



**Testimony Before the
Committee on Small Business
U.S. House of Representatives**

**Statement for Hearing entitled
“Oversight of the Small Business Innovation
Research and Small Business Technology
Transfer Programs—Part II”**

Statement of

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Good afternoon, Chairman Graves, 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 SBIR and STTR Programs NIH. 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, the Food and Drug Administration and the Administration for Children and Families, our sister agencies that also fund SBIR and STTR programs. Among the 11 Federal departments and agencies that participate in these programs, the NIH is one of the largest funders of this program, 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 more 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. Thus, while we solicit projects on specific topics, we primarily encourage small businesses to propose their own innovative research ideas that are relevant to our mission as a way of tapping those closest to the market trends and needs to drive innovation.

NIH SBIR/STTR PROGRAM REAUTHORIZATION IMPLEMENTATION OVERVIEW

I am pleased to share with you today that the implementation of the many changes included in the SBIR/STTR Reauthorization Act of 2011 are completed or nearly completed at NIH. I will now provide you with a brief update on some of our work to date.

SBIR/STTR Funding: In accordance with law, the NIH increased its set-aside for the SBIR and STTR programs to 2.8 and 0.40 percent, respectively, of its extramural research and development budget in Fiscal Year (FY) 2014. Since the reauthorization, the overall budget for the programs has increased from \$680 million in FY 2011 (pre-reauthorization) to the current FY 2014 minimum set-aside of \$758 million. That is an increase of \$78 million that are available to small businesses working in many different technology areas across the country. Throughout, NIH and DHHS continue to meet and exceed the required set-asides each year, as found by two recent GAO reports. At the same time, however, the number of SBIR/STTR applications was on a downward trend during FYs 2012 and 2013. The FY 2013 SBIR award success rate, the percentage of reviewed grant applications that receive funding, the most recent year we have full data, for SBIR programs was 13 percent for Phase I and 33 percent for Phase II. The FY 2013 combined award success rate for the SBIR and STTR programs, all phases was at 16.3 percent.

Increased Outreach Efforts: We have bolstered and diversified our outreach efforts to key stakeholders within the small business community. We are partnering and coordinating with the NIH Institutional Development Award (IDeA) program¹, as required under the reauthorization, to reach underserved small businesses in IDeA states, increasing outreach to women-owned and small disadvantaged businesses, collaborating with more state-based economic development centers to deliver regular series of webinars educating entrepreneurs and small businesses new to the programs

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>.

about the range of opportunities, and using social media to further engage small businesses. We have also done a tremendous amount of work to educate those impacted directly or indirectly from reauthorization changes through pre-submission webinars and large-scale messaging. Our data show that fully one-third of our applicants and awardees are new each year. Taken together, we believe we are reaching more future applicants and have more effective outreach based on the positive feedback we receive following each outreach event.

Reporting: The reauthorization also called for a number of new reporting requirements. During the past two years, our team held weekly meetings with numerous business units both inside and outside NIH including Small Business Administration (SBA), and stakeholders. From these meetings, we developed policies and processes to implement the reporting requirements of the reauthorization. This required making changes to a deeply integrated and complex NIH system that includes almost two hundred other funding mechanisms, and the recording and monitoring of information on tens of thousands of new awards annually. Thus you can imagine that any change, no matter how small, is far reaching and takes time to implement correctly and appropriately.

SBIR Direct Phase II Pilot and Switching Between Programs²: These two programmatic changes in particular represented a substantial effort on our part. This past February,

² The NIH Published the following Notice, NOT-OD-14-048, on February 5, 2014: NIH Implements Option for Applicants to Switch between the SBIR/STTR programs and the SBIR Direct to Phase II pilot of the SBIR/STTR Reauthorization Act of 2011 - See more at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-048.html>

we published a new SBIR Direct Phase II Pilot program funding opportunity announcement, allowing for the first time companies that have established scientific feasibility with non-SBIR/STTR support to bypass the need to apply for Phase I and compete for Phase II funding directly. We received the first round of applications in April 2014 and expect to make first funding decisions in early FY 2015. We will continue to monitor closely the impact of this pilot on our overall success rates. Let me also make an important point about this pilot program. All Direct Phase II applications go through the exact same rigorous peer review process as all other SBIR/ STTR applications. We have issued guidance to NIH scientific review officers, grants management officers, and others directly ‘touching’ these applications and continue to work with other key stakeholders to ensure consistency in review and funding decision processes. To that end, we have made the necessary systems modifications to be able to track these applications separately from regular Phase II and Fast Track awards for reporting and analysis purposes. Similarly, our NIH system is now able to accept applications that switch programs from STTR to SBIR or vice versa at Phase II or Phase IIB (our second, sequential Phase II) of the program. And we continue to conduct rigorous outreach to inform our stakeholders of these new opportunities.

12-Month Award Notification: Earlier this year we have started to notify all applicants of our intent to fund or not to fund their application in compliance with the new requirement to do so within twelve months.

Venture-backed Small Businesses: In 2013, NIH exercised the 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 award in FY 2014. As in the previously mentioned changes, we worked closely with our information technology specialists to build in the capability to separately track the amount of funding going to these projects for reporting purposes. The current demand for this flexibility is low and we will be monitoring it closely over time.

Shorten Time to Award: Perhaps the most dramatic change the NIH will be deploying soon is the requirement to reduce the time it takes to award funding to our small business applicants, an objective to which we are strongly committed. In the past year we have evaluated every detailed aspect of the life cycle of an application from the time it first arrives at NIH to the time it is awarded. We have made significant progress and are working to identify a new model that we believe will first and foremost benefit small businesses while at the same time maintaining the meritorious nature of our mandated two-tiered peer review process and meeting congressional expectations with full support of NIH Director Dr. Francis Collins.

Administrative Funding Pilot: 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. These funds, while currently temporary, have been critical so far in a number of areas across the entire Department. In my immediate office, we have been able to hire a dedicated statistician focused on programmatic analyses and helping us meet existing and new reporting requirements. We also hired a communications specialist now largely overseeing our

outreach efforts and expanding our social media capabilities, especially targeting IDeA states, women-owned and small disadvantaged businesses. NIH has begun proactively delivering a variety of webinars about the SBIR/STTR programs and drawing large numbers of attendees. Across the NIH, a number of ICs have used the funds to hire new program support staff to help with outreach, reporting, and work on improvements in their IT infrastructures for more efficient evaluation and management of their award portfolios. Our central SBIR office also issued a contract to help us redesign our NIH SBIR/STTR website; build in additional IT functionality into our Performance Outcomes and Data Systems (PODS) database that integrates all award data, success stories and other program data to now store the commercialization outcomes data that will be linking to the new SBA commercialization database; and create other centralized internal and external web-based tools for our program managers and the small business applicants and awardees. These funds have been used across NIH to increase outreach to underserved SBIR and STTR communities and to make improvements in our processes, all to the benefit of the small business community. These activities would not have been possible without the additional funds under the pilot.

PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL

We are eager to see the effects of these many changes in the coming years and are continually focused on ways to address the needs of a diverse small business community navigating through a complex regulatory landscape, ever-changing private sector risk appetite and expectations, and continually rising cost of R&D. I would stress that 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. The NIH Phase II average award size in FY 2013 was \$1.3 million for SBIR and \$1.1 million for STTR. Biomedical research presents a unique set of challenges that require appropriate resources to commercialize the next set of discoveries.

The NIH 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. Thus we help companies grow into sustainable businesses and leverage our investments in the long run.

CONCLUSION

In conclusion, I want to re-emphasize that flexibility is critical at a time when science is changing rapidly, becoming more complex, more interdisciplinary, and resource intensive. The SBIR program seeks 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 NIH's portfolio across the biomedical enterprise. NIH SBIR projects are stories of discovery. One example is IntraLase

Corporation from Irvine, California which developed the ultra-fast femtosecond (FS) laser for use in ophthalmology with more than \$400,000 in NIH SBIR funding from the National Eye Institute. The company was acquired in 2007 for \$877 million by Advanced Medical Optics, a division of Abbott, who developed it into today's LASIK technology and also uses it for advanced corneal surgery procedures. And we are committed to doing what we can to ensure that the small businesses we fund today may become the Marteks, MedImmunes, and Abbotts of tomorrow. These companies all received SBIR funding in their early stages and went on to create thousands of new jobs, deliver products that are making real and significant impact on the lives and health of millions of people, and became household names across our country.

This concludes my statement. Thank you for your attention and I look forward to answering any questions you may have.