraged for all federal funding opportunity announcements (FOAs) intended for federal labs.

**12. Expand the national Regional Innovation Program**

Regional innovation programs have proven a highly successful form of economic development for communities across the United States.[22] Programs such as the i6 Challenge and the Jobs and Innovation Accelerator Challenge have helped local, regional, and state entities leverage existing resources, spur regional collaboration, and support economic recovery and job creation in high-growth industries. The Regional Innovation Program operated by the Economic Development Administration identifies and supports regional innovation clusters, convenes relevant stakeholders, creates a cluster support framework, disseminates information, and provides targeted capital investments to spur economic growth.[23] There is great demand for this program from regions all around the nation, but in 2015 just $15 million in grants were awarded. More funding is needed, and more needs to be done to support regional innovation programs in the United States. Accordingly, the next

administration and Congress should expand funding for the Regional Innovation Program to as much as $75 million.[24]

**Attachment 4. Association of University Research Parks**

Power of Place 2.0: The Power of Innovation

Similar reforms to encourage federal agency flexibility in facility development and technology commercialization were suggested earlier in the *Power of Place and Power of Place 2.0*, issued by the Association of University Research Parks (AURP) in 2010. See, http://www.aurp.net/power-of-place

**Attachment 5. Office of Science and Technology Policy Lab to Market Initiative**

*"From Lab to Market: Accelerating Research Breakthroughs and Economic Growth*." Tom Kalil and Charina Chou. March 14, 2014.

Earlier this month, President Obama announced his 2015 budget, a roadmap for accelerating economic growth, expanding opportunity for all Americans and ensuring fiscal responsibility. The budget supports the President's Management Agenda to deliver a 21st century government that is more effective, efficient, and supportive of economic growth. One key element of the President's Management Agenda is accelerating the transfer of Federally funded research from the laboratory to the commercial marketplace – a "Lab-to-Market" agenda.

The Federal Government spends more than $130 billion on research and development (R&D) each year, conducted primarily at universities and Federal laboratories. This investment supports fundamental research that expands the frontiers of human knowledge, and yields extraordinary long-term economic impact through the creation of new knowledge and ultimately new industries – often in unexpected ways.

At the same time, some research discoveries show immediate potential for commercial products and services, and the President is committed to accelerating these promising technologies from the laboratory to the marketplace, based on closer collaboration with industry. The fruits of this Lab-to-Market process, also known as "Technology Transfer" or "R&D commercialization," are everywhere – for example, Federal laboratories developed much of the battery technology that makes electric vehicles possible, university researchers helped bring to market a breakthrough drug that effectively cures certain forms of leukemia, and Google was born as a Federally funded university spin-off company.

That's why three years ago, as part of the White House Startup America initiative, President Obama signed a memorandum directing all Federal agencies with research facilities to accelerate this kind of Lab-to-Market activity. Some innovative recent examples include:

- The Department of Energy (DOE) announced the National Incubator Initiative for Clean Energy (NIICE), a $3 million program to fund up to five specialized business incubators that help entrepreneurs commercialize clean energy technologies. NIICE will also support a national organization to coordinate these efforts.
- The Department of Defense (DOD) recently awarded $1 million to Arizona State University (ASU) to create the Pracademic Center of Excellence in Technology Transfer (PACE/T2), which will help DOD transfer technologies developed at its defense laboratories to the marketplace.
- The National Institutes of Health (NIH) teamed up with the Avon Foundation for Women to establish the Breast Cancer Startup Challenge, an opportunity for multidisciplinary teams to develop business plans and start new companies based on ten unlicensed breast cancer inventions developed at NIH's National Cancer Institute or at an Avon Foundation-funded university lab. Ten winners were announced on March 5 in recognition of their promising business plans and pitches, and these winners have been invited to launch a startup, negotiate licensing agreements, and raise seed funding.
- The National Science Foundation (NSF)'s Innovation Corps (I-Corps) program provides entrepreneurship training for NSF-funded scientists and engineers, pairing

them with business mentors for an intensive curriculum focused on discovering a demand-driven path from their lab work to a marketable product. For example, I-Corps enabled Professor Ayanna Howard of the Georgia Institute of Technology to launch a startup based on her research, which will help people with disabilities interact with computers.

The President's 2015 budget goes further, proposing $25 million to grow the NSF I-Corps program as well as $6 million to support greater interagency collaboration on Lab-to-Market efforts. As part of the President's Management Agenda, progress will be measured in pursuit of a new Lab-to-Market Cross-Agency Priority Goal to accelerate and improve the transfer of new technologies from the laboratory to the commercial marketplace, including by:

- Optimizing the management, discoverability, and ease-of-license of the 100,000+ Federally-funded patents;
- Increasing the utilization of Federally-funded research facilities by entrepreneurs and innovators;
- Ensuring that relevant Federal institutions and employees are appropriately incentivized to prioritize R&D commercialization;
- Identifying steps to develop human capital with experience in technology transfer, including by expanding opportunities for entrepreneurship education; and
- Maximizing the economic impact of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

These actions promise to significantly increase the American people's return on investment in Federally-funded research, by ensuring that more discoveries in the laboratory make the leap to the marketplace – creating more effective drugs, more resilient crops, and more powerful clean energy solutions. We look forward to working together with the government, university, and industry communities to advance the President's Lab-to-Market agenda.

*Tom Kalil is Deputy Director for Technology and Innovation at the White House Office of Science and Technology Policy (OSTP)*

*Charina Choi is a White House Fellow at OSTP*

**Attachment 6. Summary of Federal Tech Transfer Acts:**

The federal Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-4l80 is the first of a continuing series of laws to define and promote technology transfer. It made it easier for federal laboratories to transfer technology to non federal parties and provided outside organizations with a means to access federal laboratory developments. The primary focus of the Stevenson-Wydler Act concerned the dissemination of information from the federal government and getting federal laboratories more involved in the technology transfer process. The law requires laboratories to take an active role in technical cooperation and to set apart a percentage of the laboratory budget specifically for technology transfer activities. The law also established an Office of Research and Technology Applications (ORTA) in each laboratory to coordinate and promote technology transfer.

The Federal Technology Transfer Act of 1986 was the second major piece of legislation to focus directly on technology transfer. All federal laboratory scientists and engineers are required to consider technology transfer an individual responsibility, and technology transfer activities are to be considered in employee performance evaluations. This 1986 law also established a charter and funding mechanism for the previously existing Federal Laboratory Consortium for Technology Transfer (FLC). In addition, the law enabled GOGO laboratories to enter into Cooperative Research and Development Agreements (CRADAs) and to negotiate licensing arrangements for patented inventions made at the laboratories. It also required that government employed inventors share in royalties from patent licenses. Further, the law provided for the exchange of personnel, services, and equipment among the laboratories and nonfederal partners. Other specific requirements, incentives and authorities were added, including the ability of GOGO laboratories to grant or waive rights to laboratory inventions and intellectual property, and permission for current and former federal employees to participate in commercial development, to the extent that there is no conflict of interest.

**Attachment 7. Federal Lab Commercialization Authority Draft Legislation**

DRAFT LEGISLATION CREATING THE FEDERAL LABORATORY COMMERCIALIZATION AUTHORITY (FLCA)

WHEREAS, Federal laboratories and federal laboratory scientists are important institutions in the creation of new knowledge and technologies, but lag behind in research commercialization to the private sector

WHEREAS, Numerous commentators from across the country have urged federal reforms in helping federal laboratories improve their record of technology transfer

WHEREAS, Public research universities and states have used affiliated organizations as models to improve technology commercialization to the private sector

WHEREAS, Federal laboratories have varying statutory authorities and management structures that may inhibit working with the private sector

WHEREAS, A federally chartered non-profit organization modeled on best practices from public research universities and state governments would be a new administrative tool that could help federal laboratories improve their technology commercialization,

Now Therefore, the following legislation is introduced:

115th Congress

2nd Session

Senate Bill # _____

A Bill For An Act Entitled: "The Federal Laboratory Commercialization Authority"

In the Senate

A Bill

To Amend the Stevenson-Wylder Act to establish the Federal Laboratory Commercialization Authority, and for other purposes

Resolved by the U.S. Senate of the United States of America, that the following article is proposed as federal law under the jurisdiction of the United States of America, enforceable by Executive action.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, that:

Section 1. Short Title:

This Act may be cited as "The Federal Laboratory Commercialization Authority'

Section 2.

(a) There is authorized to be established a nonprofit corporation to be known as the Federal Laboratory Commercialization Authority (hereinafter in this section referred to as the "Authority") which shall not for any purpose be an agency or instrumentality of the United States Government.

The Authority shall be subject to the provisions of this section and, to the extent not inconsistent with this section, the Corporations and Associations Articles of the State of Maryland.

(b) It shall be the purpose of the Authority: (1) to carry out technology commercialization activities on behalf of and under cooperative arrangements with the Federal Laboratory Consortium (FLC) and with Offices of Research and Technology Applications established by each federal laboratory (2) to serve as a focus for the interchange of ideas, projects and partnerships among federal, private and academic sectors, and (3) to encourage the development of technologies and spin out businesses based on research funded by the federal government and performed in federal laboratories for the benefit of the federal laboratories and the economic competitiveness of the United States.

(c)(1)The Authority shall have a Council of Directors (hereinafter in this section referred to as the "Council") composed of—

(to be determined) and four members appointed by the Federal Laboratory Consortium

(2)The term of office of each member of the Council appointed under clause (C) of paragraph (1) shall be four years, except that—

(A)any person appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

(B)The terms of office of members first taking office shall expire, as designated by the ex officio members of the Council at the time of the appointment, two at the end of two years and two at the end of four years.

(3)The Council shall elect a chairman from among its members.

(d)(1)The Council shall have an Executive Director who shall be appointed by the Council and shall serve at the pleasure of the Council. The Executive Director shall be responsible for the day-to-day operations of the Authority and shall have such specific duties and responsibilities as the Council shall prescribe.

(2)The rate of compensation of the Executive Director shall be fixed by the Council.

(e)The initial members of the Council shall serve as incorporators and take whatever actions as are necessary to establish under the Corporations and Associations Articles of the State of Maryland the corporation authorized by subsection (a).

(f)Any vacancy in the Council shall not affect its powers, but shall be filled in the same manner in which the original designation or appointment was made.

(g) The Authority shall create an Advisory Council that shall include representatives from organizations representing: venture capital, angel capital, small businesses, research universities, economic development organizations and university research parks.

(h)In order to carry out the purposes of this section, the Authority is authorized to—

(1)

enter into contracts with, accept grants from, and make grants to federal laboratories for the purpose of carrying out cooperative enterprises including research, consultation, and commercialization programs, including contracts for provision of such personnel and services as may be necessary to carry out such cooperative enterprise;

(2)

take such action as may be necessary to obtain patents and licenses for technology of federal laboratories, or hold or be an agent for such patents and licenses on behalf of federal laboratories;

(3)

accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Authority

(4)

enter into contracts with individuals, public or private organizations, professional societies, and government agencies for the purpose of carrying out the functions of the Authority;

(5)

enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Authority and

(6)

charge such fees for professional services furnished by the Authority as the Executive Director determines reasonable and appropriate.

(i)A person who is a full-time or part-time employee of the Authority may not be an employee (full-time or part-time) of the federal government.

(j)The Council shall transmit to the President and Congress annually, and at such other times as the Council considers desirable, a report on the operations, activities, and accomplishments of the Authority.

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New language added to the Federal Lab Consortium enabling statute at 15 USC Section 3710(A)

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(g) With the consent of any federal laboratory, contract with the Federal Laboratory Commercialization Authority, established in this Title, to assist with the commercialization and transfer to the private sector of federally-owned intellectual property and perform related transactions.

Section 3: Effective Date: TBD