

Recommendations from the National Expert Panel

White House Conference Center May 20, 2013

White House Lab-to-Market Inter-Agency Summit: Recommendations from the National Expert Panel

The U.S. government spends approximately \$140 billion dollars annually on research and development (R&D), which has been critically important to the strength of the American economy. However, only a small portion of the resulting discoveries have been commercialized by the private sector. As our global competitors accelerate investments in R&D and increasingly commercialize products and processes, it is imperative that the U.S. optimize its commercial output from federally-funded research to benefit public health and well-being, create jobs and increase economic value.

Federal research has done exceedingly well at accomplishing its original intent, which is to increase human knowledge, meet mission needs, and undertake highrisk research of long-term importance to the U.S. economy that is beyond the reach of the private sector. But commercialization of resulting discoveries from agency research has largely been an after-thought, despite clear Congressional and Presidential intent expressed through a series of legislative mandates and Executive Orders. While research to meet agency missions is critical, the members of the Panel believe that if the U.S. is to remain globally competitive in the 21st century, it must accelerate the translation of federally-funded R&D into commercial outcomes that create economic and public value, thus maximizing the return on the public dollars invested.

Innovation in the public and private sectors is a key component in increasing competitiveness. It has driven past U.S. economic gains and will drive future prosperity. We must leverage, coordinate and align all of our capabilities and technological assets across agencies and sectors and work together to ensure that the U.S. is once again the world's most innovative and competitive nation.

The members of the National Expert Panel have several recommendations that are intended to be a "call to action" which will strengthen, accelerate, align and add value to the commercialization of federally-funded R&D.

Background

On May 20, 2013, the White House Office of Science and Technology Policy (OSTP) and the National Institutes of Health (NIH) National Heart, Lung and Blood Institute (NHLBI) convened the Lab-to-Market Summit. They gathered a panel of 20 national non-government experts to examine innovative lab-to-market programs with the aim of identifying possible synergies as well as underlying challenges to these and other federal commercialization programs. (See Appendix I for a list of the national experts.) About 60 federal agency representatives were involved as presenters and observers. Five representative agency programs designed to bridge the gap between the lab and the market were presented to the panel:

- Tech to Market, Advanced Research Projects Agency-Energy (ARPA-E), U.S. Department of Energy;
- NIH Centers for Accelerated Innovations program (NCAI), National Institutes of Health;
- NSF Innovation Corps (I-Corps), National Science Foundation;
- Innovation-6 (i6) Challenge, U.S. Department of Commerce; and
- The Technology Transfer/Commercialization Program (T2/CP),
 Telemedicine and Advanced Technology Research Center (TATRC), U.S.
 Department of Defense.

The members of the Expert Panel were asked to address

- Common barriers and approaches to lab-to-market models;
- Agency end-market or technology specific barriers;
- Resources that can be leveraged across agencies and programs;
- Mechanisms to inventory and share best practices;
- Policies that enhance cross-agency program cooperation and public-private partnerships;
- Development of cross-agency initiatives;
- Current/potential linkages with the private sector, and related local and state programs; and
- Metrics of success.

The individual members of the Panel were instructed by OSTP to make recommendations for transformational, not incremental change. The members of the Panel embraced this approach, and there was surprisingly strong consensus throughout the discussion and deliberation on its recommendations.

Expert Panel Discussion

Agency representatives from five relatively new programs presented initiatives intended to bridge the gap between federally-funded research and private sector commercialization. These programs represented some of the newest and most innovative federal practices, and they deserve further review for potential replication and scaling. However, the members of the Panel recognized that in order to fulfill their charge they needed to take a broader approach focused on identifying the underlying barriers that weaken, and in some cases prevent, the commercialization of federal agency research. The discussion quickly turned to identifying major structural barriers rather than merely "tweaking" existing programs.

It also became clear that while noteworthy efforts are being made by many individual federal programs, these programs often do not receive the recognition, funding or authority that reflect technology commercialization as a consistent and sufficiently high national priority. The Panel and the federal agency participants discussed a number of barriers and needs described below.

<u>Creating Inter-Agency Synergies and Scaling of Innovative Practices</u>

Several areas were identified that prevent greater success in the federal commercialization process including

- The lack of a cross agency process to identify and leverage common research objectives that would facilitate more efficient resource sharing, cost reductions, and leveraging of capabilities.
- The need to identify opportunities and reduce barriers that could lead to multi-agency commercialization initiatives, thus increasing efficiencies and promoting best practices.

- Insufficient funding for new, innovative commercialization programs that allow an agency to accurately determine the potential for commercial success and scaling.
- In some agencies and programs, insufficient prioritization of technology transfer and commercialization and the implementation of related Presidential Executive Orders and statutes.

Accelerating Commercialization and Aligning with Market Demand

Several barriers were identified that prevent greater commercialization success including

- The need to bring federally-funded technologies, particularly those with a high impact potential, to a sufficient development stage that attracts private sector commercialization partners.
- The absence of mechanisms to identify market demand and to align it with agency research priorities when appropriate.
- Limited knowledge, experience and connections with commercial markets, private sector customers, investors, partners and industry-specific business models.
- Industry frustration with different agency technology transfer terms, often in agreements under the same statute, unnecessary complexity of legal terms, and delays in finalizing licensing and other deals.

It became apparent that what was clearly missing was an effective body that could

- Review agency research budgets and commercialization programs for possible synergistic leveraging and coordination;
- b) Work with agencies to develop and nurture innovative programs that facilitate commercialization;
- c) Develop and promulgate the use of best practices across all government R&D agencies;
- d) Advocate in the Executive branch to preclude or mitigate disruptive bureaucratic interference or inappropriate agency practices that discourage commercialization in federal programs;
- e) Encourage adoption of expeditious standard terms for government-industry partnership agreements;

- f) Develop a consistent set of basic, outcome-based cross-agency metrics; and
- g) Map the assets of the federal research infrastructure and identify areas of intersection between the assets and market demand for new technologies.

Other goals expressed by members of the Panel would be accomplished by such a body with coordination and facilitation responsibilities and authorities. These include developing programs that could work more effectively with external investors and private sector end-users, and assisting agencies to access innovative sources of capital including partnerships with philanthropic organizations, and innovation-based, private-public sector partnerships.

Members of the Panel cautioned that while consistent standards and metrics are important for creating greater efficiencies in commercialization, it also should be taken into account that "one size does not fit all" as the nature of the commercialization process differs in various fields. For example, developing software and developing new drugs are vastly different in time to market, costs, and expected short-term results. Thus, it is important that the metrics as well as administrative and legal processes account for these differences and build in appropriate flexibility. Further, the metrics should reflect a process that involves commercialization partnerships among multiple parties including university technology transfer offices, corporations, regulatory agencies, government-related organizations, investors and others that affect capital investments. Thus, commercialization outcomes are dependent on multiple factors including deal structure, timing, marketplace, and regulatory systems.

Members of the Panel do not believe that every agency project should involve a multi-agency partnership. But with budgetary constraints stretching into the foreseeable future, coordinated efforts should be made to leverage resources and capabilities whenever possible, particularly for those agencies confronting serious budgetary constraints for their R&D programs. The aforementioned body would be useful in helping to identify common mission needs and technology areas funded by various agencies and in determining where potential collaboration would create efficiencies, accelerate commercialization and strengthen outcomes.

Members of the Panel also believe that it is imperative to seek industry input in commercialization program design and implementation. Of particular interest is input from investors and small technology companies since history has shown that they are most likely to take discoveries to the marketplace and are the nation's major job creators. Flexibility and a timely, streamlined decision making process for closing deals with the private sector are critical in accelerating commercialization, particularly with regard to partnerships involving new, high-growth small businesses.

Industry input in federally-funded commercialization program design and implementation also should involve innovative alliances with larger companies which are increasingly engaged with universities in developing market changing products through new, creative partnering strategies. As an example, many large companies are working with universities in designing proof-of-concept initiatives, sharing valuable research materials, and related strategies designed to de-risk and add value to prospective innovation-based products.

However, it is also important to recognize that most federally-funded discoveries will not be commercialized since even in the private sector only a small percentage of their market-driven research becomes successful products. Because federal agencies must focus their research primarily on mission needs, not market-driven needs, it is not reasonable to impose on federal agencies the same kind of return-on-investment metrics used by industry.

To better align research and commercial market needs, some agencies such as the Department of Defense compile lists of technologies needed to meet mission requirements and actively seek partners to develop related products through its acquisition system. The Department of Agriculture has always aligned their research with the needs of American farmers. Other agencies such as the National Science Foundation and Health and Human Services have missions that emphasize basic research where commercial applications are not readily apparent, but have historically created industry-changing breakthroughs. Thus, the federal government must have a balanced portfolio approach in funding basic and applied research.

While the members of the Panel recognize the need for a balanced approach, they also recognize that the full benefits of federally-funded R&D are only realized if the resulting discoveries are translated into products and processes by the private sector. Therefore, enabling and facilitating technology commercialization must be an important objective for all agencies regardless of their mission. The members of the Panel were very impressed with the strong commitment to

enabling technology commercialization shown by federal program representatives at the Summit and by the exemplary programs presented for the Panel's review. However, it is clear that technology commercialization is not always an agency priority despite two decades of supporting laws and Administration directives. There do not appear to be any real rewards for programs and incentives for individuals who take commercialization to heart, nor are there penalties for those who block the way forward. In any organization employees are not going to adopt new behavior when it is apparent that incentives and rewards do not match administrative directives. This leads to cultural barriers in the federal system from top management to bench scientists since technology transfer does not factor into performance reviews, promotions or funding allocations. Several universities have successfully reversed this culture by incorporating technology transfer as a factor for gaining tenure and promotion, and bringing on new hires, providing a good example for federal agencies and laboratories.

Federal laboratories and funded programs are not incentivized to make commercialization a priority since an insignificant amount of the laboratories' budgets are devoted to private sector partnerships and commercialization. Not only does the insufficient funding hamper capacity, it also sends a message that commercialization is not a true priority. Small businesses, in particular, require additional help in navigating the federal laboratory system, which is often not available.

While there is much to do, there were many innovative agency programs and specific features presented to the Panel that could be leveraged, expanded, and replicated to increase commercialization rates. Positive features of these programs include

- Providing market analyses and assessing the commercial viability of new agency-funded discoveries.
- For technologies with a viable value proposition, bringing them to a later stage of development through proof-of-concept centers and related funding mechanisms when necessary.
- When appropriate, building commercialization into the contractor's research plan from the beginning as is done by ARPA-E and its progenitor the Defense Advanced Research Projects Agency (DARPA).

- Helping federally-funded researchers identify and connect with private sector partners, investors, customers and procurement sources.
- Engaging proven entrepreneurs and other practitioners in training and mentoring of federally-funded researchers through I-Corps and other initiatives, to increase the researchers' understanding of market needs and business development.
- Helping create comprehensive regional ecosystems and private-public partnerships that link critical elements – research, expertise, education and workforce development, manufacturing, entrepreneurs, corporations, and investment capital.

There should be an ongoing, systematic effort to identify best practices, whether those are found in federal programs or local, state, private or academic programs, and a rigorous evaluation to determine those features that should be replicated and scaled. Some of the state and private sector programs that members of the Panel cited as strong models were the Coulter Translational Research Program, the Deshpande Foundation's model and Innovation Network, the von Liebig Entrepreneurism Center, the Ben Franklin Technology Partnerships, and venture philanthropy models such the Leukemia and Lymphoma Society.

Recommendations

Create a High-Level Office of Innovation and Federal Technology Partnerships

Currently, no specific body has the strategic responsibility for ensuring the effective implementation of the clear Congressional and Presidential intent that commercialization of federal research is a real priority for the federal research agencies. Therefore, all members of the National Expert Panel recommend that a new *Office of Innovation and Federal Technology Partnerships* be created with the following responsibilities.

Leveraging Cross-Agency Synergies and Increasing Efficiencies

 Assist agencies in reviewing agency R&D and technology commercialization activities to ensure that when appropriate they prioritize and incentivize the commercialization of federal research.

- Help identify synergies among programs suitable for multi-agency research and commercialization initiatives, and work with the agencies to develop such partnerships.
- Insure that fundamental cross-agency authorities such as the Federal Technology Transfer Act are implemented consistently.
- Assist in the development and implementation of effective, consistent incentives and rewards for researchers across federal agencies and laboratories that successfully engage in commercialization activities.
- With input from the investment community, identify and reduce barriers across agencies that prevent full utilization of development capital by federally-funded researchers.
- Assist in the development and adoption of effective program metrics for commercialization that (a) are clear and consistent across agencies and funding recipients, (b)reflect appropriate returns-on-investment that correspond to differing agency missions and types of technologies, and (c) are collected and analyzed on an ongoing basis, and result in improvements to the system.

Strengthening Public-Private Partnerships

- Work with the agencies to insure that agency attorneys and program officers facilitate and support commercialization partnerships with industry.
- Work with the agencies to reduce the time to complete agency partnership and licensing agreements with industry, particularly new, high-growth businesses, and reduce duplicative and burdensome paperwork associated with all contracts and agreements.
- Promote increased dialogue with the private sector on current and emerging markets, and the appropriate alignment with federal R&D and commercialization activities on these opportunities.
- In cooperation with agencies, leverage existing tools and create a webbased, "one-stop shop" to showcase federally-funded technologies and cooperative R&D opportunities in an easily accessible and useful format for the private sector.

Optimizing Federal Laboratory Commercialization

- Work with agencies to identify and implement an appropriate percentage of federal laboratory research expenditures to increase the acceleration of commercially relevant research.
- Assist agencies in making commercialization a greater priority as a condition of awards to federal laboratory contract operators, and in other federally operated laboratories.
- Assist in the development of appropriate incentives to encourage federal laboratory participation in initiatives to create regional, public-private ecosystems that leverage multi-sector capabilities.

Adapting and Implementing Innovation Best Practices

- With input from U.S. industry, investors, non-profit organizations, and state/local entities, work with agencies to identify and adapt effective acceleration and commercialization programs now used in universities, the private sector and individual federal agencies, across all federal agencies and their laboratories.
- Identify, create and share innovative uses of the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) programs to increase the commercialization of federally-funded research.

The Office of Innovation and Federal Technology Partnerships must be placed at the highest level to affect its multi-agency authority and oversight. The Office of Management and Budget (OMB) is part of the Executive Office of the President charged with overseeing budgetary development and agency performance as well as implementation of Executive Orders and Presidential Memoranda. Thus, it appears to be a good location for such a function. Establishing the Office in OMB may not require new legislation, making its prompt creation possible. This is not to say that the Office could not be established elsewhere under new legislation, but OMB's budgetary authorities and proximity to the White House gives it important clout with the agencies that might be missing if located elsewhere. Another option is the creation of a cabinet-level, U.S. Secretary for Innovation that would send a clear signal that research, innovation and commercialization are truly national priorities.

In either case, the new Office must be staffed by a leader and senior staff that have strong entrepreneurial experience capable of recognizing, nurturing, and facilitating synergistic initiatives across diverse programs and agencies, optimizing the value of federal research, and forming effective partnerships with investors, innovative small businesses and larger research intensive companies. They also must have strong backgrounds in federal innovation management policies. Industrial and investment experience is also important.

Members of the Panel strongly encourage the creation of an external Advisory Board for the Office that includes entrepreneurs, small high-growth businesses, industry, investors, academic institutions, state and local organizations, and other private and non-profit organizations actively engaged in commercialization. The Board should be actively engaged in identifying, designing, and vetting improvements to the federal commercialization system, and fostering effective public-private sector R&D partnerships.

Strengthening Capital Investments and Entrepreneurial Resources

The second major recommendation by members of the National Expert Panel involves strengthening capital investments and entrepreneurial resources to support commercialization of federally-funded research. The members of the Panel specifically recommend the following.

Creating Innovative Public-Private Partnerships and Investment Vehicles

- Create and test private sector and public-private sector vehicles to invest in commercially viable R&D. These vehicles might include (a) partnerships with philanthropic foundations, (b) a national public-private sector, earlystage "fund-of-funds" or an early-stage innovation fund, and (c) Deshpande and Coulter Foundation types of acceleration funding mechanisms.
- Implement significant tax incentives for corporations to support scale-up and proof-of-concept work of federally-funded research that could lead to licensing and commercialization, and work with the private sector to create sufficient incentives for maintaining such efforts.
- Expand entrepreneur-in-residence, mentoring, and entrepreneurial business development programs, particularly those that engage experienced entrepreneurs and venture capitalists, to all federal agency innovation and commercialization programs and major federal laboratories.

- Allow and encourage federal employees to become "scientists-inresidence" in industrial settings to increase knowledge exchange and crossagency alignment.
- Develop and provide innovation and partnership training to federal agency and federal laboratory technology transfer administrators and researchers; training might involve using technological resources such as webcasts and expanding current programs such as I-Corps and others.
- Provide education programs for business students to increase their understanding of value creation and innovation processes, especially in technical fields.
- Strengthen partnerships with state and local innovation and economic development organizations, university innovation management offices/programs and other practitioners to act as "technology translators".
 The "translators" would be experienced in the private sector and able to bridge the divide between federal laboratory and university bench scientists, the private sector and investors.
- Team public sectors researchers either through their technology transfer or business development offices with "technology translators".

Leveraging the SBIR/STTR Programs

- Repurpose a greater portion of SBIR/STTR funding (than under the current reauthorization) that would allow awardees to engage directly in a broader range of commercialization related activities and services such as intellectual property protection, marketing, and business development.
 While changes in legislation would be required, waivers might be issued on amore expeditious basis to voluntary agencies willing to test this proposed change.
- Create new contract/grant vehicles in SBIR/STTR to facilitate interdisciplinary R&D that cuts across multiple programs and agencies. These new vehicles would encourage innovative submissions that could result in transformative technologies that more broadly meet agency or multiagency missions.

While members of the Panel discussed additional recommendations, we believe that these two major recommendations are those most critically needed to develop a true federal R&D system that will maximize the commercialization of

tax payer supported discoveries. Several members of the Panel have provided additional individual recommendations that appear in Appendix II.

This one-day meeting should be just the start of an ongoing effort to bring together on a regular basis, private and public national experts to review and provide recommendations intended to improve and elevate the federal system of commercialization. This effort is critical to the return-on-investment to America's taxpayers, and for the welfare and benefit of its citizens.

Appendix I

National Expert Panel Members

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Appendix II

Additional Recommendations of Individual Panel Members

(Listed in alphabetical order)

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 Develop a long-term, integrated Innovation Strategy and Plan for the U.S. that is managed and updated by the Office of Innovation and Federal Partnerships and is reviewed by its Advisory Board /Panel.

Curt Carlson, SRI International

- Teach and use innovation best practices across all government R&D agencies. The broad use of these practices would help eliminate the major cause of wasted government resources and significantly increase commercialization returns.
- Institute a DARPA-like funding agency across all significant U.S. R&D
 agencies focused on developing major innovative initiatives. DARPA is
 closely modeled after the fundamentals of innovative success and, as a
 result, it is by far the best government model for creating high-value
 innovations.
- Not all federal laboratories are capable of successful commercialization (i.e., able to achieve a positive ROI). Select only those organizations and opportunities where the necessary criteria for success are in place. Other laboratories should stay true to their uniquely important national missions.
- Pass a Bayh-Dole like act for government funded software. This would liberate the huge amount of IP that is currently trapped within the government.
- Create a national program to more aggressively recruit and retain the most skilled entrepreneurial talent to America. A small cadre of highly motivated and talented individuals is responsible for most job growth. For example, more than 50% of Silicon Valley's CEOs were born outside of America. These individuals are the scarcest, most valuable resource in the world today.

 Reform federal regulations to treat new high-growth companies differently from large companies and mom-and-pop enterprises. High-growth companies require regulations that are appropriate for their challenges, responsibilities, and importance. In America these fast growing new companies are responsible for *all* net job growth.

Neil Kane, Illinois Partners

- Broadly adopt across agencies NSF's I-Corps program. It is the only federal program that focuses researchers on determining the commercial relevance of their innovations.
- Institute a Dutch auction to stimulate the licensing and commercialization
 of federal patents that have not been licensed within two years of issuance.
 This will help clear the backlog of tens of thousands of patents which have
 not been licensed, and it will create an active market for those that have
 residual value. Those not licensed via the Dutch auction should be
 abandoned as a matter of policy.

Diane Palmintera, Innovation Associates

- Identify and adapt appropriate, successful university commercialization initiatives and techniques to federal agencies and laboratories, and National Manufacturing Innovation Institutes.
- Create a national registry of experienced entrepreneurial mentors to assist early-stage entrepreneurs, appropriate researchers and SBIR/STTR awardees.
- Consider an experimental SBIR/STTR program to be applied to federal laboratories.
- Provide technology transfer training for Manufacturing Extension
 Partnership staff; increase facilitation of technology transfer partnerships with intermediary/"translator" organizations and innovation resources.