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

Statement for Hearing entitled
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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 (

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

SBIR/STTR Funding:

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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

outreach efforts and expanding our social media capabilities, especially targeting IDeA states, women-owned a

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

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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