

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Commercializing on Innovation: Reauthorizing the Small Business Innovation Research
and Small Business Technology Transfer Programs

Testimony before the
House Small Business Committee

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Good afternoon, Chairman Chabot, Ranking Member Velazquez and Members of the Committee. My name is Dr. Matthew Portnoy and I am the Director for the Division of Special Programs within the Office of the Director's Office of Extramural Research at the National Institutes of Health (NIH), and the Coordinator for the Department of Health and Human Services (HHS) SBIR and STTR Programs. Thank you for the opportunity to discuss the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs at the NIH, and the role they play in stimulating innovation and our economy. I would like to note that my remarks will primarily focus on NIH because our agency represents 98 percent of the Department's programs, however my office coordinates closely with the Centers for Disease and Control and Prevention (CDC), the Food and Drug Administration (FDA), Administration for Community Living (ACL), and the Administration for Children and Families (ACF), our sister HHS agencies that also fund SBIR and STTR programs. Among the 11 Federal departments and agencies that participate in these programs, the NIH is the second largest funder, and the largest Federal supporter of biomedical research. The 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.

IMPORTANCE OF THE SBIR/STTR PROGRAM AT NIH: IGNITING IMAGINATIONS AND SPURRING NEW DISCOVERIES

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 research and development (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 (ICs) 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.

TYPES OF RESEARCH NIH SUPPORTS UNDER SBIR/STTR

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. Researcher-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR/STTR program. Examples of successful NIH SBIR-funded technology includes the Lift Labs' Liftware™ that 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 SBIR/STTR PROGRAM REAUTHORIZATION IMPLEMENTATION OVERVIEW

I am pleased to share with you today that the implementation of all of the changes included in the SBIR/STTR Reauthorization Act of 2011 is complete. I will now provide you with a brief update on our work to date.

SBIR/STTR Funding: In accordance with law, the NIH increased its set-aside for the SBIR and STTR programs to 3.0 and 0.45 percent, respectively, of its extramural research and development budget in Fiscal Year (FY) 2016. Since the reauthorization, the overall budget for the programs has increased from \$680 million in FY 2011 (pre-reauthorization) to the current

FY 2016 minimum set-aside of \$877 million. That is an increase of nearly \$200 million that is available to small businesses working in many different technology areas across the country. Throughout, NIH and HHS continue to meet and exceed the required set-asides each year, as found by annual GAO reports. In FY 2015, the success rates of our both our SBIR and STTR grant programs, representing 90 percent of the portfolio, range from 15-16 percent for Phase I and 30-35 percent for Phase II. This included funding more than 1,000 new awards, and is in line with historical rates as well as with rates from other agencies. Our first year of the Direct Phase II SBIR pilot was FY 2015 and allows applicants to apply and receive a Phase II, if they have demonstrated they have done the Phase I equivalent with other funds. In FY 2015, we had a success rate of 19 percent and made 65 Direct Phase II awards.

Increased Outreach Efforts: We have bolstered and diversified our SBIR/STTR outreach efforts the past several years with the intention of further diversifying the SBIR/STTR programs. As required under the reauthorization, we continue to partner with the NIH Institutional Development Award (IDeA) program¹ to reach underserved small businesses in IDeA states, and have increased outreach to 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. This includes outreach to more than 940 women-owned small businesses (WOSB) and 650 socially and economically disadvantaged small businesses (SDB), as well as efforts targeting all 23 IDeA states and Puerto Rico. Our outreach efforts include: revamping our website and using social media; participating in the SBA Road Tour; and engaging state-based economic development centers and professional organizations

¹ The Institutional Development Award (IDeA) program broadens the geographic distribution of NIH funding for biomedical and behavioral research. See more at: <http://www.nigms.nih.gov/Training/IDeA/Pages/default.aspx>.

that reach women and minority entrepreneurs. Through these and other efforts, we anticipate increased applications from these groups, further diversifying the SBIR/STTR Programs.

SBIR Direct Phase II Pilot, Commercialization Readiness Pilot Program and Phase 0 Proof of Concept Centers: These three new provisions from the 2011 Reauthorization Act have been successfully implemented. NIH issued its first Direct Phase II SBIR solicitation in 2014 and made our first awards in FY 2015. Other Direct Phase II solicitations have since been issued. The community has responded positively to these solicitations and success rates, as predicted, track along with Phase I. NIH and CDC recently launched their Commercialization Readiness Pilot Program (CRP) in the fall of 2015. The CRP program allows us to make follow-on awards to Phase II small business for additional technical assistance or R&D to be done as they work towards commercialization. A pair of CRP solicitations was issued and we just had our first receipt date for applications in January 2016 with awards to be made this summer.² While the results of the pilot will take some time to determine, based on the number of applications received, there is demand for this new program from the small business community. NIH has also implemented the STTR Phase 0 Proof of Concept Centers provision through the NIH Research Evaluation and Commercialization Hubs (REACH) program.³ NIH issued three awards in 2015 to the University of Louisville (Louisville, KY), the University of Minnesota, and the Long Island Bioscience Hub (a consortium of Stony Brook University, Cold Spring Harbor Labs, Brookhaven National Labs, and Feinstein Institute for Medical Research at Northwell Health Systems). A program Kick-Off meeting was held in April 2015 to share best practices learned from the NIH Centers for Accelerated Innovations (NCAI), a similar program funded by the NIH National Heart, Lung, and Blood Institute and the National Institute on Drug Addiction and co-

² See <https://sbir.nih.gov/engage/news#dec4>

³ See <http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-14-005.html>.

funded by the Phase 0 authority. The REACH Hubs and NCAI Centers are working together to create a nationwide proof-of-concept network of six hubs/centers comprised of 20 high impact research institutions. The first major accomplishment of this new network is a preliminary agreement with several pharmaceutical company partners to facilitate technology transfer and industry engagement.

Venture-backed Small Businesses: In 2013 and 2014, NIH and CDC respectively exercised their authority to allow small businesses that are majority owned by multiple venture capital companies, hedge funds and private equity firms to apply for SBIR funding. We received the first applications in late FY 2013 and have made the first awards in FY 2014. The demand for this flexibility is quite low (less than 1 percent of SBIR applications and awards) and we will continue to monitor it closely over time.

Shorten Time to Award: We are strongly committed to shortening the time from application receipt to award. We have implemented a variety of measures in the past year in all aspects of our receipt to award cycle designed to shorten this time period and are adjusting these as needed. In FY 2015, NIH's average time from receipt to notice of intent to award was less than 200 days, well below the 12 month requirement, and we anticipate this number to fall over time. We are working to be responsive to this important small business need, while at the same time maintaining the meritorious nature of our mandated two-tiered peer review process and meeting congressional expectations.

Administrative Funding Pilot: HHS 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 and for the recent extension of this authority

through the end of FY 2017. These funds have been critical so far in a number of areas across the entire Department. In FYs 2013-2015, HHS has spent \$7M, \$5M, and \$10M respectively representing 0.9 to 1.5% of the HHS SBIR set-aside per year towards a variety of activities authorized by SBA and fulfilling congressional intent with these funds. The Administrative Funding Pilot enabled us to increase outreach efforts mentioned above, both in person and by webinar, including participation and co-funding of the SBA Road Tour; reaching small businesses in under-served states and women- and minority-owned businesses; hiring new outreach staff; streamlining our award cycles, including hiring new staff; increasing support for commercialization in several areas; conducting program analysis for increased efficiency; ensuring accuracy and timeliness of meeting reporting requirements; and providing support for new programs to name a few. These activities would not have been possible without the additional funds under the pilot and would likely need to be severely curtailed or eliminated without extended or permanent funding.

PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL

I would stress that HHS 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. The NIH SBIR Phase II average award size in FY 2014 was \$1.3 million.

Biomedical research presents a unique set of challenges that require appropriate resources to commercialize the next set of discoveries.

In addition to the SBIR/STTR awards and the above mentioned newly implemented programs, HHS also has a suite of funding gap and technical assistance programs to help companies accelerate their projects forward into the next stage of R&D development and help them navigate the period between discovery and commercialization. This includes our Niche Assessment Program, Commercialization Accelerator Program, and a life-science focused pilot of the National Science Foundation's (NSF) iCorps program. Thus we help companies grow into sustainable businesses and leverage our investments in the long run.

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 resource intensive. The SBIR and STTR programs seek to fund the most scientifically promising projects for which private and public funds are not traditionally available. Also, as a responsible steward of taxpayers' dollars, we strive to leverage HHS'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.