

Good afternoon, Chairman Quayle and members of the Subcommittee. My name is Dr. Sally Rockey. I am the Deputy Director for Extramural Research at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services. Thank you for the opportunity to discuss the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, and the role they play in stimulating innovation and our economy. Among the 11 Federal agencies that participate in the SBIR program, the NIH is one of the largest funders of this program, and the largest Federal supporter of biomedical research. The SBIR/STTR program is a critical component that feeds the innovation pipeline resulting in today's medical advances.

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 system, 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, medical devices, biosensors, nanotechnologies, proteomics, imaging, bioengineering, behavioral research, health services, and other technologies that reduce health disparities. Investigator-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR 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 to have those closest to the technology highway drive innovation.

NIH SBIR/STTR PROGRAM OVERVIEW

The NIH, in accordance with statute, must set aside 2.5 percent of its extramural research and development budget for SBIR program and 0.3 percent for the STTR program. The overall set-aside for NIH SBIR and STTR activities in FY 2010 was \$690 million, including \$616 million for SBIR and \$74 million for STTR that supported 681 new Phase I and 246 new Phase II SBIR projects to small businesses working in many different technology areas across the country. Once all applications go through a rigorous and competitive two-tiered peer review process, funding decisions are based on several factors: 1) ratings from the scientific and technical evaluation process; 2) areas of high program relevance; 3) program balance among areas of research; 4) available funds; and 5) the commercial potential.

The number of SBIR applications and new firms participating in the program was on a downward trend between fiscal years 2004 through 2009. However, the number of

applications increased in FY 2010, as did applications for most NIH grants, likely due to the resubmission of applications that were submitted for the American Recovery and Reinvestment Act funds but not initially funded. As a result, the award success rate in FY 2010 for SBIR programs was lower than for the NIH research line for the first time in five years. The FY 2010 combined success rate—the percentage of reviewed grant applications that receive funding—for the SBIR and STTR programs was at 17 percent, which was below the success rate of 20.6 percent overall for NIH Research Project Grants (RPGs).

Overall, the SBIR/STTR programs have complemented NIH's mission to advance science while reducing the burden of illness on public health.

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projects with great potential to produce products and launching them forward into the next R&D stage of development. In particular, the Phase II B competing renewal allows existing SBIR phase II awardees to receive additional funds to continue the project while navigating the regulatory process which often can be a complex and time-consuming process. Additionally, we manage a suite of technical assistance programs, namely the Niche Assessment Program and the Commercialization Assistance Program (CAP), that provide a market opportunity analysis and tailored business mentoring to address very specific needs of selected SBIR companies. Thus we help companies grow into sustainable businesses. Additionally, we have developed a Performance Outcomes Data and Systems (PODS) tool for internal use by NIH program staff, which integrates all data about SBIR and STTR awards, success stories, and tracking data of companies that graduated from our CAP program all into one searchable platform.

For many biomedical technology companies, the SBIR program is an important source of seed funding for unproven, early-stage ideas that dilutes the risk other investors are not initially willing to bet on. However, a venture capital, angel investor, foundation, or other financing strategy is ultimately the only way that innovative products will enter the marketplace. Research and development in public health and biotechnology is characterized by high and intense capital needs to turn an idea into a product (e.g., it takes an average of \$1.2 billion to bring a drug to the market). This usually requires long development times (i.e., 5-12 years), compliance with strict regulations, exceptionally high “burn rates” of capital, and a real need for investment by venture capital companies, some of which are or are not majority-owned by individuals. Often, the necessity for multiple rounds of venture financing to fund the extensive and essential

CONCLUSION

In conclusion, I want to reemphasize the NIH's commitment to supporting small businesses, maintaining the integrity of SBIR/STTR programs, and ensuring that technology development will help improve the health and extend the lives of all people. We are looking to small businesses, primarily through these programs, to stimulate technological innovation, help us face new challenges, and to produce not only new knowledge, but also tangible benefits that touch the lives of every individual. We are hopeful that our continuing outreach efforts and actions to modernize the SBIR/STTR programs will be helpful in that regard. Finally, we continue to believe strongly that flexibility within the SBIR program is essential to achieving greater successes in these programs. We look forward to the reauthorization of this critical program. This concludes my statement. I will be pleased to answer any questions you may have.