

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

SBIR/STTR Reauthorization: A Review of Technology Transfer

Testimony before the
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Subcommittee on Research & Technology

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Good morning, Chairwoman Comstock, Ranking Member Lipinski, and distinguished members of the Committee. My name is Dr. Michael Lauer and I am the Deputy Director for Extramural Research at the National Institutes of Health (NIH). Thank you for the opportunity to discuss the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs at the NIH in the context of NIH's research and development (R&D) portfolio. This morning, I will discuss NIH's R&D portfolio, the NIH SBIR/STTR portfolio, and principles for reauthorization for consideration by this Committee to ensure that the SBIR/STTR programs best meet the needs of the biomedical research ecosystem.

OVERVIEW OF THE NIH PORTFOLIO

As the nation's premier biomedical research agency, NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems, and to apply that knowledge to enhance human health, lengthen life, and reduce illness and disability.

NIH has been advancing our understanding of health and disease for more than a century. Scientific and technological breakthroughs generated by NIH-supported research are behind many of the improvements our country has enjoyed in public health. For example, our Nation has gained about one year of longevity every six years since 1990.¹ A child born today can look forward to an average lifespan of about 78 years – nearly three decades longer than a baby born in 1900. Deaths from heart attack and stroke have been reduced by more than 70 percent in the past 60 years. Thanks to NIH-developed anti-viral therapies, HIV-infected people in their 20s today can expect to live into their 70s. This compares to a life expectancy measured in months when the disease first appeared in the 1980s. Cancer death rates have been dropping about one percent annually for the past 15 years.

¹ http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf

Many recent breakthroughs stem from our nation's commitment to investing in basic science research. Basic science lays the foundation for advances in disease diagnosis, treatment, and prevention by providing the building blocks for clinical applications. Basic science is generally not supported in the private sector, and NIH's focus on understanding fundamental biological processes not only has led to 148 Nobel Prizes to our grantees, but fosters innovation and ultimately leads to effective ways to treat complex medical conditions.

In fiscal year (FY) 2016, NIH's \$32.3 billion budget will support biomedical research in every state and nearly every Congressional district. The NIH portfolio is split into two broad categories. First, our extramural program supports scientists throughout the country at universities, hospitals, academic medical centers, and small businesses and represents about 83 percent of the budget. Second, our intramural program supports research conducted by NIH scientists within our own laboratories and represents about 11 percent of the budget. For the extramural program, NIH provides support through grants, cooperative agreements, and contracts; and we have an array of different funding mechanisms to match the variety of types of science we support. Researcher-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR/STTR program. NIH supports the foundation of the entire biomedical research enterprise.

Studies have shown that NIH grants lead to novel inventions and patents. From 2000 to 2013, NIH-funded researchers produced 20,441 unique patents. NIH research funding directly yields approximately 6 new patents for every \$100 million of grant and contract funding.²

² "Patents as Proxies Revisited: NIH Innovation 2000 to 2013" Batelle Technology Partnership Practice, prepared for The Academy of Radiology Research, 2015.
http://www.battelle.org/docs/tpp/battelle_2015_patents_as_proxies.pdf

Furthermore, each year's new round of funding can be expected to generate at least 100 to 120 new inventions.³

NIH investment also spurs private-sector patents, because the biotechnology and pharmaceutical industries build on knowledge generated by NIH funding. Every \$10 million increase in NIH funding generates 3.26 additional private sector patents, which translates to one private-sector patent for every two NIH grants.⁴

It is important to remember that many years and financial resources are necessary to bring medical innovations into the practice of medicine. It's been estimated that it takes 11-14 years and approximately \$2.6 billion to bring a new drug to market.^{5,6} While basic science lays the foundation for advancing our knowledge about the nature and behavior of living systems, this knowledge must then be applied and translated and later approved through the regulatory system before patients can benefit. NIH, as well as universities, created technology transfer offices to aid researchers to commercialize their discoveries. The small business community benefits from all of these opportunities resulting from the formative research supported by NIH.

THE NIH SBIR/STTR PROGRAMS

Among the 11 Federal departments and agencies that participate in the SBIR/STTR programs, the NIH is the second largest funder, and the largest Federal supporter of biomedical research. The NIH SBIR/STTR programs continue to be critical to feeding the innovation pipeline that promises to deliver the medical advances of tomorrow and have complemented NIH's mission to advance science while bringing new health care solutions to the public.

³ Kalutkiewicz, Michael J. and Ehman, Richard L., Patents as proxies: NIH hubs of innovation, *Nature Biotechnology*, June 2014.

⁴ Pierre Azoulay et al. "Public R&D Investments and Private-sector Patenting: Evidence from NIH Funding Rules" NBER working paper, 2015. <http://www.nber.org/papers/w20889>

⁵ DiMasi, Joseph A., Ronald W. Hansen, and Henry G. Grabowski. 2003. [The Price of Innovation: New Estimates of Drug Development Costs](#). *Journal of Health Economics* 22: 151–85.

⁶ DiMasi JA, Grabowski HG, Hansen RA. [Innovation in the pharmaceutical industry: new estimates of R&D costs](#). *Journal of Health Economics* 2016; 47:20-33.

The NIH SBIR/STTR programs are ideally suited for creating research opportunities for U.S. small businesses to stimulate technological innovation. Part of a complex innovation ecosystem, these programs provide dedicated funding for U.S. small businesses to conduct early-stage R&D to explore the feasibility of innovative ideas that may eventually result in products or services that will lead to better health for everyone. The NIH SBIR/STTR programs are one means by which NIH Institutes and Centers accomplish their R&D objectives. A key feature that sets SBIR/STTR apart from other NIH programs is a focus on commercialization of the results of research. Thus, the programs serve to supplement the basic and applied research programs of NIH.

Examples of the types of research that NIH supports through the SBIR/STTR programs include, but are not limited to: drug discovery, drug and pharmaceutical development, medical devices, biosensors, nanotechnologies, proteomics, imaging, bioengineering, behavioral research, health services, and other technologies that enhance health, lengthen life, and reduce illness and disability. Successful NIH SBIR-funded technology include the Lift Labs' Liftware,TM which creates stabilizing technologies to help people with Essential Tremors and Parkinson's disease and Senestech, which has technology to manage rodent populations using a non-toxic approach that limits reproduction.

NIH's SBIR and STTR programs have grown significantly with the increases provided in the 2011 reauthorization. Between FY 2011 and FY 2016, the NIH budget increased about 4.5 percent while the NIH SBIR and STTR funding increased approximately 30 percent, more than six times the NIH budget increase.

NIH is grateful for the financial and human resources support provided through the administrative fund pilot authority to enhance our management of the SBIR/STTR programs in

new and better ways. One example of how we have used this authority is that we have bolstered and diversified our SBIR/STTR outreach efforts the past several years, with a major focus on women-owned and socially- and economically-disadvantaged businesses. During FYs 2013-2015, we have reached over 24,400 individuals from all 50 states and the District of Columbia and Puerto Rico, including more than 940 women-owned small businesses and 650 socially and economically disadvantaged small businesses. Through these and other efforts, we anticipate increased applications from these groups, further diversifying the SBIR/STTR Programs.

The NIH attributes the success and effectiveness of its programs to several factors, the most significant of which is a flexible and proactive approach that adapts to the changing nature of biomedical and behavioral research while maintaining a highly competitive and effective program.

Examples of program flexibility include the ability to propose research projects in fields that have the most biomedical potential; the ability for an applicant to resubmit an unfunded application; and the ability to fund Phase I and Phase II awards at appropriate budgets that may exceed the established guidelines if the science proposed warrants such an exception to ensure successful outcomes. Biomedical research presents a unique set of challenges that require appropriate resources to commercialize the next set of discoveries.

REAUTHORIZATION PRINCIPLES

The NIH and Obama Administration strongly support the SBIR and STTR programs. For decades, these programs have served as vital sources of Federal funding for innovative American small businesses, including startups, which make outsized contributions to technology commercialization and job creation across the country. The programs should be permanently

reauthorized to provide American's small businesses and participating Federal agencies with much-needed long-term certainty.

Future growth in SBIR/STTR programs should be realized through overall extramural R&D budget increases for each SBIR/STTR funding agency. For example, Congress provided NIH a \$2 billion increase in FY 2016, which meant that our SBIR/STTR programs increased by 12.4 percent from the previous fiscal year (4.5 percentage points of that growth attributed to the statutory increase in the set aside with the remainder due to the overall budget increase) compared to a 6.6 percent increase for NIH. The annual set-aside amounts for agency SBIR/STTR programs should be maintained at the FY 2017 levels (3.2 percent/0.45 percent), which represent greater than 30 percent increase over the FY 2011 levels (2.5 percent/0.3 percent). The biomedical research enterprise now suffers from hyper competitiveness with researchers competing against each other for available research dollars. Historically, NIH success rates have been about one in three (32 percent in FYs 1999 - 2001) while now they are down to less than one in five (18 percent in FY15). Dedicating a larger proportion of NIH's extramural research dollars to these two specific programs would threaten the diversity of the research portfolio when the portfolio's diversity is one of the major keys to its success. It would be more effective to increase overall R&D budgets so all programs benefit.

Furthermore, it is imperative that NIH and other Federal agencies participating in the program dedicate resources for effective administration, oversight, and outreach as well as reasonable flexibility on award size and sequencing, consistent with the diverse needs of small businesses in different industries and technology areas.

CONCLUSION

In conclusion, I want to emphasize that flexibility is critical at a time when science is changing rapidly, becoming more complex, more interdisciplinary, and more resource intensive. NIH plays a foundational role in the biomedical research enterprise, supporting all stages of research. Also, as a responsible steward of taxpayers' dollars, we strive to leverage NIH's portfolio across the biomedical enterprise. This concludes my statement. Thank you for your attention and I look forward to answering any questions you may have.